AN AMERICAN DRUG PROBLEM: RECLAIMING CONSUMERS' RIGHTS UNDER THE HATCH-WAXMAN ACT

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I. AN INTRODUCTION TO THE PROBLEM

Generic drugs cost 20–90% less than brand name drugs, but consumers continue to pay high prices for prescription drugs.[1] In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act") to increase the manufacture and marketing of generic drugs and to increase innovation in the pharmaceutical industry in general. This Article is about reclaiming consumers' rights under the Hatch-Waxman Act.

The introduction of generic drugs has been hindered by the settlement of patent infringement lawsuits in which brand name firms pay generic firms to delay their market entry. Because money flows from the patent holder to the alleged infringer (the opposite of a typical patent settlement) these agreements are referred to as "reverse payment settlements." In many instances, the settlement amount greatly exceeds what the generic firm would have earned had it won the lawsuit and entered the market.

When the parties settle, the brand name company retains its patent, along with its monopoly profits, and the generic company receives a pay-off. Ultimately, it is the consumers who lose. According to a recent study by the Federal Trade Commission (FTC), reverse payment agreements cost consumers and tax payers $3.5 billion a year.[2] Studies show that prescription drugs are the fastest growing segment of health care costs.[3] In this time of economic crisis, high drug prices place significant strain on consumers' pocketbooks. And in situations where consumers are priced out of buying a drug, these high prices can lead to long-term suffering and even death. There are Americans who need their prescription drugs to stay alive.

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1. Press Release, Fed. Trade Comm'n, FTC Staff Report Finds 60 Percent Increase in Pharmaceutical Industry Deals That Delay Consumers Access to Lower-Cost Generic Drugs (May 3, 2011), *available at* http://www.ftc.gov/opa/2011/05/mmareport.shtm.

2. *Id.*

3. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-306R, PRESCRIPTION DRUGS: TRENDS IN USUAL AND CUSTOMARY PRICES FOR COMMONLY USED DRUGS (2011), *available at* http://www.gao.gov/new.items/d11306r.pdf (illustrating annual change in the usual and customary price indexes for commonly used brand name and generic drugs).

The Hatch-Waxman Act should be helping those Americans, but reverse payment settlements are interfering with that goal.

At least four different bills have been introduced in Congress with the intent of making reverse payment settlements illegal.[4] These bills are stalled in various stages of the legislative process. [5] Furthermore, consumers and the FTC have challenged these settlements under the antitrust laws with very little success. In fact, the Third Circuit's decision in *In re K-Dur Antitrust Litigation* (K-Dur), which was decided in July 2012, is arguably the first pro-consumer circuit court decision since 2002.[6]

In this Article, I discuss how the courts' reliance on the policy favoring settlement has resulted in a total absence of antitrust scrutiny of reverse payment settlements. In choosing to blindly promote settlement, the courts have created the exclusionary scope analysis, which concludes that a patent is valid and infringed based on zero evidence. This is problematic because a patent only operates as a legal monopoly when it is valid and when it excludes only infringed products. The policy favoring settlement is premised on the idea that settlements serve the public interest.[7] But if a settlement actually harms the public, why should courts rely on this policy?

This Article argues that courts should not rely on the policy favoring settlement in situations where settlements have an actual adverse effect on the public interest. A fact-based application of the policy favoring settlement would lead courts to conclude that it should not be considered when analyzing reverse payment settlements. Data, research, and experience demonstrate that these agreements overwhelmingly harm consumers.

Courts should focus instead on the public interest in removing invalid patents. An analysis founded on this policy will require courts to decide the merits of the underlying patent claims and, ultimately, whether these settlements really violate the antitrust laws.

Part II of this Article provides an overview of the Hatch-Waxman Act and explains how a particular provision has become the impetus for reverse payment settlements. Part III discusses how reverse payment settlements affect consumers. Part IV discusses the circumstances under which a

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4. *See* America's Affordable Health Choices Act of 2009, H.R. 3200, 111th Cong. § 2563 (2009); Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009) (died in committee and reintroduced as S. 27 on January 25, 2011); Drug Price Competition Act of 2009, S. 1315, 111th Cong. (2009); Protecting Consumer Access to Generic Drugs Act of 2012, H.R. 3995, 112th Cong. (2012).

5. In fact, the first two bills never made it out of committee.

6. *In re* K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012).

7. *See, e.g.*, Owen M. Fiss, Comment, *Against Settlement*, 93 YALE L.J. 1073, 1085 (1984) (explaining that "[t]he dispute-resolution story makes settlement appear as a perfect substitute for judgment . . . In that story, settlement appears to achieve exactly the same purpose as judgment -- peace between the parties -- but at considerably less expense to society").

reverse payment settlement will violate antitrust law. Part V reviews how the courts have responded to cases challenging reverse payment settlements and argues that the exclusionary scope analysis results in no antitrust scrutiny. Part VI discusses how the policy favoring settlement is being used by the courts to justify the exclusionary scope analysis. Part VII argues that the courts should focus instead on the public interest in removing invalid patents. Part VIII argues that the policy favoring settlement should not apply at all to reverse payment settlements. Part IX argues that courts should decide the merits of the underlying patent claims when analyzing antitrust challenges to reverse payment settlements. And Part X discusses why the analysis in the recent Third Circuit decision will fail to resolve this problem.

II. THE HATCH-WAXMAN ACT

A. Overview

Under the Federal Food, Drug, and Cosmetic Act, pharmaceutical companies must file new drug applications (NDAs) with the Food and Drug Administration (FDA) before marketing a new drug to the public.[8] In 1984, Congress enacted the Hatch-Waxman Act, which amended the Food, Drug, and Cosmetic Act, to allow manufacturers of bioequivalent generic drugs to file abbreviated new drug applications (ANDAs)[9] relying on the safety and efficacy tests of brand name drug manufacturers.[10]

When an ANDA is filed, the generic firm must certify with respect to each patent that claims the brand name drug, or that claims a use of the brand name drug, either "(I) that [the] patent information has not been filed, (II) that [the] patent has expired, (III) . . . the date on which [the] patent will expire, or (IV) that [the] patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ."[11] When an ANDA filer certifies under Paragraph IV that the relevant patent is invalid or not infringed, it must notify the patent owner and the brand name drug manufacturer.[12] After the brand name company receives notice, it has forty-five days to initiate a patent infringement action.[13] If a patent infringement action is initiated, the FDA will not approve the ANDA for thirty months, or until a district court

8. 21 U.S.C. § 355(a) (2006).
9. H.R. REP. NO. 98-857, pt. 1, at 1 (1984); 21 U.S.C. § 355(j)(1).
10. H.R. REP. NO. 98-857, at 1; 21 U.S.C. § 355(j)(2).
11. 21 U.S.C. § 355(j)(2)(A)(vii).
12. *Id.* § 355(j)(2)(B)(iii).
13. *Id.* § 355(j)(5)(B)(iii).

decides that the patent is invalid or not infringed, whichever is earlier.[14]

The primary purpose of the Hatch-Waxman Act was to make low-cost generic drugs more accessible by accelerating their entry into the public market through the use of the ANDA process.[15] When the generic drug company files an ANDA, it is not required to conduct the costly clinical trials that are necessary when filing the entire NDA.[16] Furthermore, if a court finds that the generic drug does not infringe the relevant patent, or that the patent is invalid, the generic drug can enter the market before the expiration of the patent term.

To encourage patent challenges, the Hatch-Waxman Act provides a 180-day exclusive marketing period for the first generic company that challenges an invalid or non-infringed patent.[17] In this way, the Act provides an incentive for the testing of potentially weak patents through litigation.[18] Furthermore, by excluding the need for costly clinical trials, the Hatch-Waxman Act redistributes the risk in patent infringement lawsuits.[19] Whereas the generic drug manufacturer has little to lose since it has not yet invested in the development and marketing of the drug, the brand manufacturer stands to lose millions or even billions if its patent is invalidated.[20]

The Act also sought to increase innovation by restoring time lost on patent life while preparing for and awaiting FDA approval.[21] Although the statutory patent term in the United States was seventeen years, pharmaceutical products were marketed for less time because the patents were obtained before FDA approval was granted.[22] To counteract this issue and encourage innovation, the legislature included a patent term extension for pharmaceuticals undergoing regulatory review.[23] This extension may not exceed five years.[24] Furthermore, brand name manufacturers received a

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14. *Id.*
15. H.R. REP. NO. 98-857, at 14.
16. *Id.* at 15.
17. 21 U.S.C. § 355(j)(5)(B)(iv).
18. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 61 (2009); *see also* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006) (noting that the 180-day "bounty" can be worth several hundred million dollars, inducing generic companies to challenge brand name drug patents).
19. *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 206–07 (2d Cir. 2006).
20. *Id.*
21. H.R. REP. NO. 98-857, at 14–15 ("Purpose and Summary").
22. *Id.* at 17 ("Patent Term Restoration"); 35 U.S.C. § 154(a)(2) & 1994 Amendments, Pub. L. No. 103-465 (When the Hatch-Waxman Act was enacted, the patent term was seventeen years. In 1994, the patent term was changed to twenty years from the date of filing).
23. 35 U.S.C. § 156(g) (2006).
24. *Id.* § 156(g)(6).

three-year market exclusivity period for new forms and uses of previously approved drugs.[25]

Hence, in enacting the Hatch-Waxman Act, Congress sought not only to increase generic drug competition, but also to increase innovation by brand name drug manufacturers.[26]

B. The Significance of the 180-Day Exclusive Marketing Period

The first generic firm to file a Paragraph IV ANDA (ANDA-IV) alleging patent invalidity or non-infringement is entitled to 180 days of exclusive marketing. Until this period expires, no other ANDA-IVs will be approved.[27] However, if a subsequent ANDA-IV filer challenges the patent and proves invalidity or non-infringement, the 180-day exclusive marketing period of the first ANDA-IV filer is triggered, enabling subsequent ANDA-IV filers to enter after the 180-day period has ended.[28]

Although subsequent ANDA-IVs can be approved after a successful challenge to validity or infringement, subsequent ANDA-IV filers will likely choose not to challenge the patent for two reasons. First, if they prevail, they need to wait at least 180 days to enter the market. These six months of delay result in six months of no profits. Second, a significant portion of a generic firm's profits is derived from the 180-day exclusive marketing period—the period when the first ANDA-IV filer and the brand firm are the only competitors.[29] Since the 180-day reward only goes to the first ANDA-IV filer, subsequent ANDA-IV filers cannot take advantage of this opportunity, even if the first ANDA-IV filer settles and the subsequent ANDA-IV filer succeeds in proving lack of infringement or patent invalidity. The purpose of the 180-day reward was to encourage ANDA filers to challenge the patents of brand firms through litigation. Without this incentive, subsequent ANDA filers are not likely to challenge the patents.[30]

The 2003 Medicare Prescription Drug Improvement and Modernization Act created events that would cause a first ANDA-IV filer to lose its 180-

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25. 21 U.S.C. § 355(c)(3)(E)(iii) (2006).

26. Carrier, *supra* note 18, at 45, 62 (arguing that the Hatch-Waxman Act created a "nuanced equilibrium between competition and innovation").

27. Hemphill, *supra* note 18, at 1578 (noting that the "legal form" of the exclusive period is a delay in FDA approval of all other ANDA-IVs); *see also* Carrier, *supra* note 18, at 47 (noting that the FTC cannot approve other ANDAs until the 180-day period expires).

28. Hemphill, *supra* note 18, at 1587.

29. *Id.* at 1590.

30. *See* C. Scott Hemphill, Comment, *Collusive and Exclusive Settlements of Intellectual Property Litigation*, 2010 COLUM. BUS. L. REV. 685, 708 (2010) (arguing that generic firm challenges are promoted by the 180-day period, and that reverse payment settlements are encouraged by the fact that the generic firm retains the 180-day exclusive marketing period even if it settles).

day exclusive marketing period. However, this modification has not reduced the number of reverse payment settlements because the 180-day reward is still not transferred to the next ANDA-IV filer. [31] If the 180-day reward evaporates into thin air, then future generic manufacturers have no incentive to file an ANDA-IV and challenge the patent.[32]

Even if a subsequent ANDA-IV filer wants to challenge the patent, it may not be able to do so. Under the Hatch-Waxman Act, when a generic company files an ANDA-IV, the brand company can sue the generic company for patent infringement within forty-five days.[33] If it chooses to sue, then the generic company can defend by asserting that the patent is invalid, not infringed, or both. However, it is not clear whether a generic company can sue for declaratory judgment.[34] If the brand company chooses not to sue the subsequent generic company, the generic company may be left with no options. If it cannot use litigation to trigger the 180-day period of the first ANDA-IV filer, the most it can do is wait for another forfeiture provision to kick in.

Thus, when the brand company pays the first ANDA-IV filer to delay its entry into the market, it essentially prevents all other generic companies from entering the market for the duration of the settlement.[35] If the first generic company is the only applicant entitled to the 180-day exclusive marketing period, then other generic companies are not incentivized to challenge the patent.

In sum, a reverse payment guarantees the brand company's monopoly for the duration of the settlement agreement. Brand companies have a strong incentive to make these payments to preserve their monopoly profits. If they continue the litigation and lose, the brand companies would lose millions, or even billions of dollars. In contrast, the generic companies have very little to lose since they have not yet begun to market their product. The settlements are desirable for the generic companies because the payments

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31. 21 U.S.C. § 355(j)(5)(D) (2006); *see also* Hemphill, *supra* note 30, at 708 (noting that reverse payment settlements "are encouraged by the fact that the generic firm retains eligibility for the exclusivity period even if it settles").

32. Hemphill, *supra* note 30, at 708 (arguing that requiring the generic firm to give up the 180-day period when it settled would reduce the harm of reverse payment settlements).

33. 21 U.S.C. § 355(j)(5)(B)(iii).

34. *See* Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 RUTGERS L.J. 83, 100 (2009) (noting that the case law on this issue is unclear).

35. Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1755 (2002) (noting that if the brand firm pays the generic firm to delay entry, this postpones the start of the 180-day marketing period, locking other generics out of the market).

often exceed what they would have earned after winning the lawsuit and entering the market.[36]

The Hatch-Waxman Act itself has provided the impetus for reverse payment settlements.[37] As the courts like to say, reverse payment settlements are the "natural by-product" of the Act's 180-day exclusive marketing provision.[38] The very legislation that was created to lower drug prices for consumers has provided the foundation for a settlement process that keeps prices high.

III. REVERSE PAYMENT SETTLEMENTS AND THEIR EFFECT ON THE PUBLIC

The FTC has challenged reverse payment settlements through its enforcement proceedings.[39] In the FTC's view, these agreements are presumptively anticompetitive.[40] The FTC's Bureau of Economics has determined that these settlements cost consumers $3.5 billion a year.[41] Furthermore, the Congressional Budget Office estimates that passing legislation making these agreements illegal would reduce federal government debt by $4.8 billion over ten years.[42] At least four attempts have been made to pass such legislation.[43]

In the last few years, the Antitrust Division of the Department of Justice has stood with the FTC on this issue, filing amicus briefs in private

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36. Carrier, *supra* note 18, at 39. When the brand firm delays entry by generic firms, it increases its monopoly profits. *Id.* The brand firm then uses a portion of the profits to pay the generic firm more than it would have received through market entry. *Id.*

37. Hovenkamp, Janis & Lemley, *supra* note 35, at 1755 (noting that it is generally accepted that the 180-day period of exclusive marketing provides the potential for collusive settlement agreements between brand and generic firms).

38. Schering-Plough v. FTC, 402 F.3d 1056, 1074 (11th Cir. 2005) (quoting *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003)); *see also* Hemphill, *supra* note 18, at 1579 (concluding that the 180-day bounty ensures that a reverse payment settlement is an attractive option for both the brand and generic firms).

39. *See, e.g.*, Schering-Plough, 402 F.3d at 1061; *In re* Bristol Myers Squibb Co., 135 F.T.C. 444 (2003); *In re* Hoechst Marion Roussel, Inc., 131 F.T.C. 924 (2001); *In re* Abbott Labs. & Geneva Pharms., Inc., No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000).

40. Press Release, Fed. Trade Comm'n, Statement of the Federal Trade Commission Chairman Jon Leibowitz on the U.S. Court of Appeals for the Third Circuit Ruling on the K-Dur 20 Matter (July 16, 2012), *available at* http://www.ftc.gov/opa/2012/07/kdur.shtm.

41. Fed. Trade Comm'n, *supra* note 1.

42. CONG. BUDGET OFFICE, COST ESTIMATE ON S. 27: PRESERVE ACCESS TO AFFORDABLE GENERICS ACT (2011), *available at* http://aging.senate.gov/publications/s27.pdf.

43. *See* Protecting Consumer Access to Generic Drugs Act of 2012, H.R. 3995, 112th Cong. (2012) (died in committee); America's Affordable Health Choices Act of 2009, H.R. 3200, 111th Cong. § 2563 (2009) (passed in committee but superseded by H.R. 3962 on November 7, 2009) ; Drug Price Competition Act of 2009, S. 1315, 111th Cong. (2009) (died in committee); Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009) (died in committee and was reintroduced as S. 27 on January 25, 2011).

lawsuits as well.[44] In addition to the amicus briefs filed by the FTC and the Antitrust Division, courts have also received amicus briefs from the Attorneys General of various states.

Plaintiffs in the private lawsuits include individual consumers, wholesale drug companies, pharmacies, workers' unions, and health plans. These antitrust claims have challenged settlements involving Cipro, Plavix, Nolvadex, Naprelan, Procardia, Hytrin, Cardizem CD, BuSpar, and K-Dur.[45]

Most of the scholarship written in this area has voiced concern that these agreements are anticompetitive and hurt consumers.[46] Like the FTC, scholars are concerned that settlement payments that exceed the patent holders' litigation costs are not indicative of the parties' expectation of success on the merits.[47] When it pays the generic company for delay, the brand firm extends the monopoly period beyond the point permitted by the strength of the patent. Although different analyses have been proposed, the majority of scholars appear to favor a presumption of illegality for reverse payment settlements.[48]

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44. Brief for the United States in Response to the Court's Invitation at 11, Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010) (No. 05-2852-cv) (arguing that "[r]everse payment agreements that delay entry by a potential generic competitor in exchange for a payment from a branded drug manufacturer with market power presumptively violate section 1 of the Sherman Act").

45. *See, e.g.*, *In re* K-Dur Antitrust Litig., 686 F.3d 197, 205–06 (3d Cir. 2012); Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 98–99 (2d Cir. 2010); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 206–07 (2d Cir. 2006); Andrx Pharm., Inc. v. Elan Corp., 421 F.3d 1227, 1231 (11th Cir. 2005); *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 899 (6th Cir. 2003); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1296 (11th Cir. 2003); Kroger Co. v. Sanofi-Aventis, No. 1:06-CV-163-HJW, slip op. at 1 (S.D. Ohio July 31, 2006); *In re* Buspirone Patent Litig., 185 F. Supp. 2d 363 (S.D.N.Y. 2002); Biovail Corp. v. Mylan Labs, Inc., No. 1:01CV66, 2002 U.S. Dist. LEXIS 6726, at *6 (N.D. Va. Mar. 22, 2002).

46. *See, e.g.*, Herbert Hovenkamp, *Patents, Property, and Competition Policy*, 34 J. CORP. L. 1243, 1251–52 (2009); Hemphill, *supra* note 30, at 703–04; Carrier, *supra* note 18, at 76.

47. *See* Hemphill, *supra* note 30, at 703–04 (arguing that when a brand manufacturer includes a payment as part of the settlement it obtains a later entry date, and thus less competition, than what is warranted by the patent alone); *see also* Michael A. Carrier, *Innovation for the 21st Century: A Response to Seven Critics*, 61 ALA. L. REV. 597, 612 (2010) (arguing that in most cases, payments that exceed the patent holder's litigation costs are being used to buy a later generic entry than the patent itself can provide); Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 25 (2004) (noting that even a plaintiff who is sure of success would be willing to pay less than its litigation costs to settle the case).

48. *See* Hemphill, *supra* note 18, at 1561–62 (concluding that these "settlement[s] should be accorded a presumption of illegality"); *see also* Hemphill, *supra* note 30, at 708 (proposing that courts accord a presumption of illegality for agreements that contain a substantial payment); Carrier, *supra* note 18, at 37–38 (noting that "[t]hese reverse-payment settlements threaten significant harm" and arguing that "courts should treat such settlements as presumptively illegal"); Hovenkamp, Janis & Lemley, *supra* note 35, at 1720–21 (arguing that reverse payments that exceed litigation costs should be presumptively illegal).

However, not all scholars believe that reverse payment settlements should be presumptively illegal. Professor Crane argues that the idea that settlement money should flow from the alleged infringer to the patent holder is a false generalization.[49] In his opinion, the direction in which the payment flows is not a sufficient "basis for evaluating the potential anticompetitive effects of a settlement agreement."[50] He insists that multiple factors that are not related to the merits of the patent holder's claim affect the direction in which the settlement payment flows.[51] For example, Crane cites the expense of litigation, the uncertainty of the outcome, whether the generic product has reached the market, the parties' bargaining power during negotiations, their financial strength, their level of risk aversion, and how shareholders view management.[52] Crane also argues that if the product has not yet reached the market, which is the case in Hatch-Waxman cases, then the settlement payment must out of necessity flow from the patent holder to the generic company because there are no damages.[53]

Crane raises some valid points. Given the positions of the parties when litigation commences, it follows that any payment would naturally flow from the brand company to the generic company. But as Professor Carrier notes, other aspects of reverse payment settlements do raise valid concerns.[54]

First, in a reverse payment settlement, the patent holder is paying the generic firm not to enter the market.[55] Removing a potential competitor from a market hurts competition. This differs from a typical patent infringement settlement where the alleged infringer pays the patent holder to enter (or stay in) the market.[56]

Second, not only does the payment remove the first generic firm from the market, it delays, and in some cases completely prevents, other generic firms from entering the market. This is because the first generic firm holds on to its 180 days of exclusive marketing, deterring other generic firms from challenging the patent and gaining FDA approval.[57]

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49. Daniel Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 771 (2002).

50. *Id.* at 776.

51. *Id.*

52. *Id.* at 774–75.

53. *Id.* at 774.

54. Carrier, *supra* note 47, at 611.

55. *Id.*

56. *Id.*; *see also* Hovenkamp, Janis & Lemley, *supra* note 35, at 1750–51 (explaining that in a perfectly functioning market, a monopoly producer would choose to produce all output itself, or license part of the output to a rival. It would have no incentive to pay another firm to stay out of the market, because it can exclude without paying the rival).

57. Hemphill, *supra* note 18, at 1578 (noting that the "legal form" of the exclusive period is a delay in FDA approval of all other ANDA-IVs); *see also* Carrier, *supra* note 18, at 47 (noting that the

Third, in many of these cases, the payment exceeds the patent holder's litigation costs. The payments are so large that they often exceed what the generic firm would have made had it entered the market. But, although the payment is large, the brand firm still makes much more than if the generic firm had entered the market—it essentially splits its monopoly profits with the first ANDA-IV filer. The large amounts suggest that brand firms are buying a longer delay than the patent can provide.[58] They suggest that the patents have a good chance of being found invalid in litigation.[59] As Professor Hovenkamp argues, "a larger payment suggests a more socially costly outcome—namely, preserving the exclusion power of the patent, at least vis-à-vis this particular defendant, even though the patent is likely to be invalid. The result is to deny the public the benefits of competition that it could otherwise obtain."[60]

Finally, in response to Crane's argument that the settlement payment must flow from the patent holder to the generic firm out of necessity, I suggest that a reverse payment is not necessary to settle these cases. In 2010, 73% of Hatch-Waxman settlements did not contain a reverse payment.[61] If there is no payment, then the length of the delay is a product of the strength of the patent and, therefore, indicative of the strength of the parties' litigation positions.[62] If 73% of these cases settled without a payment, one has to wonder: What were the brand companies in the other cases trying to buy with their million dollar payments?

FTC cannot approve other ANDAs until the 180-day period expires); Hovenkamp, Janis & Lemley, *supra* note 35, at 1757 (arguing that reverse payment settlements are attractive because they exclude not only the immediate generic company but also prevent other generic companies from entering as well).

58. *See* Hemphill, *supra* note 30, at 703–04 (arguing that when a brand company makes a payment instead of relying solely on the strength of its case, it secures a later date of entry—one that is not warranted by the patent alone).

59. Carrier, *supra* note 47, at 612 (arguing that paying generics more than they would have earned had they entered the market raises a red flag of potential invalidity); Hovenkamp, Janis & Lemley, *supra* note 35, at 1758 (concluding that the size of the exclusion payment is inversely related to the strength of the patent holder's case). "[T]he less likely the patentee is to win, the more it is willing to pay a generic to stay out of the market." *Id.*

60. Hovenkamp, *supra* note 47, at 25.

61. BUREAU OF COMPETITION, FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2010 (2011), *available at* http://www.ftc.gov/os/2011/05/1105mmagreements.pdf.

62. *See* Hemphill, *supra* note 30, at 703 (noting that a better argument on the part of the brand-name firm will result in a later date of entry for the generic firm); *see also* Carrier, *supra* note 47, at 612 (noting that an agreement to delay the generic's entry date, with no payment, often reflects the parties' likelihood of success in litigation).

IV. WHEN REVERSE PAYMENT SETTLEMENTS VIOLATE ANTITRUST LAW

Antitrust law and patent law have a tense relationship. The Sherman Antitrust Act forbids monopolies and agreements to restrain trade or commerce.[63] But when a person or entity obtains a patent, it obtains a legal right to exclude competitors. For this reason, some refer to patents as "legal monopolies." [64]

If a person has a valid patent, it can exclude competitors that infringe that patent without violating antitrust law. As a result, reverse payment settlements between a brand firm and a generic firm would only violate antitrust law in three situations: 1) if the patent is invalid; 2) if the generic drug does not infringe the patent; or 3) if the terms of the settlement are not covered by the patent. If any one of these conditions exists, then the settlement between the brand manufacturer and generic firm would be a horizontal market allocation agreement, which is *per se* illegal under antitrust law.[65] Plaintiffs and the FTC have challenged reverse payment settlements under Section 1 of the Sherman Act and Section 5 of the FTC Act.

V. TAKING THE EASY WAY OUT: HOW COURTS HAVE RESPONDED TO REVERSE PAYMENT SETTLEMENTS

In *In re Cardizem CD Antitrust Litigation*, the Sixth Circuit determined that a reverse payment settlement between Andrx and Hoechst Marion Roussell was a *per se* illegal market allocation agreement.[66] The court stated: "[t]here is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade."[67] Presently, the Sixth Circuit is the only circuit court to find a reverse payment agreement *per se* illegal. However, in its opinion, the court noted that the agreement restrained generic firm Andrx from marketing other versions of Cardizem CD that were not covered by the patent litigation.[68] As a result, many scholars and practitioners believe that

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63. 15 U.S.C. §§ 1, 2 (2006).

64. Hovenkamp, *supra* note 46, at 1244 (observing that the antitrust laws have historically "treated patents as a species of monopoly").

65. United States v. Topco Assocs., Inc., 405 U.S. 596, 608 (1972); Palmer v. BRG of Ga., Inc., 498 U.S. 46, 49–50 (1990).

66. *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 911 (6th Cir. 2003).

67. *Id.* at 908.

68. *Id.* at 908 n.13.

the Sixth Circuit did not intend to find all reverse payment agreements to be *per se* illegal, but rather, only those agreements that restrict competition beyond the scope of the patent.[69]

Since *Cardizem* was decided, courts have migrated to the other end of the spectrum when analyzing reverse payment settlements, applying what some have referred to as a rule of "*per se* legality."[70] In general, courts have been reluctant to decide whether the patents are valid or whether the generic drug infringes the patent. Rather, the courts decline to reach the issue stating, quite conveniently, that they should not decide those questions on the merits due to the public interest in settlement.[71]

As a result, courts have constructed the exclusionary scope analysis, a simpler test that presumes that the patent is valid and that the generic drug infringes the patent. This analysis was first utilized by the Eleventh Circuit and has since been adopted by the Second Circuit and the Federal Circuit.[72] In the exclusionary scope analysis, the court inquires whether the settlement agreement restricts competition beyond the exclusionary effects of the patent.[73] To answer this question, the court examines: "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the [settlement] agreement[] exceed[s] that scope; and (3) the resulting anticompetitive

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69. *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1335 (Fed. Cir. 2008) (finding that "although the Sixth Circuit found a per se violation" in *Cardizem*, the facts are distinguishable from other decisions in part because "the agreement provided that the generic manufacturer would not market non-infringing versions of the generic drug" and, therefore, "clearly had anticompetitive effects outside the exclusion zone of the patent").

70. *See* Hemphill, *supra* note 30, at 705–06 (noting that the courts "have adopted a rule that verges upon per se legality").

71. Hovenkamp, *supra* note 46, at 1251 (noting that courts strongly favor the settlement of patent disputes and rarely second-guess them).

72. *See* Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 104–05 (2d Cir. 2010) (framing the question as "whether patent settlements in which the generic firm agrees to delay entry into the market in exchange for payment fall within the scope of the patent holder's property rights, or whether such settlements are properly characterized as illegal market-sharing agreements"); *Ciprofloxacen*, 544 F.3d at 1332–33, 1336 (agreeing with the district court's conclusion that the settlement agreement had no anticompetitive effects beyond the exclusionary zone of the patent and, therefore, did not violate the Sherman Act); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 208, 209 n.22, 213 n.27 (2d Cir. 2006) (explaining the issue as whether the exclusionary effects of the agreement go beyond the scope of the patent); Schering-Plough v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005) (finding that the proper analysis should examine the extent to which the agreement exceeds the exclusionary scope of the patent).

73. *See Schering-Plough*, 402 F.3d at 1066 (finding that the proper analysis should examine the extent to which the agreement exceeds the exclusionary scope of the patent); *Tamoxifen*, 466 F.3d at 208, 209 n.22, 213 n.27 (explaining the issue as whether the exclusionary effects of the agreement go beyond the scope of the patent); *Ciprofloxacen*, 544 F.3d at 1332–33, 1336 (agreeing with the district court's conclusion that the settlement agreement had no anticompetitive effects beyond the exclusionary zone of the patent and, therefore, did not violate the Sherman Act); *Bayer AG*, 604 F.3d at 104–05 (framing the question as "whether patent settlements in which the generic firm agrees to delay entry into the market in exchange for payment fall within the scope of the patent holder's property rights, or whether such settlements are properly characterized as illegal market-sharing agreements").

effects."[74] In applying this analysis, the courts review the language of the settlement agreement. If there is no language that exceeds the scope of the patent, then the antitrust case is dismissed.

The courts did not examine the validity of the patent at issue in any of the post-*Cardizem* cases.[75] In fact, except for the recent Third Circuit *K-Dur* decision, all of the courts concluded that the patent was valid without examining any evidence. For example, in *In re Tamoxifen Citrate Antitrust Litigation*, the Second Circuit presumed that the patent was valid, despite the district court finding it invalid prior to Zeneca and Barr entering into their settlement agreement.[76] In concluding that the patent was presumptively valid, the Second Circuit relied on 35 U.S.C. § 282,[77] which states that "[a] patent shall be presumed valid."[78] Like the Second Circuit, the Eleventh and Federal Circuits also based the defendants' right to exclude on the presumption of validity that applies to patents under 35 U.S.C. § 282.[79]

However, this approach is seriously flawed. The presumption of validity is merely a procedural presumption that allocates the burden of proof between the parties.[80] It is not substantive evidence of validity.[81] Furthermore, 35 U.S.C. § 282 also states that "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity."[82] In other words, the presumption of validity was intended to be a rebuttable presumption.

The exclusionary scope analysis treats the presumption of validity as dispositive evidence of validity and deprives plaintiffs of their right to rebut the presumption. In applying this analysis, courts ignore the fact that an invalid patent cannot have a scope in the first place.[83] Furthermore, in cases where validity is not disputed but infringement is, utilizing the exclusionary scope analysis creates a presumption of infringement that does not exist. In

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74. *Schering-Plough*, 402 F.3d at 1066 (quoting Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003)).

75. *Id.* at 1068; *Tamoxifen*, 466 F.3d at 200; *Ciprofoxacen*, 544 F.3d at 1336; *Bayer AG*, 604 F.3d at 108.

76. *Tamoxifen*, 466 F.3d at 208, 209 n.22.

77. *Id.*

78. 35 U.S.C. § 282 (2006).

79. *Schering-Plough*, 402 F.3d at 1066–67; *Tamoxifen*, 466 F.3d at 208, 209 n.22; *Ciprofoxacen*, 544 F.3d at 1337.

80. *See* Hemphill, *supra* note 30, at 705–06 (noting that the courts "have adopted a rule that verges upon per se legality").

81. *See* Carrier, *supra* note 34, at 86 (noting that the presumption of validity is merely a "procedural evidentiary presumption"); *see also* Carrier, *supra* note 18, at 64 (noting that patentees cannot rely on this presumption as substantive evidence in preliminary injunction proceedings).

82. 35 U.S.C. § 282.

83. Carrier, *supra* note 18, at 66. "[I]f the patent is not valid, there is no scope at all." *Id.*

patent law, the burden of proof is on the *patent holder* to prove infringement. There is no presumption of infringement.

If there is no infringement or if the patent is invalid, then the reverse payment settlement would violate Section 1 of the Sherman Act. By concluding that the patent is valid and infringed based on zero evidence, the exclusionary scope analysis fails to examine the very issues that determine whether an antitrust violation exists. The practical result of the exclusionary scope analysis is a total absence of antitrust scrutiny for reverse payment settlements.

VI. THE COURTS' JUSTIFICATION – THE POLICY FAVORING SETTLEMENT

Each of the courts that utilized the exclusionary scope analysis expressed concern that reaching the merits of the patent dispute would chill settlement activity. Ultimately, each concluded that its analysis was justified in light of the policy favoring settlement.

For example, in *Schering Plough v. FTC*, the Eleventh Circuit stated that "[t]he general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits."[84] In justifying its decision, the court also stated:

> Given the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative 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.[85]

Similarly, in *Tamoxifen*, the Second Circuit stated: "We begin our analysis against the backdrop of our longstanding adherence to the principle that 'courts are bound to encourage' the settlement of litigation . . . . Where a case is complex and expensive, and resolution of the case will benefit the public, the public has a strong interest in settlement."[86]

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84. *Schering-Plough*, 402 F.3d at 1072.

85. *Id.* at 1076.

86. *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 202 (2d Cir. 2006) (quoting Gambale v. Deutsche Bank AG, 377 F.3d 133, 143 (2d Cir. 2004)).

Finally, in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, the Federal Circuit noted: "[T]here is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation."[87]

Although the potential public benefits of settlement have been recognized for years, one cannot help but wonder whether the courts' decision to defer to settlement in this context is due more to their reluctance to deal with the complex underlying patent issues than their desire to help the public.[88]

There has been a movement in recent years to utilize settlement to expedite the resolution of civil cases. This is especially true for patent and other complex cases that result in large litigation expenses and are generally believed to consume a significant amount of judicial resources.[89] The removal of a complex case from the court docket will always make a judge's life easier. But it will not always result in benefits to the public. When a case settles, the parties have reached a peace that satisfies both their interests. But the parties are not interested in what is good for the public.[90] Courts can, and do, take the public into consideration when rendering a judgment.[91] They cannot do that if a settlement is reached.

VII. AN OVERLOOKED POLICY – THE PUBLIC INTEREST IN REMOVING INVALID PATENTS

The policy promoting settlement is premised on the idea that settlements serve the public interest. But should we always assume that all settlements will serve the public interest?[92] And, if a party can prove that a settlement actually hurts the public, should courts rely on the policy?

Eighty years ago, the Supreme Court announced that settlements in patent infringement suits are not precluded by antitrust law.[93] But the lower courts have taken this instruction to an extreme by blessing reverse payment

87. *In re* Ciprofloxacen Hydrochloride Antitrust Litig., 544 F.3d 1323, 1333 (Fed. Cir. 2008).

88. *See* Fiss, *supra* note 7, at 1086 (noting that judges' relief upon hearing that a case has settled has nothing to do with whether justice has been rendered, but rather, the relief is based on the knowledge that a case has been moved off their docket); *see also* Hovenkamp, *supra* note 46, at 1243, 1251 (arguing that the courts' reluctance to examine the underlying merits of the patent claim is not due to the policy favoring settlement, but rather, the difficulty inherent in determining patent validity and scope).

89. *See* Matthew B. Zisk, *Mediation and Settlement of Patent Disputes in the Shadow of the Public Interest*, 14 OHIO ST. J. ON DISP. RESOL. 481, 483 (1999).

90. *See* Fiss, *supra* note 7, at 1085–86 (arguing that parties may settle in a manner that leaves justice undone).

91. *Id.* at 1081.

92. *See id.* at 1075 (disagreeing with the position that settlement is always better than judgment and arguing instead that settlement should not be utilized "on a wholesale and indiscriminate basis").

93. Standard Oil Co. v. United States, 283 U.S. 163, 171 (1931).

settlements after a cursory glance. In their zeal to promote settlement, the circuit courts have completely ignored another deeply rooted public policy—the public interest in challenging invalid patents.[94]

In *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery*, the Supreme Court observed that:

> The possession and assertion of patent rights are "issues of great moment to the public." A patent by its very nature is affected with a public interest. . . . At the same time, a patent is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.[95]

Twenty-five years later, the Court reaffirmed the public's interest in challenging invalid patents in *Lear, Inc. v. Adkins*, announcing that "federal law requires that all ideas in general circulation be dedicated to the common good unless they are protected by a valid patent."[96] In *Lear*, the Court held that a license agreement did not prevent a licensee from attacking the validity of the licensor's patent.[97] The Court decided that the public interest in challenging invalid patents was stronger than contract law's interest in holding a purchaser to his promise.[98]

If a patent is valid, the anticompetitive effects of the patent are outweighed by the public benefits produced by innovation. In the pharmaceutical context, this innovation takes the form of a new drug. But if the patent is invalid or not infringed, it does not serve the public interest. If the holder of an invalid patent excludes all competitors through a reverse payment settlement, the anticompetitive effects (such as higher drug prices) are not outweighed by any public benefit. Unfortunately, the courts and commentators spend little time (if any) discussing the public's interest in challenging invalid patents.

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94. *See* Hemphill, *supra* note 30, at 707 (noting that the courts' promotion of settlement ignores the countervailing view that the public interest is served when patents are tested).

95. Precision Instrument Mfg. Co. v. Auto. Maint. Mach., 324 U.S. 806, 815–16 (1945) (quoting Hazel-Atlas Glass Co. v. Hartford Empire Co., 322 U.S. 238, 246 (1944)).

96. Lear, Inc. v. Adkins, 395 U.S. 653, 668 (1969).

97. *Id.* at 670–71.

98. *Id.*

VIII. WHY THE POLICY FAVORING SETTLEMENT SHOULD NOT APPLY TO REVERSE PAYMENT SETTLEMENTS

The real issue before the courts is the tension between the policy favoring settlement and the public's interest in removing invalid patents. Although courts would normally seek to balance these policies when presented with an antitrust challenge to a settlement agreement, the general rule that courts should encourage settlement should not apply at all to reverse payment settlements because they are against the public interest. There are multiple reasons why courts should view these settlements as atypical patent settlements that hurt the public.

First, unlike settlements in typical patent infringement cases, reverse payment settlements prevent future patent challenges.[99] Under the Hatch-Waxman Act, generic drug companies are sued within forty-five days of filing their ANDA-IV.[100] At this point, they have not started to market their drug, but under the Act, filing an ANDA-IV is considered an act of infringement.[101] The first generic company that asserts that a patent is invalid or that a drug does not infringe a patent receives a reward—180 days of exclusive marketing.[102] But if the first generic company accepts a payment and settles, the clock will not begin to run on the 180-day period unless a second generic firm challenges the patent and wins, or a forfeiture provision kicks in.[103] The problem is that a second generic firm has no incentive to challenge the patent. If it challenges the patent and wins, it has to wait 180 days to market its drug.[104] Furthermore, even if a forfeiture provision has kicked in, the second generic is not likely to challenge the patent because it will not have access to the 180-day reward, which is a major source of income.[105] In sum, by blocking all future patent challenges, reverse payment settlements prevent all generic drugs from entering the market for the term of the settlement agreement. This means that consumers

99. Carrier, *supra* note 34, at 84 (explaining that reverse payment settlements are not typical settlements because they are agreements "that dispose of the validity and infringement challenges central to the Hatch-Waxman scheme").

100. 21 U.S.C. § 355(j)(5)(B)(iii) (2006).

101. H.R. REP. NO. 98-857, pt. 1, at 28 (1984).

102. 21 U.S.C. § 355(j)(5)(B)(iv).

103. 21 U.S.C. § 355(j)(5)(D)(i); Hemphill, *supra* note 18, at 1587.

104. Hemphill, *supra* note 18, at 1578 (noting that the "legal form" of the exclusive period is a delay in FDA approval of all other ANDA-IVs); *see also* Carrier, *supra* note 18, at 47 (noting that the FTC cannot approve other ANDAs until the 180-day period expires).

105. Hemphill, *supra* note 18, at 1590.

will continue to pay high prices for the duration of the settlement agreement.[106]

In contrast, in regular patent infringement cases, the defendant is sued after it begins to market its product. Competing firms can and will sue because they can market their product immediately if they win (or they never stopped marketing their product, if a motion for preliminary injunction was denied).[107] Regular patent infringement cases usually settle with a license agreement, allowing the infringing company to sell the product in exchange for a royalty payment.[108] The patent holder has no incentive to pay an exit payment because the payment would not protect it from competition.

Second, most scholars and the government agree that the enormous settlement amounts raise a red flag. For example, the *Cipro* settlement totaled $398.1 million and delayed all generic entry until the end of the patent term.[109] The general view is that payments not exceeding the brand company's litigation costs do not raise a red flag.[110] However, excessive payments are harmful to consumers because they extend the monopoly period longer than the strength of the patent would naturally permit.[111] According to a recent FTC study, in generic challenges between 1992 and 2000, generic companies prevailed in 73% of cases, and brand companies only won 27% of cases.[112] A recent survey by the Federal Circuit also

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106. *See* Hemphill, *supra* note 30, at 704 (arguing it is easy to see why reverse payment settlements are bad). "A pay-for-delay settlement transfers wealth from consumers to drug makers in the form of continued high prices." *Id.*

107. Carrier, *supra* note 18, at 61. Carrier notes that unlike pay-for-delay agreements, general patent settlements do not prevent other competitors from challenging the patent. *Id.* In regular patent cases, if a defendant settles and agrees not to challenge the patent, "many others often wait in the wings to do so." *Id.*

108. Carrier, *supra* note 47, at 611; *see also* Hovenkamp, Janis & Lemley, *supra* note 35, at 1750–51 (explaining that in a perfectly functioning market, a monopoly producer would choose to produce all output itself, or license part of the output to a rival, and that it would have no incentive to pay another firm to stay out of the market, because it can exclude without paying the rival).

109. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1329, 1329 nn.4–5 (Fed. Cir. 2008).

110. *See generally*, Hovenkamp, Janis & Lemley, *supra* note 35, at 1758–60 (noting that even a patentee that is sure to win is willing to pay a sum up to the cost of the litigation to end the patent infringement lawsuit); Hovenkamp, *supra* note 47, at 25 (noting that even a patentee who is certain of success is willing to make a payment that is less than the anticipated litigation costs).

111. *See* Hemphill, *supra* note 30, at 703–04 (arguing that when a brand company makes a payment instead of relying solely on the strength of its case, it secures a later date of entry—one that is not warranted by the patent alone); *see also* Hovenkamp, Janis & Lemley, *supra* note 35, at 1758 (concluding that the size of the exclusion payment is inversely related to the strength of the patent holder's case). "[T]he less likely the patentee is to win, the more it is willing to pay a generic to stay out of the market." *Id.*

112. FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 16 (2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

revealed that brand companies prevail in only 30% of cases.[113] Given the high success rate of generic companies, courts should be concerned that brand manufacturers are paying off generic companies to acquire a monopoly that is not permitted under the law.

Reverse payment settlements also frustrate the purposes of the Hatch-Waxman Act. The purpose of the Hatch-Waxman Act was to provide low cost, prescription drugs by encouraging generic firms to challenge potentially invalid patents.[114] The 180-day exclusive marketing period was created to encourage generic firms to challenge weak patents and enter prior to patent expiration. Because reverse payment settlements foreclose all patent challenges, thus eliminating all generic drug entry prior to patent expiration, they undermine the purpose of the Hatch-Waxman Act. It is important to remember that, through the Hatch-Waxman Act, Congress has expressed its preference regarding the proper balance between innovation and competition.[115] In other words, Congress has already decided what amount of competition and innovation serves the public interest. Reverse payment settlements are private agreements that alter that balance.[116] Why should we assume that a privately negotiated settlement is more likely to serve the public than legislation that was passed by Congress?

Because data and research demonstrate that reverse payment settlements harm the public, the public interest in settlement should be given no weight when reviewing reverse payment settlements. *Aro Corporation v. Allied Witan Co.*, a case that was cited by the exclusionary scope courts, supports the idea that other public interests may prevail over the interest in settlement.[117] In *Aro*, the parties stipulated to dismissal without prejudice. They entered into a settlement agreement that included a license to Allied.[118] When Allied failed to make its royalty payment, Aro went to court to enforce the settlement agreement.[119] Allied argued that it should be permitted post-settlement to argue that the patent is invalid.[120] In deciding to order specific performance of the settlement agreement, the

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113. Paul M. Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 20 (2006).

114. *See* Carrier, *supra* note 18, at 60 ("[E]ven a cursory consideration of the statute underscores the importance of patent challenges."); *see also* Hemphill, *supra* note 18, at 1614 (describing litigation as the instrument by which the Hatch-Waxman Act accomplishes its goals).

115. Hemphill, *supra* note 18, at 1614 (argues that the Hatch-Waxman Act creates "a particular balance between innovation and competition").

116. *Id.* (arguing that the balance between innovation and competition that the Hatch-Waxman Act creates for a specific drug is upset by a private settlement that favors more innovation over consumer access).

117. Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1374 (6th Cir. 1976).

118. *Id.* at 1370.

119. *Id.*

120. *Id.*

court balanced the public interest in excluding invalid patents against the public interest in settlement.[121] Specifically, the court stated:

> In balancing the public interest in settlement of lawsuits against that of removing invalid patents . . . [e]vidence, not monopolophobia, should control. Where it can be shown that a patent does in fact have the effect of a "tax on the public," is in fact a cause of increased pricing, is in fact serving to limit competition in its product line or does in fact exert substantial effect upon the public and where it can be shown that the proffered challenge is the only one likely to be made, it may be that judicial policy should place determination of the possibility that such patent may be invalid ahead of holding litigants to their settlement agreements. [122]

Aro advocates a factual inquiry into the effect that a patent has on the public. If the patent harms the public, then the public interest in excluding invalid patents should prevail.

The overwhelming evidence suggests that reverse payment agreements are atypical patent settlements with anticompetitive consequences that cost consumers billions of dollars. As a result, courts should not hide behind the policy favoring settlement to avoid reaching the difficult patent issues in these cases.

IX. THE SOLUTION: WHEN ANALYZING AN ANTITRUST CHALLENGE TO A REVERSE PAYMENT SETTLEMENT, COURTS SHOULD DECIDE THE MERITS OF THE UNDERLYING PATENT CLAIMS

Unfortunately, the courts and commentators spend little time (if any) discussing the public's interest in challenging invalid patents. For example, in an article they recently co-authored, Professors Hovenkamp, Janis, and Lemley argue that patent infringement settlements are pro-competitive in some industries but not others. Their article advocates an industry-specific approach to analyzing patent settlements.[123] In their opinion, Hatch-Waxman settlements differ from other patent infringement settlements in that their unique characteristics present opportunities for the formation of settlement agreements that are against the public interest.[124] Ultimately, the authors propose an abbreviated analysis of the merits of the patent claim

121. *Id.* at 1374.
122. *Id.*
123. Hovenkamp, Janis & Lemley, *supra* note 35, at 1736–39.
124. *Id.* at 1722, 1752–55.

and suggest that their analysis will encourage drug manufacturers to negotiate pro-competitive settlements rather than impeding settlement activity altogether.[125]

Similarly, Professor Carrier argues that the general preference for settlement has been displaced by the specific regulatory framework of the Hatch-Waxman Act, which promotes patent challenges.[126] In making his case for an industry-specific approach, Carrier relies on the Supreme Court's decision in *Verizon Communications v. Law Offices of Curtis V. Trinko*, which stated that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue."[127] According to Professor Carrier, the Hatch-Waxman Act created a regulatory regime that balances innovation and competition and demonstrates the secondary relevance of the settlement-related policies on which the courts have focused their analysis.[128] Nevertheless, he argues that courts should not reach the merits of the underlying patent claim when analyzing an antitrust challenge to a reverse payment agreement.[129]

These scholars display a lingering concern for settlement. They advocate for either an abbreviated analysis of the merits or absolutely no analysis of the merits. In contrast, I believe the courts should completely discard the policy favoring settlement and decide the merits of the underlying patent dispute.

Although they advocate different approaches to dealing with reverse payment settlements, all scholars concede that litigating the underlying patent issues is the most straightforward way to decide these antitrust cases. However, in addition to their lingering concerns about the implications for settlement, scholars worry that patent litigation is "extremely difficult" and involves "complex issues" that cannot easily be included in an antitrust case.[130] Although I agree that patent litigation is difficult and involves complex issues, I find this argument surprising for a few reasons. First, the district courts have decided patent cases for years. Although difficult, claim construction and infringement analysis is not something new for the federal district courts. Second, a typical antitrust case also involves difficult and complex issues. When deciding antitrust cases, the courts examine highly technical industries and consider expert economic analysis. Deciding the underlying patent issues would be difficult and time consuming. But given that courts already deal with these or similar issues in other cases, I would

125. *Id.* at 1759–61.
126. Carrier, *supra* note 18, at 61; Carrier, *supra* note 34, at 84.
127. Verizon Commc'ns v. Law Offices of Curtis V. Trinko, 540 U.S. 398, 411 (2004).
128. Carrier, *supra* note 18, at 69.
129. *Id.* at 73, 80.
130. Carrier, *supra* note 34, at 91.

argue that this is a poor reason for taking the full litigation option off of the table.

In order to balance the policy favoring settlement against the interest in removing invalid patents, courts need to grapple with the underlying patent issues on some level. Unfortunately, the exclusionary scope analysis gives no weight to the public's interest in challenging invalid patents. Although an abbreviated analysis of the underlying patent issues may be warranted in an antitrust challenge to a regular patent settlement, I believe that a full analysis is warranted for reverse payment settlements, since research demonstrates that they are more likely to be anticompetitive. An abbreviated analysis would balance the interest in settlement against the interest in removing invalid patents. In contrast, a full analysis relegates the interest in settlement to an almost non-existent status. Because reverse payment settlements have been shown to harm the public, they should be subjected to a full analysis of the underlying patent issues.

X. THOUGHTS ON THE RECENT THIRD CIRCUIT OPINION

Recently, the Third Circuit reversed an order of dismissal in *In re K-Dur Antitrust Litigation*.[131] The district court followed the analysis used by the Second and Federal Circuits and granted the pharmaceutical defendants' motion to dismiss. On appeal, the Third Circuit rejected the exclusionary scope test, finding that it failed to subject reverse payment agreements to any antitrust scrutiny, and that it undermined the policies of the Hatch-Waxman Act.[132]

While acknowledging that the exclusionary scope test encourages settlement, which courts generally support, the court set the test aside with the following statement:

> [T]he judicial preference for settlement, while generally laudable, should not displace countervailing public policy objectives or, in this case, Congress's determination—which is evident from the structure of the Hatch-Waxman Act and the statements in the legislative record—that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers.[133]

131. *In re* K-Dur Antitrust Litigation, 686 F.3d 197, 218 (3d Cir. 2012).
132. *Id.* at 214.
133. *Id.* at 217.

This statement suggests that settlement may not always be in the public interest, especially in situations where there are countervailing policies (such as the interest in removing invalid patents) or a determination by Congress that litigation is more likely to protect consumers than settlement. In its opinion, the court discussed in particular the public interest in removing invalid patents.[134]

Ultimately, the Third Circuit adopted a quick look rule of reason analysis that would apply to settlements with reverse payments only.[135] The FTC proposed a similar approach in its amicus brief.[136] Under this test, a reverse payment settlement is prima facie evidence of an unreasonable restraint of trade.[137] This first step appears to incorporate the concept of presumptive illegality that most commentators and the FTC favor. After evidence of a reverse payment has been proffered, the prima facie case can be rebutted.[138] The court provides two examples of how the prima facie case can be rebutted. First, the drug manufacturers can demonstrate that the payment was not for delay, but for another reason.[139] Second, defendants can demonstrate that the payment creates a pro-competitive result that could not have been achieved absent the reverse payment—such as enabling a generic company with limited funds to avoid bankruptcy and eventually market its drug.[140] The court opined that this second situation is probably rare.[141]

I applaud the Third Circuit for stating that we should focus instead on the public interest in removing invalid patents. However, I believe that under the proffered analysis, drug manufacturers can easily manipulate their transactions to ensure that a prima facie case can be rebutted.

First, it is easy for drug companies to disguise an exit payment as an innocuous transaction "for another reason."[142] In fact, that is what the drug companies were attempting to do in *K-Dur*. Schering Plough (the brand manufacturer) promised to pay Upsher $60 million for three years to license

134. *Id.* at 215.

135. *Id.* at 217–18.

136. *See* Brief of the Federal Trade Commission as Amicus Curiae at 22–23, *In re* K-Dur Antitrust Litigation, 686 F.3d 197 (3d Cir. 2012) (No. 10-2077) (proposing that exclusion payment settlements should be evaluated under the rule of reason "which embraces a range of analyses—from full market analysis to abbreviated 'quick look' scrutiny"); *see also* Carrier, *supra* note 18, at 76–78 (advocating a similar approach to that proposed by the FTC in its amicus brief).

137. *K-Dur*, 686 F.3d at 218.

138. *Id.*

139. *Id.*

140. *Id.*

141. *Id*.

142. *See* Carrier, *supra* note 34, at 93 (noting that the payments from brand firms to generic firms are often hidden in other transactions). For example, instead of giving the generic firm a simple cash payment for delay, the brand companies are paying generics for IP licenses, products and/or raw materials, and for advertising assistance. *Id.*

Niacor-SR. After the settlement agreement was signed and the board ratified the acquisition of the license, plans to make and market Niacor-SR were abandoned. The antitrust plaintiffs argued that the license agreement payment was in fact compensation to Upsher in return for its agreement not to enter the market.

The second rebuttal option could apply to multiple situations as well. Many generic companies are cash starved. Moreover, perhaps it is incorrect to view the payment as providing a pro-competitive result in this situation. After all, the generic company would likely not be cash starved if it were permitted to market its drug immediately. The cost and delay of litigation is likely what is draining the generic company's finances in the first place.

Last, the Third Circuit's approach mentions the public interest in challenging invalid patents but fails to really consider it, since it utilizes a quick look rule of reason analysis in which the issues of patent validity and infringement are not examined at all. The court concluded that it was unnecessary to consider the underlying merits of the patent suit because it was presumed that the purpose of the payment was to prevent entry beyond a date that would be a reasonable compromise given the strength of the parties' cases.[143] I agree that there should be a presumption of illegality for reverse payment settlements. However, by choosing not to reach the merits at any level, the court ignores the very issues that determine whether there was an antitrust violation in the first place. In my opinion, the only proper way to rebut the presumption of illegality is for the defendants to demonstrate that the patent is valid and infringed.

If the patent is in fact valid and infringed, then the brand company can rely on the patent to exclude competition and, hence, the reverse payment settlement is not considered a market allocation agreement.[144] But if the patent is invalid or not infringed, then the agreement is a market allocation, which is *per se* illegal.[145] "There are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use."[146] The Supreme Court has determined that an agreement among competitors to allocate markets is a "classic example" of

143. *K-Dur*, 686 F.3d at 218.

144. Carrier, *supra* note 34, at 91.

145. United States v. Topco Assocs., 405 U.S. 596, 608 (1972); Palmer v. BRG of Georgia, Inc., 498 U.S. 46, 49–50 (1990); *see also* Carrier, *supra* note 18, at 72 (noting that if a patent is invalid or not infringed, there is no legitimate justification for delaying competition, and the reverse payment agreement is a cover for market allocation).

146. *Topco*, 405 U.S. at 607 (quoting N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958)).

a *per se* violation of Section 1 of the Sherman Act.[147] Because of their classification as "per se illegal," the anticompetitive effects of a market allocation agreement cannot be rebutted with a pro-competitive justification. Pro-competitive justifications, which are considered in a rule of reason analysis, are irrelevant when dealing with an agreement that is *per se* illegal. If there is a market allocation agreement, the rule of reason should not apply.[148] Hence, I believe that the Third Circuit's decision to rely on a quick look rule of reason analysis in the *K-Dur* case was incorrect.

XI. CONCLUSION

In this Article, I argue that the courts' blind reliance on the policy favoring settlement has resulted in a total absence of antitrust scrutiny of reverse payment settlements. In choosing to promote settlement, the courts have created the exclusionary scope analysis, which concludes that a patent is valid and infringed based on zero evidence.

The policy promoting settlement is premised on the idea that settlements serve the public interest. But a fact-based application of this policy would lead courts to conclude that it should not be considered when analyzing reverse payment settlements. This is because reverse payment settlements have effects that harm the public.

Reverse payment settlements cost consumers billions of dollars each year. Unlike regular patent settlements, they block future patent challenges and eliminate competition. The excessive payments extend the monopoly period longer than the strength of the patent would naturally permit, allowing brand firms to purchase a monopoly that is not sanctioned under the law. Finally, unlike typical patent settlements, reverse payment settlements are the product of a particular regulatory system that was created by the Hatch-Waxman Act. Through the Act, Congress has decided that in the pharmaceutical context, litigation, not settlement, will benefit consumers. Because reverse payment settlements harm the public, courts should not rely on the preference for settlement when analyzing these agreements.

The *K-Dur* decision is a step in the right direction. The opinion appears to acknowledge that the preference for settlement should not apply to settlements that do not serve the public interest. However, the court's quick look rule of reason test is misplaced and will not resolve the problem.

The central issue is whether the patent is valid and infringed. If it is,

147. *Id.* at 608.
148. *Id.*

then there is no antitrust violation. The patent holder has a statutory right to exclude competitors. But if the patent is invalid or not infringed, then what we have is a market allocation agreement. Thus, the Third Circuit's decision to apply the quick look rule of reason is not appropriate, since market allocation agreements are *per se* illegal.

Once courts accept that the policy favoring settlement should not apply to reverse payment settlements, they will have to address the public interest in challenging invalid patents. To do this, courts will have to grapple with the underlying patent issues. Despite their reluctance, courts must address the merits of the underlying patent claim when analyzing an antitrust challenge to a reverse payment settlement. It is only through this process that courts can properly determine whether a reverse payment agreement violates antitrust law.