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SHORTSIGHTED RESPONSE TO REVERSE PAYMENTS: HOW THE
THIRD CIRCUIT MAY CAUSE CONSUMERS TO “PAY FOR THE
DELAY” OF NEW DRUG DEVELOPMENT

JUDE STEININGER*

“The premise of laws against copying, however, is that humanity’s innate or socially determined desire to create is simply not enough in a modern innovation-based economy. To have sustained innovation—and to do so in areas that require significant investments of time and money—it is necessary to have a reliable expectation of economic reward.”¹

I. INTRODUCTION

Almost everyone, at some point in his or her life, has been affected by pharmaceutical innovation.² Whether it was as minor as needing cough medicine from your local pharmacy or as severe as needing medications to survive an operation, nearly everyone can relate.³ Often, trivial sickness comes and goes without real consideration for the resources needed to create the prescription drugs necessary to cure the illness.⁴ Recently an issue has developed that has the capacity to affect our medical landscape and threaten drug innovation in the future.⁵

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1. Chris Sprigman, *Does Copying Kill Creativity?*, PSYCHOLOGY TODAY BLOG (Sept. 26, 2012), <http://www.psychologytoday.com/blog/the-knockoff-economy/201209/does-copying-kill-creativity>.

2. See JACK A. MEYER, ASSESSING THE IMPACT OF PHARMACEUTICAL INNOVATION: A COMPREHENSIVE FRAMEWORK 8 (2002), available at <http://www.scribd.com/doc/7074694/Assessing-the-Impact-of-Pharmaceutical-Innovation-A-Comprehensive-Framework> (scanning wide variety of multiple health condition improvements that have resulted from pharmaceutical innovation). Studies have shown that certain innovative drug developments have shown positive health benefits that coincide with a reduction in health costs. See *id.* (asserting positive impact on health and economics provided through drug innovation).

3. See CENTERS FOR DISEASE CONTROL AND PREVENTION, THERAPEUTIC DRUG USE (2011), <http://www.cdc.gov/nchs/fastats/drugs.htm> (stating statistical data of therapeutic drug use from 2005–2008).

4. See Michael Dickson & Jean Paul Gagnon, *The Cost of New Drug Development and Discovery*, DISCOVERY MEDICINE (June 20, 2009), <http://www.discoverymedicine.com/Michael-Dickson/2009/06/20/the-cost-of-new-drug-discovery-and-development/> (discussing high costs involved with creating medications). Drug discovery and development usually costs the pharmaceutical companies hundreds of millions of dollars. See *id.* (explaining incredibly high costs involved in drug innovation and development).

5. See *Reverse-Payments Ban Dropped: What’s at Stake for Pharma and Consumers*, MAKOVSKY INTEGRATED COMMUNICATIONS,

This issue derives from the 1984 legislation known as the Hatch-Waxman Act.⁶ Congress sought to create a mechanism that would allow for a greater influx of generic alternatives in the pharmaceutical marketplace.⁷ Through this legislation, generic manufacturers were provided an abbreviated application process for seeking Food and Drug Administration (FDA) approval of a bioequivalent alternative to a formerly patented drug.⁸

In response to the ensuing challenges, branded pharmaceutical corporations sought out settlements that would help reinforce their exclusionary patent rights.⁹ The resulting agreements became known as pay-for-delay, or reverse payment settlements.¹⁰ Essentially, the generic challenger agrees to keep their generic alternative off the shelves in return for payments from the patent holder's future profit margin.¹¹ The resulting monopolistic effects have led to pharmaceutical wholesalers and retailers taking legal action.¹² Claiming antitrust violations under Section 1 of the Sherman Antitrust Act, these parties allege that reverse payment settlements cause an unreasonable restraint of trade in the pharmaceutical industry.¹³

Over the past decade, multiple circuit courts have struggled to formulate a consistent method of examining these settlements.¹⁴ Recently a Third Circuit

<http://www.makovsky.com/insights/strategies/reverse-payments-ban-dropped> (last visited Oct. 10, 2012) [hereinafter *Reverse-Payments Ban Dropped*] (asserting strong concern for future pharmaceutical innovation).

6. See Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 63 (2010) (explaining that reverse payment settlements occur in setting of Hatch-Waxman Act).

7. See Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281, 283 (2011) (asserting first goal of Hatch-Waxman Act to be increasing amount of lower cost generic drugs available to general public).

8. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 203 (3d Cir. 2012) (explaining short-form application process offered to generic manufacturers through Hatch-Waxman Act).

9. See Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1553 (2006) (asserting that in past decade pharmaceutical drug makers have turned to reverse payment settlements to end litigation in this area).

10. See Kendyl Hanks et al., *"Pay-for-Delay" Settlements: Antitrust Violation or Proper Exercise of Pharmaceutical Patent Rights?*, BUS. L. TODAY 1, 1–2 (2011), available at <http://apps.americanbar.org/buslaw/blt/content/2011/01/article-hanks.pdf> (explaining that these settlements are known as reverse payment settlements or pay-for-delay settlements).

11. See Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 494–95 (explaining mechanics of reverse payment settlements); see also Steven W. Day, *Leaving Room for Innovation: Rejecting the FTC's Stance Against Reverse Payments in Schering-Plough v. FTC*, 57 CASE W. RES. L. REV. 223, 230 (2006) (discussing payment from patentee to alleged infringer).

12. See *K-Dur*, 686 F.3d at 208 (discussing private claim brought by wholesalers and retailers). The plaintiffs stated, "On April 14, 2008, the Special Master certified a class of plaintiffs consisting of forty-four wholesalers and retailers who purchased K-Dur directly from Schering." *Id.*

13. See Butler & Jarosch, *supra* note 6, at 60 (asserting that claims brought against reverse payment settlements are alleged violations of Sherman Act). The claims allege that the reverse payment settlements unreasonably restrain trade therefore violating section one of the Sherman Antitrust Act. See *id.*

14. See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *In re*

decision has further substantiated an evident circuit split.¹⁵ The inconsistency in reverse payment analysis calls for Supreme Court intervention, and without the appropriate clarification, the pharmaceutical industry could suffer detrimental consequences.¹⁶

Part II of this Note explains the legislation of the Hatch-Waxman Act (Act), its purpose, and the mechanics that led to the resulting reverse payment settlements.¹⁷ Part III surveys the landscape of prior case law throughout the circuit courts.¹⁸ Part IV discusses the recent Third Circuit decision in *In re K-Dur Antitrust Litigation* that has rekindled the Hatch-Waxman debate.¹⁹ Part V analyzes the policy concerns advanced by opposing sides of the argument and the economic fallout likely to result.²⁰ Finally, part VI concludes with the assertion that the Supreme Court must intervene and establish the most beneficial standard of analysis for reverse payment settlements.²¹

II. THE HATCHING OF A PROBLEMATIC ACT

The legislation of the Hatch-Waxman Act has sparked a heated debate in the pharmaceutical industry.²² Congress acted in an attempt to counter the high prices of pharmaceuticals, and their decision has further endangered medical consumers.²³ A thorough examination of the motivations of the Act, the functionality of the Act, and the resulting litigation, leads to the logical conclusion that efficient and effective reform is essential.²⁴

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); Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799 (D.C. Cir. 2001).

15. See *K-Dur*, 686 F.3d at 197 (holding reverse payments to be prima facie evidence of illegality).

16. See Aaron Barkoff, *Third Circuit Issues Landmark Decision in Reverse Payment Case, Setting Up Supreme Court Review*, ORANGE BOOK BLOG (July 17, 2012), <http://www.orangebookblog.com/2012/07/3rd-circuit-issues-landmark-decision-in-pay-for-delay-case-setting-up-supreme-court-review.html> (asserting likely Supreme Court intervention to resolve conflict); cf. *Reverse-Payments Ban Dropped*, supra note 5 (explaining detrimental effects that will likely result from banning reverse payment settlements).

17. For an examination of the legislation, purpose, and results of the Hatch-Waxman Act, see *infra* notes 25–50 and accompanying text.

18. For an overview of previous case law developed in other circuit courts, see *infra* notes 51–71 and accompanying text.

19. For an examination of the recent Third Circuit opinion, see *infra* notes 72–118 and accompanying text.

20. For an analysis of the policy concerns advanced by different circuit courts and the economic consequences likely to result from each approach, see *infra* notes 119–210 and accompanying text.

21. For concluding remarks and a brief assertion of the analysis needed to derive the best long-term effects, see *infra* notes 211–17 and accompanying text.

22. See Dolin, supra note 7 at 283 (discussing how reverse payment agreements have developed as result of Hatch-Waxman incentives).

23. See *id.* at 286 (explaining Congress's intent to bring lower cost generic drugs into market). But see *Reverse-Payments Ban Dropped*, supra note 5 (discussing innovative consequences likely to be seen following ban of reverse payment settlements).

24. See *Reverse-Payments Ban Dropped*, supra note 5 (asserting strong concern for push to end reverse payment settlements and need for proper resolution). For further discussion of the Act's functionality and effects, see *infra* notes 25–50 and accompanying

A. *Enactment of the Hatch-Waxman Act as an Attempt to Counter High Market Prices*

The issue of reverse payment settlements has its origins in the enactment of the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act.²⁵ As a response to the high consumer costs experienced in the pharmaceutical industry, this legislation was proposed to encourage and increase the availability of generic alternatives to branded pharmaceutical medications.²⁶ Congress formed the Hatch-Waxman Act, attempting to achieve three main objectives with the new application and approval process.²⁷

First, Congress looked to expedite the process of bringing cheaper generic alternatives into the market by streamlining the procedure for filing a patent challenge.²⁸ Second, the Act was created to incentivize drug manufacturers to focus more on new drug development.²⁹ Finally, Congress intended for the Act to assist in clearing the landscape of invalid patents.³⁰ Congress attempted to strike the precise balance between encouraging pharmaceutical innovation and

text.

25. See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (explaining legislation known as Hatch-Waxman Act and how amendments work); see also Dolin, *supra* note 7, at 283 (discussing rise of reverse payment settlements as consequence of incentives that derive from Hatch-Waxman Act).

26. See Butler & Jarosch, *supra* note 6, at 63 (asserting that Hatch-Waxman Act sought to provide greater incentives for generic companies to market generic versions of drugs available from higher priced pharmaceutical companies); see also FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010), available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf> [hereinafter PAY-FOR-DELAY] (stating that pay-for-delay settlements cost American consumers 3.5 billion dollars every year). For further discussion of the economic impact of the act and the resulting consequences, see *infra* notes 158–210 and accompanying text.

27. See Dolin, *supra* note 7, at 286–87 (suggesting that enactment of Hatch-Waxman Act looked to achieve several purposes by streamlining approval process for generic alternatives to patented medications). For further discussion of the objectives sought through this Act, see *infra* notes 51–71 and accompanying text.

28. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 203 (3d Cir. 2012) (explaining that Congress hoped to jump-start generic entry into market by passing Hatch-Waxman Act). Congress used the new act to allow for an abbreviated application process for FDA approval. See *id.* (explaining process in place with Hatch-Waxman Act that allows for Abbreviated New Drug Applications); see also Dolin, *supra* note 7, at 286–87 (suggesting three objectives that Congress had anticipated achieving with legislation of this Act).

29. See Scott A. Backus, *Reversing Course on Reverse Payment Settlements in the Pharmaceutical Industry: Has Schering-Plough Created the Blueprint for Defensible Antitrust Violations?*, 60 OKLA. L. REV. 375, 380 (2007) (discussing that first reason for Hatch-Waxman Act is to induce pharmaceutical firms to effectively invest in research and development of new drugs); Reza Bagherian, *The Preserve Access to Affordable Generics Act: Will Congress's Response to Reverse Payment Patent Settlements Enhance Competition in the Pharmaceutical Market?*, 7 J. MARSHALL REV. INTELL. PROP. L. 150, 152 (2007) (discussing hope that Act would result in new expenditures into research and development of certain products for market).

30. See Dolin, *supra* note 7, at 286–87 (asserting that final goal of Hatch-Waxman Act was to help clear out invalid patents). The Act looked to encourage litigation over the patents protecting these pharmaceutical drugs. See *id.* (explaining how Act would result in eliminating invalid patents).

ensuring fair competition.³¹

With this delicate equilibrium in mind, Congress included a 180-day exclusivity period, allowing an exclusive right to sell for the first generic challenger who brought forward a drug sufficient to enter the market.³² Congress utilized this exclusivity period in the hope that it would incentivize a greater influx of generic challengers.³³ While on its face the enticement seems likely to produce the sought-after balance of innovation and competition, the functionality of the exclusivity period, and the Act as a whole, has actually resulted in the anticompetitive issues at hand.³⁴

B. *The Hatch-Waxman Process and Functionality*

With the enactment of the 1984 Hatch-Waxman Act, generic companies were given a procedure that allows patent challenges to accelerate through the application process by making use of an Abbreviated New Drug Application (ANDA).³⁵ The procedure begins by a generic manufacturer seeking FDA approval of a new generic medication through the filing of the ANDA.³⁶ The generic drug manufacturer asserting the ANDA must certify that one of the following four conditions are met: (1) no patent related to the pioneer drug has been filed; (2) the relevant patent has expired; (3) the patent will expire on a certain date; or (4) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug entity.³⁷ Most Hatch-Waxman litigation and resulting reverse payment settlements arise when the challenger

31. See Backus, *supra* note 29, at 380 (explaining that Hatch-Waxman Act emerged from Congress hoping to balance two conflicting policy issues).

32. See *K-Dur*, 686 F.3d at 203–04 (explaining that first challenger to bring forward generic medication suitable for market will be allowed 180-day exclusivity period). The FDA agrees to not approve another Abbreviated New Drug Application in the 180 days following the marketing of the first generic drug. See *id.* (discussing protocol that will follow from successful patent challenge and exclusivity benefit first company will receive).

33. See *id.* at 204 (suggesting that first challenger to patent medication will then be most motivated due to this exclusivity period); see also Hemphill, *supra* note 9, at 1579 (stating that reward for generic company that successfully challenges patent on major drug can be worth several hundred million dollars).

34. See *K-Dur*, 686 F.3d at 203–04 (explaining that if first filer either settles, loses, or withdraws, subsequent filers will not be awarded this 180-day exclusivity period). This results in only the first filer having any real motivation to go through with challenging the patent. See *id.* (discussing heightened motivation from first challenger as opposed to any subsequent challengers); see also Hemphill, *supra* note 9, at 1588–91 (explaining that resulting settlement between pharmaceutical company and first generic manufacturer will likely end up dividing profits from remaining term of patent between two parties).

35. See *K-Dur*, 686 F.3d at 203 (explaining process put in place following enactment of Hatch-Waxman Act amending Federal Food, Drug, and Cosmetic Act). This short-form application allows reliance on the FDA's prior consideration of safety and efficacy regarding the patented drug. See *id.* (explaining how new ANDA utilizes FDA's prior considerations to expedite approval process); see also Hanks et al., *supra* note 10, at 1–2 (asserting that Hatch-Waxman Act allowed for generic manufacturers to file ANDA prior to expiration of patent rights without automatically triggering infringement).

36. See *K-Dur*, 686 F.3d at 203 (explaining that new application process begins with filing ANDA).

37. See 21 U.S.C.A. § 355(j)(2)(A)(vii) (West 2012) (explaining four options available).

files a paragraph four certification.³⁸

Once the generic manufacturer files the ANDA, it is required to notify the patent holder of the application and certification under paragraph four.³⁹ A forty-five day patentee response period follows, which allows the challenged pharmaceutical company to file an infringement claim automatically staying the ANDA approval process.⁴⁰ When a conclusion is reached, or the stay is concluded, the first ANDA filer receives their 180-day exclusivity period as long as there is no failure to market their product.⁴¹ Pharmaceutical companies have responded by settling cases, effectively allowing them to maintain their patent rights and eliminate the exclusivity period privilege using the failure to market provision.⁴²

C. Reverse Payment Settlements as a Controversial Solution

Pharmaceutical companies often respond to Hatch-Waxman litigation by settling prior to the generic drug entering the market.⁴³ While settlements are a

38. See *K-Dur*, 686 F.3d at 203 (stating that generic company at issue in present case used paragraph four certification, causing issue at hand); cf. Butler & Jarosch, *supra* note 6, at 64 (explaining that nearly all reverse payment settlements ultimately stem from challengers using fourth option for certification).

39. See Backus, *supra* note 29, at 382–83 (explaining that generic manufacturer must provide notice). Further, the notice must provide a detailed statement of factual and legal grounding for the claim that the patent is either invalid or will not be infringed. See *id.* (describing what information notice must contain in order to give proper warning); see also Brian Range, *The ANDA Patent Certification Requirement and Thirty-Month Stay Provision: Is it Necessary?* 2 (2001) (unpublished third year paper, Harvard Law School), available at <http://leda.law.harvard.edu/leda/data/355/Range.pdf> (noting that generic filer of ANDA under paragraph four must notify patent holder of challenge); cf. Bagherian, *supra* note 29, at 153 (stating that generic manufacturer must notify patent holder of intent to enter market).

40. See *K-Dur*, 686 F.3d at 203–04 (explaining that filing suit will result in automated stay preventing FDA approval for thirty months or until conclusion of court hearing). Following 2003 amendments to the Act, only one thirty-month stay is allowed in an attempt to prohibit strategically delaying a resolution. See *id.* (stating that automated stay is in effect for thirty months or until resolution is reached); cf. Dolin, *supra* note 7, at 292 (discussing that only one thirty month stay is available to avoid over-extending postponement of resolution).

41. See Wansheng Jerry Liu, *Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Cases*, 18 ALB. L.J. SCI. & TECH. 441, 453 (2008) (explaining that under new provisions, 180-day exclusivity period can be forfeited if first ANDA filer fails to market their generic version of patented drug prior to expiration dates).

42. See Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 191 (2008) (describing loophole that has allowed pharmaceutical companies to utilize settling as tool to not only keep their patent rights alive, but also to eliminate incentive for subsequent generic manufacturer). Whether the generic company ends up losing the exclusivity period or not, the pharmaceutical company effectively eliminates the incentive in place. See *id.* at 192 (explaining that if generic manufacturer forfeited exclusivity period, then subsequent generic challengers do not have access to exclusive selling rights because they are only offered to first ANDA filer). Once the exclusivity period is not utilized, the generic manufacturer will forfeit the rights through the seventy-five day marketing provision put in place. See *id.* (explaining that if generic manufacturer does not market drug within seventy-five days, exclusivity period is forfeited and therefore eliminated for subsequent challengers).

43. See Hemphill, *supra* note 9, at 1553 (suggesting that challenging party often abandons suits that would likely increase competition, thus resulting in more settlements).

common resolution to patent claims, reverse payment settlements have come under scrutiny because they result in patent holders paying to keep alternative drugs off the shelves.⁴⁴ This ingenious approach allows pharmaceutical companies to maintain patent rights for the relatively small price of sharing a designated amount of profits with the opposing generic producer.⁴⁵ Furthermore, the resolution eliminates any incentive for subsequent challengers to come forward with true intentions of entering the market because the exclusivity period is only granted to the first ANDA filer.⁴⁶

These reverse payment settlements have been criticized for having anticompetitive effects in the pharmaceutical industry.⁴⁷ Wholesalers and manufacturers have begun filing class action claims against the settling parties involved in the agreements.⁴⁸ These claims assert that the alleged anticompetitive consequences drive industry prices up and negatively affect consumer welfare.⁴⁹ The resulting litigation has left the circuit courts in

44. See Dolin, *supra* note 7, at 293 (explaining that reverse payment settlements are unusual in that alleged infringing party receives payment and patent holder maintains patent rights). About forty-five percent of settlements in this area of law result in such payments. See *id.* (discussing statistics of settlements in relevant types of cases and prevalence of reverse payments in such settlements); cf. *The Legality of "Reverse Payments"*, ANTITRUST COUNSELOR (Am. Bar Ass'n) (2010), at 1 (expressing that sometimes these reverse payment settlements keep generic drugs out of market).

45. See Scott Bergeson, *A Vaccine Approach to the Reverse Payment Illness*, 18 RICH. J.L. & TECH. 14, *2 (2012) (explaining that instead of risking financial benefits of losing their patent rights, pharmaceutical companies pay generic companies portion of profits in order to keep stronghold on monopolistic benefits of patent).

46. See *id.* at *4 (expressing further concern that this result eliminates exclusivity incentive for successive challengers); see also Dolin, *supra* note 7, at 292–93 (explaining that generic company can settle with patent holder, while still receiving financial benefits of exclusivity period).

47. See Backus, *supra* note 29, at 375 (asserting that FTC found reverse payment settlements to unfairly restrict generic entry into marketplace); see also Ian Y. Liu & Rebecca McNeill, *The Pay-for-Delay Dilemma: Changes and Challenges Are on the Horizon for Innovative Pharmaceutical Companies*, PHARMACEUTICAL FORMULATION & QUALITY 14 (2011), available at http://www.nxtbook.com/nxtbooks/wiley/pfq_20110607/ (explaining that pay-for-delay settlements are controversial business practice).

48. See generally *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) (summarizing claim that reverse payment settlement agreement between pharmaceutical company and generic manufacturer was anticompetitive in nature); see also *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1330 (Fed. Cir. 2008) (analyzing whether similar settlement illegally restricted competition); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 194 (2d Cir. 2006) (discussing settlement involving license to sell unbranded version of pertinent drug, along with cash payment in return for staying out of market); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (discussing reverse payment settlement); *Valley Drug Co. v. Geneva Pharms, Inc.*, 344 F.3d 1294, 1298–1300 (11th Cir. 2003) (analyzing settlement involving payment of substantial sums from patent holder to generic manufacturer); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001) (discussing settlement involving reverse payments).

49. See, e.g. *K-Dur*, 686 F.3d at 207–08 (explaining wholesalers and retailers brought suit against settling parties involved in *K-Dur* 20 generic alternatives); see also Butler & Jarosch, *supra* note 6, at 60 (discussing how challenges have been brought by both FTC and private litigants); cf. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 50 (2009) (asserting that reverse payment settlements can cost consumers upwards of thirty-five billion dollars over ten years).

disarray, searching for the appropriate resolution to these disputes.⁵⁰

III. A CIRCUIT COURT PRECEDENT IN DISARRAY

Although each settlement resulting from Hatch-Waxman challenges may differ in terms, the antitrust questions that arise are always a consequence of the underlying reverse payments.⁵¹ The circuits that first addressed the issue analyzed the relevant settlements under strict antitrust scrutiny, essentially creating a presumption of illegality.⁵² More recently, circuit courts have departed from the strict scrutiny approach, shifting towards a “scope of the patent” test.⁵³ This method of examination attempts to determine whether the pertinent settlement exceeds the exclusionary scope of the related patent.⁵⁴ The conflict in analytical approaches has created a muddled precedent in need of Supreme Court intervention.⁵⁵

A. *The D.C. and Sixth Circuits Put a “Per Se” Stop to Reverse Payment Settlements*

In 2001, the D.C. Circuit handed down the first decision pertaining to reverse payment agreements.⁵⁶ The court considered an arrangement that

50. See *K-Dur*, 686 F.3d at 209 (discussing different approaches taken by five previous circuit courts that have weighed in on issue); see also Butler & Jarosch, *supra* note 6, at 66 (describing conflicting approaches by different circuits resulting in circuit split); Hanks et. al, *supra* note 10, at 2 (explaining that as result of conflict over reverse payment settlements, split among circuit courts has emerged).

51. See Dolin, *supra* note 7, at 294 (explaining how settlements may have different terms, but there are common features in reverse payments).

52. See *K-Dur*, 686 F.3d at 209 (discussing first two circuits to address issues and analysis that were used in reaching conclusion); *Cardizem*, 332 F.3d 896 at 908 (holding that reverse payment settlement was per se illegal restraint of trade); *Andrx*, 256 F.3d at 813 (holding that reverse payment was prima facie evidence of illegality of agreement).

53. See, e.g., *Ciprofloxacin*, 544 F.3d at 1336 (holding that inquiry is whether agreements restrict competition beyond scope offered through protection of patent); *Tamoxifen*, 466 F.3d at 213 (holding that there is no cognizable injury as long as restraints are within scope of patent).

54. See *K-Dur*, 686 F.3d at 209 (explaining change in approach that has developed with latter three circuit decisions involving reverse payment settlements); *Ciprofloxacin*, 544 F.3d at 1336 (holding that inquiry is whether agreements restrict competition beyond scope offered through protection of patent); *Valley Drug Co. v. Geneva Pharms. Inc.*, 344 F.3d 1294, 1311 (11th Cir. 2003) (holding that analysis should be whether any part of agreement went beyond protections provided by issued patent); *Tamoxifen*, 466 F.3d at 213 (holding that there is no cognizable injury as long as restraints are within scope of patent).

55. See *K-Dur*, 686 F.3d at 209 (explaining how approach taken by circuit courts had changed from presumed illegality to scope of patent inquiry); see also Bernard Persky & Morissa Falk, *Reverse Payment Settlements: The Time for Change has Arrived*, 3 BLOOMBERG L. REP. 1, 5–6 (2010), available at <http://knowledgegenetwork.labaton.com/upload/Reverse-Payment-Settlements-The-Time-for-Change-has-Arrived.pdf> (explaining possibility for Supreme Court or congressional intervention resulting from circuit split).

56. See *K-Dur*, 686 F.3d at 210 (discussing decision in *Andrx*). See generally *Andrx*, 256 F.3d 799 (resolving case involving reverse payments to keep generic manufacturer from entering market while patent litigation ensued).

effectively extended monopolistic effects by delaying generic entry into the market until a resolution to the litigation was reached.⁵⁷ As a response to this proposed anticompetitive activity, the D.C. Circuit took the drastic measure of applying strict antitrust scrutiny.⁵⁸ The court held the payment to be prima facie evidence of an illegal agreement not to compete.⁵⁹ This decision established per se illegality for reverse payments.⁶⁰

Affirming the D.C. Circuit's approach, the Sixth Circuit added to per se precedent for examining reverse payments.⁶¹ In 2003, the Sixth Circuit contemplated the first reverse payment settlement that attracted public scrutiny.⁶² The court held that the relevant agreement was "a classic example of a *per se* unreasonable restraint of trade."⁶³ This decision validated a per se approach that stood as preliminary legal precedent for reverse payment antitrust analysis.⁶⁴

57. See *Andrx*, 256 F.3d at 803 (explaining terms of agreement in question). The terms of the agreement included payment of forty million dollars per year, paid quarterly, beginning the day of FDA approval of the generic drug and ending the day that the generic manufacturer decided to begin selling the new drug. See *id.* at 803–04 (describing exact financial terms of agreement and outlining start and end date of payments). The settlement in *Andrx* utilized a reverse payment to delay the marketing of the generic medication while the patent litigation unfolded. See *id.* (discussing that agreement was in effect until resolution of litigation, not settlement to litigation).

58. See *id.* at 813 (implying that ten million dollar quarterly payment induced generic manufacturer, in this case *Andrx*, to not enter market when it otherwise would have). "Andrx's argument that any rational actor would wait for resolution of the patent infringement suit is belied by the *quid* of HMRI's *quo*." *Id.*

59. See *id.* (treating payment from patent holder to generic manufacturer as prima facie evidence of agreement not to compete); see also *K-Dur*, 686 F.3d at 210 (asserting that *Andrx* court found payment to be prima facie evidence of an illegal agreement).

60. See *K-Dur*, 686 F.3d at 209–10 (discussing first approach of strict antitrust scrutiny presuming illegality). "Two of those courts—the first two to consider the question—concluded that such agreements should be subject to strict antitrust scrutiny, at least where the settling parties attempted to manipulate the 180-day exclusivity period to block all potential generic competition." *Id.* at 209.

61. See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) (applying per se illegality to agreement); see also *Carrier*, *supra* note 49, at 53 (asserting that Sixth Circuit would hold agreement to be per se illegal because patent holder not only delayed entry by challenging generic manufacturer but also delayed all entry of generic alternatives into market).

62. See generally *Cardizem*, 332 F.3d 896 (deciding legality of reverse payment settlement resolving Hatch-Waxman Act dispute); see also *Dolin*, *supra* note 7, at 294 (explaining that real reverse settlement landscape began with *Cardizem* because it was one of first cases to attract public eye to controversial settlements).

63. *Cardizem*, 332 F.3d at 908 (quoting court's reasoning verifying illegality). The agreement exchanged cash payments in return for the insurance that the generic manufacturer would stay out of the market, even after receiving FDA approval. See *id.* at 910 (explaining that plaintiffs asserted agreement between accused parties and put cash payment into effect when there was FDA approval, therefore delaying entry of approved generic alternative and delaying triggering of exclusivity period granted to that company); see also *K-Dur*, 686 F.3d at 210–11 (explaining that agreement in *Cardizem* prevented other generic manufacturers from entering market by delaying triggering of first filer's 180-day exclusivity period); cf. *Butler & Jarosch*, *supra* note 6, at 68 (asserting that court found term of agreement ensuring delay of exclusivity period to be extension of anticompetitive nature, which denied access to all generic competitors).

64. See *Cardizem*, 332 F.3d at 907–09 (dismissing all of defendants pro-competitive

B. *Subsequent Circuits Respond by Reversing the Trend of Reverse Payment Analysis*

Following the initial outcry for the illegality of reverse payment settlements, subsequent circuits diverged from per se analysis.⁶⁵ Fortunately, in a later 2003 decision, the Eleventh Circuit asserted the right to exclude provided through patent protection.⁶⁶ The court emphasized that an agreement advancing only patent protection could not be per se illegal.⁶⁷ Instead, the inquiry turned on whether the settlement at issue stretched beyond the scope of the patent, consequently establishing the “scope of the patent” test.⁶⁸

Additionally, the Second and Federal Circuits would later add to the Eleventh Circuit’s precedent by applying a presumption of patent validity when utilizing the scope of the patent test.⁶⁹ The courts advanced a strong judicial preference for allowing settlement, which outweighed any threat posed by invalid patents.⁷⁰ The courts had begun to clearly deviate from the highly

arguments and declaring per se illegality). The court believed such a settlement could not be justified through expressing the need to enforce the patent rights because the settlement went beyond patent enforcement. *See id.* at 908 (suggesting that it is not fair to describe settlement as simply enforcing patent rights, rather it was attempt to illegally extend benefits); *see also Dolin, supra* note 7, at 295 (explaining Sixth Circuit concluded agreements to be per se violation).

65. *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006) (applying presumption of patent validity); *Valley Drug Co. v. Geneva Pharms. Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003) (analyzing policy concerns in favor of these settlements); *see also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1330 (Fed. Cir. 2008) (maintaining scope of patent test as appropriate analysis for reverse payment settlements).

66. *See Valley Drug*, 344 F.3d at 1305 (asserting that name brand manufacturer had patent that allowed right to exclude competitors for designated time). The agreement stopped alternatives from entering the market until after the patent expired. *See id.* at 1300 (explaining that agreement between patent holder and generic manufacturer entailed that challenger agree to not sell or market alternative drug until patent was to expire). Further, the generic manufacturer agreed to not transfer its rights under the ANDA filing, including the right to the 180-day exclusivity period. *See id.* (discussing remaining terms of contract that allowed for patent holder to keep all generic alternatives out of market). In return for agreeing to not enter the market or waive its ANDA rights, the generic manufacturer was paid in increments based on an agreed upon schedule. *See id.* (discussing details of agreement); *see also Persky & Falk, supra* note 55, at 5 (discussing three factors involved in determining antitrust liability, which include patent holder’s right to exclude).

67. *See Valley Drug*, 344 F.3d at 1301 (discussing district court’s ruling that agreements were per se antitrust violations of Section 1 of Sherman Act). *But see id.* at 1306 (reversing district court’s decision). The Eleventh Circuit believed the rationale was flawed and that the agreements were not per se violations. *See id.* (asserting that exclusionary effect of patent must be considered in determining restraint of trade caused by agreements).

68. *See id.* at 1311–12 (asserting that before applying any range of antitrust analysis, courts must look to whether agreement goes beyond patent protections). The court here is explaining that it neither will apply a per se antitrust violation or the alternative rule of reason analysis provided for antitrust examinations. *See id.* at 1312 (explaining that antitrust analysis ranges from per se to rule of reason, but one must first look at scope of patent protection for reverse payment settlements).

69. *See Ciprofloxacin*, 544 F.3d at 1336 (Fed. Cir. 2008) (asserting no need to consider patent validity); *Tamoxifen*, 466 F.3d at 213 (2d Cir. 2006) (applying assumption of patent validity).

70. *See Tamoxifen*, 466 F.3d at 211 (explaining that judicial preference for settlement counters possibility of weak patents being able to extend their monopoly). The court

assumptive per se approach; however, this trend would progress no further following the Third Circuit's decision in *In re K-Dur Antitrust Litigation*.⁷¹

IV. IN RE K-DUR ANTITRUST LITIGATION

The recent Third Circuit case *In re K-Dur Antitrust Litigation* addressed reverse payment settlements that were a result of challenges to the patent protecting the technology in the drug K-Dur 20.⁷² The Third Circuit's decision to retreat back to a per se approach has generated more fear in the pharmaceutical industry and created a legitimate threat to pharmaceutical innovation.⁷³ This substantiation of an evident circuit split validates the need for Supreme Court intervention and affirms a necessity for a resolution that allows reverse payment settlements to effectively and efficiently resolve Hatch-Waxman disputes.⁷⁴

A. Facts and Procedure

The issues in *In re K-Dur Antitrust Litigation* stem from two prior patent disputes that resulted in reverse payment settlements.⁷⁵ K-Dur 20, a drug

explained that the mechanics of the Hatch-Waxman Act offer logical reasons supporting settlement for both parties involved. *See id.* at 206–07 (explaining that Hatch-Waxman litigation encourages both sides to settle). Unlike normal patent infringement cases, Hatch-Waxman disputes take place prior to any generic investment into the market. *See id.* (explaining difference between normal patent infringement cases and Hatch-Waxman cases). Further, the patentee will not be able to recover any infringement damages if they push the litigation through. *See id.* (discussing incentive for pharmaceutical patent holder to settle as well). Settlement results in financial benefits for generic manufacturers prior to market investment and guarantees the patent holder that no infringement will take place. *See id.* at 207 (asserting mutual benefits resulting from settling Hatch-Waxman disputes); *see also K-Dur*, 686 F.3d at 214 (stating that Second Circuit determined that risk of weak patents being extended is counterbalanced by judicial preference for allowing settlement resolutions).

71. *See Tamoxifen*, 466 F.3d at 212–13 (holding that as long as competition is restrained within scope of patent, then no injury to market is cognizable under existing antitrust law). The court reaffirmed the Eleventh Circuit approach and additionally presumed patent validity. *See id.* (asserting that patent validity is presumed and will only be questioned if accessed through fraud); *see also Ciprofloxacin*, 544 F.3d at 1336 (holding that scope of patent test is to be applied). “[T]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent.” *Id. But see K-Dur*, 686 F.3d at 214 (holding that scope of patent test improperly restricts antitrust analysis needed to correctly evaluate reverse payment settlements).

72. *See K-Dur*, 686 F.3d at 197 (examining reverse payments surrounding patented drug K-Dur 20).

73. *See id.* at 218 (holding existence of reverse payments is prima facie evidence of illegality); *cf. Reverse-Payments Ban Dropped*, *supra* note 5 (asserting concerns for future pharmaceutical innovation).

74. *See Liu & McNeill*, *supra* note 47, at 15 (discussing opposing sides of argument that have been taken).

75. *See K-Dur*, 686 F.3d at 202 (stating that this case originates from two previous patent cases involving drug K-Dur 20). Settlement was reached when Upsher filed the first ANDA seeking approval for a generic version of K-Dur 20, asserting a different chemical compound make-up. *See id.* at 205 (explaining first reverse payment settlement involving Schering's K-Dur 20 drug). Settlement was also reached when ESI Lederle filed an ANDA seeking approval of a generic form of K-Dur 20, allegedly utilizing different technology. *See*

originally manufactured by Schering-Plough Corporation (Schering), received the #743 patent for the “microencapsulation” process utilized in the drug.⁷⁶ This newly patented development allowed for the slow dispersion of drug particles over an interval of time.⁷⁷ The #743 patent was officially granted on September 5, 1989.⁷⁸ Subsequently, two generic manufacturers brought challenges against this patent claiming a paragraph IV certification under the Hatch-Waxman Act.⁷⁹

1. *Schering-Upsher Settlement*

In August 1995, the generic manufacturer Upsher Smith Laboratories filed the first ANDA seeking approval for a generic form of K-Dur 20.⁸⁰ Providing a paragraph IV certification, Upsher claimed there was no patent infringement due to the use of a different chemical make-up in their controlled release coating.⁸¹ Following Upsher’s vigorous defense, the two parties settled just hours before the district court delivered a summary judgment decision.⁸²

The terms of the agreement allowed Upsher to maintain its claim that there was not patent infringement.⁸³ Furthermore, Schering included a reverse payment incentive of sixty million dollars over the course of three years.⁸⁴ In

id. (discussing second settlement reached, further delaying generic entry of K-Dur 20 into market); *see also* Barkoff, *supra* note 16 (explaining two settlements at issue in this case were Schering-Upsher Smith agreement and Schering-ESI agreement).

76. *See K-Dur*, 686 F.3d at 204–05 (explaining that Patent and Trademark Office issued patent #743 to Schering following their application to patent microencapsulation). After clarifying a difference in viscosity levels, the PTO approved a revised application for patent protection. *See id.* at 205 (explaining differentiating factor in patent approval was greater viscosity level as compared to patent #399).

77. *See id.* (describing process of microencapsulation technique, which allows for slow dispersion of drug particles); *see also* RONALD T. DODGE CO., MICROENCAPSULATION, <http://www.microencapsulation.net> (last visited Sept. 10, 2012) (explaining process of microencapsulation).

78. *See K-Dur*, 686 F.3d at 205 (stating date that revised application was officially granted patency).

79. For a further discussion regarding the challenges to the #743 patent, *see infra* notes 80–93 and accompanying text.

80. *See K-Dur*, 686 F.3d at 205 (explaining that Upsher filed first ANDA paragraph IV certification and was seeking FDA approval of generic alternative to K-Dur 20); *see also* Barkoff, *supra* note 16 (explaining that Upsher filed initial ANDA, which was shortly followed by ESI challenges and settlement).

81. *See K-Dur*, 686 F.3d at 205 (asserting Upsher’s defense to patent infringement was due to differences in chemical composition of controlled release system).

82. *See id.* (explaining that agreement was reached in early morning of June 18, 1997, just hours before district court was to rule on pending motions for summary judgment). “The settlement was memorialized in an eleven-page short-form agreement dated June 17, 1997.” *Id.*

83. *See id.* (asserting that agreement provided Upsher did not have to concede validity, infringement, or enforceability of #743 patent).

84. *See id.* at 205–06 (explaining Schering’s initial down payment was sixty million dollars over three-year period as well as pending additional payments in smaller sums); *see also Third Circuit Agrees With FTC in Applying Stricter Reverse Payment Settlement Test*, ANTITRUST TODAY, (July 31, 2012), <http://www.antitrusttoday.com/2012/07/31/third-circuit-agrees-with-ftc-in-applying-stricter-reverse-payment-settlement-test/> (discussing plaintiff’s argument that sixty million dollars was sham and paid as royalty for exchanged licenses in *K-*

return for Schering's payment offer, Upsher agreed to refrain from marketing this new generic alternative until September 1, 2001, extending Schering's market hold for approximately six more years.⁸⁵ An additional term, which the parties later used to support the legality of the reverse payment, was Upsher's authorization of licenses allowing Schering to make and sell products developed by Upsher.⁸⁶ This initial settlement provided Schering a brief window of security; however, a subsequent challenger would soon follow suit.⁸⁷

2. *Schering-ESI Settlement*

Shortly after the Schering-Upsher settlement, ESI Lederle (ESI) filed another ANDA certifying the same absence of patent infringement.⁸⁸ ESI claimed that its generic drug contained different chemical technology.⁸⁹ After Schering's claim of patent infringement, the two parties decided to mediate, and eventually settle.⁹⁰

The settlement agreement promised ESI a royalty-free license under the #743 patent starting January 1, 2004, which delayed their entry by almost nine years.⁹¹ Additionally, Schering agreed to a structured reverse payment of five million dollars and a successive varying sum based upon the FDA's

Dur).

85. *See K-Dur*, 686 F.3d at 205 (explaining that Upsher agreed to stay out of market with its generic alternative to K-Dur 20 until September 1, 2001). Schering agreed that on September 1, 2001, Upsher would receive a non-royalty, non-exclusive license under #743 patent to freely sell its generic alternative in the open market. *See id.* (asserting that Upsher had availability of open market following conclusion of agreement).

86. *See id.* at 205–06 (explaining dispute regarding reverse payments from Schering to Upsher). While the settling parties, as defendants, insisted the payments to be consideration for the licenses, plaintiffs alleged reverse payments were strictly for delaying market entry. *See id.* at 206 (discussing two sides to dispute); *see also Third Circuit Agrees with FTC*, *supra* note 84 (explaining that plaintiffs alleged settlements were scams because they believed payment was simply to keep generic alternative from entering market and not for reasons asserted by defendants).

87. *See K-Dur*, 686 F.3d at 206 (discussing second ANDA filed and resulting settlement). The Schering-ESI litigation was settled with a similar reverse payment agreement. *See id.* (discussing settlement that was reached).

88. *See id.* (explaining ESI Lederle filed subsequent challenge in December 1995); *see also* Paolo Morante & Jarod M. Bona, *Third Circuit Rekindles Uncertainty in Patent Settlements Under Hatch-Waxman Act*, DLA PIPER (July 25, 2012), available at <http://www.dlapiper.com/us/publications/detail.aspx?pub=7262> (discussing December 1995 ANDA filing from ESI and resulting litigation).

89. *See K-Dur*, 686 F.3d at 206 (discussing paragraph IV certification). ESI claimed its generic alternative used a coating with two different ingredients. *See id.* (explaining ESI's explanation for paragraph IV filing).

90. *See id.* (explaining that Schering and ESI agreed to court-supervised mediation to attempt to solve dispute). In the fall of 1996, the two parties attempted to resolve their issues through mediation and eventually would reach the settlement at issue. *See id.* (addressing mediation and results in fall of 1996); *see also* Barkoff, *supra* note 16 (explaining that Schering-ESI dispute ending in settlement).

91. *See K-Dur*, 686 F.3d at 206 (discussing agreement calling for ESI to be granted royalty-free license as of January 1, 2004 for patent #743). The product from ESI was then approved in May 1999, but Schering paid an additional ten million dollars as part of the agreement between the two parties. *See id.* (explaining FDA approval of generic alternative, which would have allowed for generic entry into market if not for settlement with Schering).

determination of ESI's ANDA filing.⁹² Both the initial Schering-Upsher settlement and the later Schering-ESI agreement would eventually fall under scrutiny from both the Federal Trade Commission (FTC) and various private parties.⁹³

3. Resulting Litigation

Initially, the FTC brought an action alleging the Schering settlements unreasonably restrained trade.⁹⁴ While the Eleventh Circuit ultimately dismissed the FTC action, the holding in *K-Dur* seemed to validate the muddled circuit split.⁹⁵ The Third Circuit's decision in *K-Dur* poses a serious threat to future drug innovation and illustrates the need for Supreme Court intervention.⁹⁶

B. Third Circuit's Analysis of Reverse Payment Settlements

The Third Circuit began its analysis in *K-Dur* by surveying the general landscape of antitrust law.⁹⁷ Applying the Sherman Act, the court stated,

92. See *id.* (discussing structured payments flowing from Schering to ESI if ESI agreed to stay out of market). Schering paid five million dollars up front and then agreed to pay anywhere from \$625,000 to ten million dollars based upon FDA approval. See *id.* (explaining that Schering agreed to pay even more to ESI if generic drug was approved for market by FDA).

93. See *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056, 1068–76 (11th Cir. 2005) (determining legality of settlements at issue in FTC action). The Eleventh Circuit overruled an FTC ruling claiming the settlements were illegal because they unreasonably restrained trade. See *id.* at 1076 (discussing holding of court). “Simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law.” *Id.* “This alone underscores the need to evaluate the strength of the patent.” *Id.* “Our conclusion, to a degree, and we hope that the FTC is mindful of this, reflects policy.” *Id.*; see also *K-Dur*, 686 F.3d at 206–09 (discussing actions brought by FTC, as well as private litigants in form of wholesalers and retailers).

94. See *K-Dur*, 686 F.3d at 206–08 (discussing FTC action brought against settlements prior to private litigants alleging claim). In March 2001, the FTC filed a claim against all three parties, Schering, ESI, and Upsher, alleging their settlements unreasonably restrained trade. See *id.* (asserting FTC's claims against parties alleging violations of antitrust law); see also *Schering-Plough*, 402 F.3d at 1060–62 (examining FTC claims brought against settlements between Schering and generic competitors).

95. See *Schering-Plough*, 402 F.3d at 1076 (holding FTC claims did not show unreasonable restraint of trade); *K-Dur*, 686 F.3d at 218 (holding private litigants' claims to be sufficient to hold Schering's settlements illegal); see also Barkoff, *supra* note 16 (asserting that resulting circuit split will likely result in Supreme Court intervention). Because there have been disagreements as to what tests to apply, the Supreme Court will likely weigh in to clarify the appropriate analysis for reverse payment settlements. See *id.* (discussing differences in analysis of reverse payments).

96. See *K-Dur*, 686 F.3d at 214–19 (holding that settlements between Schering and their generic competitors were illegal due to unreasonable restraint of trade). The Third Circuit believed that the scope of the patent was insufficient in determining legality of such settlements. See *id.* at 214 (discussing disagreement with use of scope of patent test).

97. See *id.* at 208–09 (discussing general antitrust law and its applications). The antitrust laws prohibit activity that restrains trade. See *id.* (discussing basic standard for antitrust law under Sherman Act). The Supreme Court has read the Act as applying to actions that only unreasonably restrain trade. See *id.* (explaining what interpretation of Act has

“[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.”⁹⁸ While the text of the Sherman Act appears to prohibit any restraint of trade, the Supreme Court has interpreted it to prohibit only an unreasonable restraint of trade.⁹⁹ Furthermore, in analyzing the reasonableness of an alleged restraint of trade, the court discussed the scope of inquiry, which ranged from unyielding per se illegality to a more thorough “rule of reason” examination that utilizes the scope of the patent test.¹⁰⁰

The Third Circuit relied on general antitrust law and reverse payment precedent to establish the guiding criteria for their analysis of the Schering-Upsher and Schering-ESI settlements.¹⁰¹ After examining the case law for reverse payment settlements, the court proposed two options for determining the validity of the agreements.¹⁰² The court could subject the settlements to strict antitrust scrutiny with a presumption of per se illegality or it could apply the scope of the patent test.¹⁰³ Ultimately, the Third Circuit contradicted the recent circuit court trend and refused to apply the scope of the patent test.¹⁰⁴

developed to become).

98. 15 U.S.C. § 1 (2004) (explaining activity prohibited by Act); *see also K-Dur*, 686 F.3d at 208 (quoting Sherman Antitrust Act).

99. *See* 15 U.S.C. § 1. *But see K-Dur*, 686 F.3d at 209 (discussing Supreme Court’s interpretation of Act). “Under a literal reading, this provision would make illegal every agreement in restraint of trade.” *Id.* at 208–09. “However, it has not been so interpreted. Rather the Supreme Court has long construed it to prohibit only unreasonable restraints.” *Id.* at 209.

100. *See K-Dur*, 686 F.3d at 209 (discussing analysis used to examine activity alleged of unreasonably restraining trade). A rule of reason analysis is traditionally used. *See id.* (examining factors considered when determining legality of activity alleged illegal under antitrust law). Courts have also acknowledged that some activities clearly restrain free trade and therefore are deemed per se illegal. *See id.* (stating that courts have held certain activities per se illegal therefore shifting burden to restraining party); *cf.* Butler & Jarosch, *supra* note 6, at 66 (discussing array of applications when analyzing reverse payments). Some courts have given reverse payment settlements a heightened level of scrutiny, while others have applied very little or no antitrust scrutiny. *See id.* (asserting stark differences in antitrust analysis applied to reverse payment settlements when examined by different circuit courts).

101. *See K-Dur*, 686 F.3d at 208–15 (surveying antitrust law along with case law precedent). The court established antitrust analysis, along with diverging approach taken by previous circuit court. *See id.* (examining law that court had to pull from in order to analyze alleged anticompetitive settlement).

102. *See id.* at 210–15 (examining previous circuit court precedent that had been established since enactment of Hatch-Waxman Act). For further discussion of the court’s options in reviewing the reverse payment settlement, *see infra* notes 103–04 and accompanying text.

103. *See K-Dur*, 686 F.3d at 214 (discussing options of addressing issue at hand). The court could use the approach taken by the first circuits to handle reverse payments, or side with the more recent migration towards a scope of the patent test. *See id.* (explaining differences in approaches previously used by circuit courts when addressing legality of reverse payment settlements); *cf.* Backus, *supra* note 29 at 405–12 (scanning range from per se illegality approach, to rule of reason analysis, to hybrid rule of reason application). The main differences regarding the middle ground approach deals with shifting burden of proof between claimant and patent holder. *See id.* at 410–11 (discussing blended quick-look rule of reason approach).

104. *See K-Dur*, 686 F.3d at 214 (discussing decision to not apply scope of patent test). “After consideration of the arguments of counsel, the conflicting decisions in the other

In disagreeing with the scope of the patent test, the court first took aim at the presumption of patent validity that corresponds with the assessment.¹⁰⁵ The court's analysis referred to the high success rates of paragraph IV challenges under the Hatch-Waxman Act, noting the high percentage of patents that are eventually determined to be invalid.¹⁰⁶ The court stressed that patents are a legal conclusion issued by the Patent Office and the judicial system should play an important role in carefully analyzing the strengths and weaknesses of these challenged patents.¹⁰⁷ Moreover, the court dismissed the proposition that subsequent challengers would effectively follow and eliminate weak patents.¹⁰⁸ The Third Circuit contended that the monopolistic profit margin stemming from reverse payment settlements would allow for the patent holder to pay off numerous generic manufacturers while still maintaining strong earnings.¹⁰⁹

circuits, the Report of the Special Master, and our own reading, we cannot agree with those courts that apply the scope of the patent test." *Id.*; see also *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d at 1336 (Fed. Cir. 2008) (concurring with Eleventh and Second Circuits in applying scope of patent test); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 200 (2d Cir. 2006) (holding that appropriate approach is to insert scope of patent examination); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1298 (11th Cir. 2003) (applying scope of patent test to reverse payment).

105. See *K-Dur*, 686 F.3d at 214 (asserting court's disapproval of scope of patent test). "First, we take issue with the scope of the patent test's almost un rebuttable presumption of patent validity." *Id.*; cf. Backus, *supra* note 29, at 408–10 (discussing proponents for settlements that support presumption of legality). The presumption of legality in reverse payment settlements allows for reduced costs and increased efficiency. See *id.* at 408 (explaining why presumption of legality is sometimes supported). The Eleventh and Second Circuits applied this presumption of legality. See *id.* (noting circuit court precedent in support of this approach).

106. See *K-Dur*, 686 F.3d at 215 (asserting that generic challenger ultimately prevails in seventy-three percent of challenges). An FTC study concluded that a high percentage of challengers are successful in their claims. See *id.* (discussing court's disagreement with allowing presumption of legality); see also FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* 16 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> [hereinafter *GENERIC DRUG ENTRY*] (examining statistical data regarding challenges by generic manufacturers and results produced). The generic manufacturers succeeded at a high rate when challenging existing patent holders. See *id.* (citing percentages in favor of generic challengers that bring paragraph IV claims).

107. See *K-Dur*, 686 F.3d at 214–15 (discussing need for judicial supervision and intervention when analyzing patents). The court stressed the concern for allowing holders of weak patents to use their stronger financial position to extend the monopolistic effects of their patent. See *id.* at 215 (asserting need for judicial system to play part in limiting monopolistic abilities of weak patents).

108. See *id.* (questioning Second Circuit assumption that subsequent challengers would effectively eliminate weak patents). "We note that the initial generic challenger is necessarily the most motivated because, unlike all subsequent challengers, it stands to benefit from the 180-day exclusivity period of 21 U.S.C. § 355(j)(5)(B)(iv)." *Id.*; cf. Dolin, *supra* note 7, at 292–93 (explaining mechanics of Hatch-Waxman Act, particularly exclusivity period allowed for first filers).

109. See *K-Dur*, 686 F.3d at 215 (expressing concern over monopolistic margins that enable patent holder to pay off series of generic manufacturers challenging patent); cf. Kal Raustiala & Chris Sprigman, *Why Do Patent Holders Sometimes Pay Patent Copiers?*, *FREAKONOMICS* (July 30, 2012), <http://www.freakonomics.com/2012/07/30/why-do-patent-holders-sometimes-pay-patent-copiers/> (explaining gains made from patented drug sales). A case involving the drug Cipro dealt with an antibiotic that had annual sales exceeding one

After assessing the policy concerns, the circuit court detailed the test they would employ and its implications moving forward.¹¹⁰ The court stressed that once parties include a reverse payment in a settlement, antitrust analysis is triggered and the scope of the patent test is not sufficient.¹¹¹ Furthermore, the court concluded that any payment from patent holder to generic manufacturer must be treated as *prima facie* evidence of an unreasonable restraint of trade.¹¹² Ultimately, the Third Circuit regressed reverse payment analysis to an approach of *per se* illegality.¹¹³

C. *Consequences of the K-Dur Decision Moving Forward*

Through the Third Circuit decision in *K-Dur*, reverse payment precedent has shifted back towards the *per se* rule.¹¹⁴ It has left lower courts with six circuit court decisions that attempt to advance conflicting policy objectives.¹¹⁵ This reversion back to *per se* illegality has endangered business incentives that patent law uses to drive pharmaceutical innovation.¹¹⁶ The Supreme Court

billion dollars. *See id.* (explaining how patent drug sales create margins exceedingly higher than most reverse payment settlements).

110. *See K-Dur*, 686 F.3d at 218 (rejecting scope of patent test). “In its place we will direct the District Court to apply a quick look rule of reason analysis based on the economic realities of the reverse payment settlement rather than the labels applied by the settling parties.” *Id.*

111. *See id.* at 216–17 (expressing caution to limit *K-Dur* decision to reverse payments in this setting). “We caution that our decision today is limited to reverse payments between patent holders and would be generic competitors in the pharmaceutical industry.” *Id.*

112. *See id.* at 218 (asserting reverse payments as *prima facie* evidence of unreasonable restraint of trade). “In holding that a reverse payment is *prima facie* evidence of an unreasonable restraint of trade, we follow the approach suggested by the DC Circuit in *Andrx . . .*” *Id.*

113. *See id.* (holding reverse payments to be *prima facie* evidence of unreasonable restraint of trade); *cf.* Butler & Jarosch, *supra* note 6, at 66 (examining circuit split over analyzing reverse payment settlements). The first circuit courts to analyze this issue held reverse payment settlements to be *per se* illegal. *See id.* at 66–67 (explaining *per se* illegality and its reinstatement by Third Circuit).

114. *See K-Dur*, 686 F.3d at 218 (applying *per se* approach to hold that reverse payments are *prima facie* evidence of illegality).

115. *See id.* (holding reverse payments as *prima facie* evidence of unreasonable restraint of trade); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) (holding that correct application is scope of patent test); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006) (holding presumption of patent validity and applying scope of patent test); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) (holding reverse payments to be *per se* illegal); *Valley Drug Co. v. Geneva Pharms. Inc.*, 344 F.3d 1294, 1311–12 (11th Cir. 2003) (holding that court should examine whether agreement went beyond protections afforded by patent in question); *Andrx Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 813 (D.C. Cir. 2001) (holding reverse payments to be *prima facie* evidence of illegality).

116. *See* Butler & Jarosch, *supra* note 6, at 66 (discussing circuit split and policy objectives driving each position). “On one hand, patents give their holders exclusive rights to use the patented good, spurring innovation.” *Id.*; *see also* Carrier, *supra* note 49, at 62 (discussing courts’ reasoning to defer to settlements because of innovation). By disallowing settlement in such cases, the courts could possibly harm innovative incentives by increasing uncertainty in patent law. *See id.* (examining impact that courts’ disallowance of reverse payment settlements could have on pharmaceutical innovation).

must act to establish clear precedent and allow for reverse payment settlements to properly resolve patent litigation.¹¹⁷ The Third Circuit overlooked economic and policy concerns that must be highlighted in order to ensure that the most economically effective analytical approach is established for evaluating reverse payment settlements.¹¹⁸

V. THIRD CIRCUIT'S "PER SE" APPROACH IS A "PER SE" CONCERN TO THE FUTURE OF NEW DRUG INNOVATION

To have a comprehensive evaluation of reverse payment settlements, there must be a detailed examination of both policy incentives and the resulting economic effects.¹¹⁹ Circuit court precedent has pitted patent exclusion against protecting consumer costs.¹²⁰ The fallout from each side of the disagreement carries with it extensive consequences for consumers in the pharmaceutical industry.¹²¹

117. See Barkoff, *supra* note 16 (stating that many observers believe Supreme Court will intervene after *K-Dur* holding). "Because of the circuit split, many observers believe that with this case, the Supreme Court will finally address the legality of reverse payment settlements." *Id.*; see also Raustiala & Sprigman, *supra* note 109 (recognizing likely Supreme Court intervention). *But see* Holman, *supra* note 11, at 573–78 (expressing unlikelihood of Supreme Court intervention at time of publication). Prior to the Third Circuit's *K-Dur* decision, the scope of patent test was regarded as the likely test moving forward. See *id.* at 577–78. "Some have implied that, without Supreme Court intervention, the Second Circuit's test will essentially be locked in as the law of the land, because defendants will appeal all FTC decisions to the Second Circuit." *Id.*

118. See *K-Dur*, 686 F.3d at 214–19 (discussing policy concerns driving Third Circuit approach). The court identified issues regarding consumer protection and patent weakness, but failed to address innovation incentives provided by patent law. See *id.* (asserting clear position against reverse payments without considering positive effects they may have). *But see* Dolin, *supra* note 7, at 318 (discussing problems posed by reverse payment analysis). By disallowing reverse payment settlements to resolve these issues, exclusion rights offered by patent law are affected and litigation would increase; therefore, generic entry would be delayed further and the very purpose of the Act would fail. See *id.* at 319 (arguing that disallowance of reverse payment settlements "would push more disputes into litigation where the outcome is far from certain").

119. See Backus, *supra* note 29, at 380 (discussing policy objectives that must be balanced through Hatch-Waxman resolution). The Act and its results need to weigh the delicate balance between continuing to encourage innovation, while still bringing cheaper alternatives into the market. See *id.* (asserting need to maintain balance and consider both policy objectives); see also Hanks et al., *supra* note 10, at 1 (explaining financial impact of resolution of reverse payment issues). The resolution of the question regarding reverse payment settlements involves billions of dollars. See *id.* (showing economic impact of resolution regarding issue of reverse payment settlements).

120. See Bagherian, *supra* note 29, at 160–66 (discussing different approaches taken by courts, such as per se approach, rule of reason analysis, and scope of patent test); see also Butler & Jarosch, *supra* note 6, at 86–87 (discussing policy reversal regarding approach to reverse payment settlements). The analysis gravitated from a per se approach to a more detailed inquiry known as rule of reason analysis. See *id.* (noting that policy reversal had taken place over time).

121. See Hanks et al., *supra* note 10, at 1 (asserting that reverse payment settlements protect twenty billion dollars in sales of patented drugs from generic competition). In addition, "the FTC estimates that reverse payment settlement cost consumers \$3.5 billion a year—or \$35 billion over the next 10 years." *Id.*

A. *Misguided Policy Objectives Overshadow More Important Innovative Consequences*

The Third Circuit has reignited arguments that do not address the entirety of the reverse payment settlement issue.¹²² While the court concentrated on the immediate concerns of high consumer costs and weak patents, it failed to sufficiently examine the more prominent long-term effects on pharmaceutical innovation and consumer needs.¹²³ By applying this approach to reverse payment settlements, courts risk endangering the entire pharmaceutical industry and creating uncertainty in patent protection.¹²⁴

1. *The Per Se Attempt to Eliminate Reverse Payment Settlements*

The Third Circuit has rekindled the per se approach, declaring reverse payments to be prima facie evidence of illegality.¹²⁵ The court highlighted concerns including the high rate of success for generic manufacturers in Hatch-Waxman litigation, a patent holder's ability to utilize high profit margins to forcefully maintain market control, and a divergence from enforcing the very purposes of the Hatch-Waxman Act.¹²⁶ The court asserted the belief that reverse payment settlements would hamper generic entry and consequently, consumer costs would continue to increase.¹²⁷

According to oppositions of the scope of the patent test, this examination fails to address the issue of weak or invalid patents because it coincides with a presumption of patent validity.¹²⁸ A Federal Trade Commission (FTC) study asserted that seventy-three percent of paragraph IV challenges pushed to

122. See *K-Dur*, 686 F.3d at 214–19 (asserting concerns for high costs and weak patents).

123. See *id.* (expressing concern for invalid patents and high costs). But see *Reverse-Payments Ban Dropped*, *supra* note 5 (asserting concerns for more important issues of long-term innovation and consumer welfare in future).

124. See *Reverse-Payments Ban Dropped*, *supra* note 5 (insisting that ban on reverse payment settlements would lead to detrimental effects in entire pharmaceutical industry).

125. See *K-Dur*, 686 F.3d at 218 (declaring payments from patent holder to challenger as prima facie evidence of unreasonable restraint of trade).

126. See *id.* at 215 (citing to FTC conclusions finding generic manufacturer to be successful seventy-three percent of time). “[T]he high profit margins of a monopolist drug manufacturer may enable it to pay off a whole series of challengers . . .” *Id.* (expressing concern for patent holder's ability to pay off multiple challengers, resulting in market hold). “The goal of the Hatch-Waxman Act is to increase the availability of low cost generic drugs.” *Id.* at 217 (asserting goals of Hatch-Waxman Act that have been overlooked recently).

127. See *id.* at 217 (discussing goal of Act, which is to lower cost). The goal is undermined by applying scope of the patent test and allowing reverse payment settlements because it allows patent holder to keep generic alternatives out of the market. See *id.* (expressing concern for goals of Act); cf. Hanks et al., *supra* note 10, at 1 (asserting cost to consumers caused by reverse payment settlements). The FTC estimated the consumer cost to be roughly thirty-five billion dollars over the next ten years. See *id.* (expressing extreme financial effects).

128. See *K-Dur*, 686 F.3d at 214–15 (discussing disagreement with assumption of patent validity). The scope of the patent test had previously been applied by circuit courts with a presumption of patent validity and the Third Circuit does not agree with such an approach. See *id.* (expressing issue based on FTC study showing many paragraph IV challenges to ultimately be successful).

litigation are successful; therefore, some courts have highlighted a need for judicial resolve they felt was necessary to clear the weak patents.¹²⁹ Ultimately, courts have taken clear anti-settlement stances at times.¹³⁰

2. *A Sufficient Conflict Insufficiently Addressed*

While several circuits have encouraged judicial activism in clearing the patent landscape, those courts have overlooked some important considerations when applying this per se rule.¹³¹ First, although weak patents may exist, the regulatory patent process helps to promote innovation and development.¹³² The Patent and Trademark Office (PTO) issues patents to parties that have invested in new inventions, whether in the pharmaceutical industry or any other.¹³³ If there is a need for system maintenance, the legislature could take action to improve the PTO's effectiveness.¹³⁴

When reviewing reverse payments, courts should consider the anticompetitive effects of the reverse payment, not the strength of the patent.¹³⁵ Through judicial activism, the courts will intervene in the patent process and risk interfering with the agency duties of the PTO.¹³⁶ Further, courts are

129. *See id.* at 215 (citing to FTC study); *see also* GENERIC DRUG ENTRY, *supra* note 106 (asserting statistical data showing seventy-three percent of paragraph IV challenges to be successful). The generic manufacturer had a very high success rate, which would result in increased generic alternatives if not for reverse payment settlements. *See id.* (discussing how reverse payment settlements inhibit generic availability in market).

130. *See K-Dur*, 686 F.3d at 218 (holding that reverse payment settlement was prima facie evidence of unreasonable restraint of trade).

131. *See Reverse-Payments Ban Dropped*, *supra* note 5 (raising concern about possible bans on reverse payment settlements). Arguing that future drug innovation from branded pharmaceutical companies would be endangered and generic companies would be dissuaded from challenging patents without the option to settle claims prior to expensive litigation. *See id.* (expressing concern for branded pharmaceutical companies and generic manufacturers if reverse payment settlements were banned).

132. *See* ORG. FOR ECON. CO-OPERATION & DEV., PATENTS AND INNOVATION: TRENDS AND POLICY CHALLENGES 9 (2004), *available at* <http://www.oecd.org/science/scienceandtechnologypolicy/24508541.pdf> (discussing patent system's ability to foster innovation). "Viewed from the angle of innovation policy, patents aim to foster innovation in the private sector by allowing inventors to profit from their inventions." *Id.*

133. *See K-Dur*, 686 F.3d at 215 (explaining that patent is legal conclusion issued by patent office); *see also* PATENTS AND INNOVATION: TRENDS AND POLICY CHALLENGES, *supra* note 132, at 9 (discussing patents' purpose of fostering innovation through allowing inventors to profit from inventions).

134. *See Dolin*, *supra* note 7, at 319–20 (discussing current reexamination process in place for PTO). "After a patent issues, it is presumed valid." *Id.* at 319. While reverse payment settlements avoid litigation and preserve the presumption of validity, the PTO provides another option for reexamination. *See id.* (explaining that although court will not address patent validity if presented with reverse payment settlement, patent can still be reexamined by PTO).

135. *See* 35 U.S.C. § 282 (2006) (stating that patents shall be presumed valid); *see also* Carrier, *supra* note 49, at 62–63 (discussing presumption of validity previously applied by courts). The Patent Act states that patents shall be presumed valid. *See id.* at 62 (explaining why patents should be presumed valid).

136. *See Dolin*, *supra* note 7, at 319 (explaining how antitrust approach to clearing weak patents is insufficient). "Patent law, the very tool Congress used to create the Hatch-

muddying the analysis of reverse payment settlements by considering patent strength or weakness.¹³⁷ The court's departure from a presumption of patent validity further complicates the issue and likely will cause undesirable results.¹³⁸ An independent examination of the restraint of trade should determine the validity of reverse payments.¹³⁹

Second, the Third Circuit called attention to the high profit margins that allow patent holders to pay off generic challengers.¹⁴⁰ This may be a plausible assertion, but the court failed to contemplate the importance of maintaining these profit margins to ensure future development.¹⁴¹ Pharmaceutical companies continue to strive for more innovation because they have the financial security of patent law.¹⁴² Judicial interpretation of patent strength in these cases will apply a level of scrutiny that will bring uncertainty to the future of intellectual property rights.¹⁴³ Courts must consider the consequences of this increased scrutiny.¹⁴⁴

Waxman Act, is a far better instrument to address these issues." *Id.*

137. *See* Carrier, *supra* note 49, at 63 (discussing mixing of analysis when analyzing reverse payment settlements). Courts have made it clear that there is no legal support for public property rights in private disputes and agreements. *See id.* (explaining that public's rights to lower prices should not be considered in private lawsuits). The settling parties in these cases have no duty to outside public parties to lessen monopolistic effects in the market. *See id.* (discussing settling parties).

138. *See id.* at 63 (explaining courts concern for adverse effects on patent licenses); *see also* Bagherian, *supra* note 29, at 167 (discussing per se approach to ruling settlements invalid could have chilling effect on patent settlement).

139. *See* Dolin, *supra* note 7, at 318–19 (examining tension between antitrust law and patent law). There is a sharp conflict between a patent's right to exclude and antitrust issues under the Sherman Act. *See id.* (elaborating on conflict between these two areas of law).

140. *See* *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 215 (3d Cir. 2012) (discussing policy concerns regarding patent holder's ability to pay off list of subsequent challengers). The high profit margins give patent holder opportunity to give up some profits instead of losing exclusionary rights offered through its patent. *See id.* (asserting strong concern with financial position of patent holder).

141. *See* Hemphill, *supra* note 9, at 1574–75 (discussing considerations of competition and innovation). "The innovator's argument is that a lenient policy toward settlement increases patentee profits, which preserves and improves the incentive to innovate." *Id.* at 1575. This strong preference for promoting innovation should be followed by antitrust law through allowing a lenient approach to analyzing reverse payment settlements. *See id.* (promoting antitrust law's merging towards favoring settlement).

142. *See* Holman, *supra* note 11, at 503–04 (discussing high profitability of branded drugs). When patent protections cease, profit margins and market share are quickly eroded by generic entry. *See id.* at 503 (explaining sharp decrease in value when patent expires). "The high profitability of branded drugs motivates drug patent owners to take extreme measures to maintain and enforce their patent rights." *Id.* at 503–04.

143. *See* Hemphill, *supra* note 9, at 1600–01 (discussing Patent Act). Antitrust liability is often withheld when dealing in the area of patent protection. *See id.* (explaining judicial recognition of patent exceptionalism). Cases dealing with reverse payment settlements have been sprinkled with notions to withhold antitrust analysis because one party possesses a patent, which carries with it exclusionary rights. *See id.* (explaining that antitrust analysis has often been handled in this area of law).

144. *See* Butler & Jarosch, *supra* note 6, at 90 (discussing how reverse payment settlements allow innovator to increase patent value). "Because reverse-payment settlements increase the value of the underlying patent to the patent holder, they also increase the brand-name company's incentive to innovate . . ." *Id.*; *see also* Carrier, *supra* note 49, at 62 (discussing how restricting settlements can lead to more uncertainty for patent holders).

Finally, the Third Circuit stressed that reverse payment settlements conflict with the purposes of the Hatch-Waxman Act.¹⁴⁵ Reverse payment settlements have developed as the most effective solution to Hatch-Waxman disputes because they benefit both parties involved.¹⁴⁶ These settlements are a consequence of faulty mechanics and should not be eliminated through judicial intervention.¹⁴⁷ The effects of the Hatch-Waxman legislation may not have been as intended but amending the procedure should be left to the legislature.¹⁴⁸

3. *Dependence of Pharmaceutical Innovation on the Proper Resolution to Reverse Payment Settlements*

The policy concerns advanced in *K-Dur* are important, but they do not fully encompass the problem.¹⁴⁹ Applying per se illegality to reverse payment settlements may help clear the landscape of invalid patents and allow for more generic entry into the market, but it does not address the implications for innovation.¹⁵⁰ The per se approach fails to consider its long-term effects on

Denying reverse payment settlements will increase uncertainty and delay innovation. *See id.* (asserting policy concern).

145. *See K-Dur*, 686 F.3d at 217 (discussing Hatch-Waxman Act goal of encouraging more challenges to weak or invalid patents). “One method Congress employed was to encourage litigation challenges by generic manufacturers against the holders of weak or narrow patents.” *Id.*

146. *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206 (2d Cir. 2006) (asserting that Hatch-Waxman Act encouraged reverse payment settlements); *see also* Day, *supra* note 11, at 230 (explaining that some have argued reverse payment settlements inevitably result from Hatch-Waxman Act). “Others have argued that reverse payments are an inevitable by-product of the Hatch-Waxman context and so long as the settlement does not exceed the scope of the patent holder’s right to exclude, reverse payments are acceptable.” *Id.*; Raustiala & Sprigman, *supra* note 109 (discussing how reverse payment is beneficial to both sides involved). The patent holder keeps market control and the generic competitor buys itself financial certainty. *See id.* (elaborating on benefits of reverse payment settlements).

147. *See Dolin, supra* note 7, at 320–22 (discussing reexamination process and patent validity determination). If the Patent Office Director determines that a substantial new question is raised affecting any claim of a patent, then there can be reexamination for resolution of the question at hand. *See id.* at 320–21. (explaining process of allowing reexamination of patent by PTO).

148. *See id.* at 318 (discussing goals of Hatch-Waxman Act). Antitrust law is an imperfect tool to address the issue of reverse payment settlements and to advance Congress’s goals. *See id.* at 319 (explaining inefficacy of antitrust law in fulfilling congressional intent).

149. *See K-Dur*, 686 F.3d at 214–15 (discussing policy concerns in favor of per se approach). “First, we take issue with the scope of the patent test’s almost un rebuttable presumption of patent validity.” *Id.* at 214. “[T]he high profit margins of a monopolist drug manufacturer may enable it to pay off a whole series of challengers rather than suffer the possible loss of its patent through litigation.” *Id.* at 215. The court found serious issue in the alleged ability for would-be competitors to share in monopolistic gains. *See id.* at 216 (expressing concern for allowing these parties to settle in this manner).

150. *See id.* at 214–15 (considering policy issues of patent validity and monopolistic market effects); *see also* Dolin, *supra* note 7, at 286–87 (discussing objectives of Hatch-Waxman Act). The Act attempted to bring a greater amount of lower priced generic drugs to the market and assist in clearing the landscape of weak or invalid patents. *See id.* (elaborating on multiple purposes of Act).

patent incentives in the pharmaceutical industry.¹⁵¹

Reducing consumer costs is an issue that should be addressed, but it is important to maintain patent rights so that the system in place ensures the medical field will continue to advance.¹⁵² The financial motivations stemming from patent exclusion rights present pharmaceutical companies with a certain level of assurance.¹⁵³ Without preserving that level of certainty, patent law will be unable to continue incentivizing pharmaceutical innovation.¹⁵⁴

There is a clear difference of opinion as to what approach is needed to appropriately resolve the issue of reverse payment settlements.¹⁵⁵ Important policy concerns have been addressed and contemplated, but all theoretical declarations remain hollow without concrete analysis to support their claims.¹⁵⁶ Through an economic examination, the per se approach is shown to have negative consequences over time.¹⁵⁷

151. See Hemphill, *supra* note 9, at 1562–63 (discussing drug makers' strong reliance on profits from patents). "New drugs are developed in anticipation of the profits that patents secure." *Id.* at 1562. The pharmaceutical field faces innovation problems not seen in others industries. See *id.* at 1562–64 (discussing cumulative innovation).

152. See *id.* at 1562–63 (discussing importance of patents in pharmaceutical industry). "[P]harmaceuticals have been associated with the case for strong patents." *Id.* at 1564; see also Butler & Jarosch, *supra* note 6, at 90 (discussing increase of patent power equating to more incentive to innovate). Innovation leads to more consumption, greater profit margins, and better competition in the pharmaceutical industry. See *id.* (explaining that competition is key driver of innovation in pharmaceutical industry).

153. See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 203 (2d Cir. 2006) (asserting concerns regarding increased uncertainty and delayed innovation); see also Carrier, *supra* note 49, at 62 (addressing previously stated issue of hampering goals of patent system). The *Tamoxifen* court noted the increased uncertainty caused by restricting settlements, which could lead to delayed innovation. See *id.* (discussing drawbacks to restricting settlements); Holman, *supra* note 11, at 503 (asserting pharmaceutical branded companies rely heavily on protection offered by patents). "[A] branded drug company's profit margins are to a large extent dependant upon the market exclusivity provided by patents." *Id.*

154. See Josh Bloom, *Yes: Innovation Demands It*, WALL ST. J. (Jan. 23, 2012), <http://online.wsj.com/article/SB10001424052970204542404577156993191655000.html#articleTabs%3Darticle> (asserting serious need for patent protection and extension). "Without extended patent protection for new discoveries, the industry won't be able to fund the current level of research." *Id.*

155. See *K-Dur*, 686 F.3d at 217 (applying per se approach); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1330 (Fed. Cir. 2008) (applying scope of patent test with presumption of patent validity); *Tamoxifen*, 466 F.3d 187, 194 (2d Cir. 2006) (applying scope of patent test); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (applying per se approach); *Valley Drug Co. v. Geneva Pharms, Inc.*, 344 F.3d 1294, 1298 (11th Cir. 2003) (changing analysis to scope of patent approach); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001) (applying per se approach).

156. See Butler & Jarosch, *supra* note 6, at 57 (explaining that more detailed analysis is needed for reverse payment settlements because effects are not obvious); cf. Hemphill, *supra* note 9, at 1558 (discussing substantial attention offered to these cases). Economists and legal scholars devote much analysis to reverse payment settlements in light of their economic importance and deepening confusion about their resolution. See *id.* (explaining complex situation analyzed by scholars and economists).

157. See Butler & Jarosch, *supra* note 6, at 63 (asserting that application of per se rule comes with significant risks). "Courts that limit the antitrust analysis of reverse payments by applying per se rules risk committing significant errors." *Id.*

B. *Future Economic Impact of a Resolution to the Reverse Payment Conflict*

By applying a per se approach to reverse payment settlements, courts essentially attempt to eliminate the option to settle in this fashion.¹⁵⁸ Those supporting a per se approach believe that eliminating these agreements will result in a greater volume of generic alternatives and consequently lower consumer costs.¹⁵⁹ Although this argument, on its face, appears to address the problem of high costs, further economic analysis renders contrary results.¹⁶⁰ Banning reverse payment settlements would have negative effects on branded pharmaceutical manufacturers' incentives to innovate, threaten the cash liquidity positions of generic developers, and dramatically increase the risk of pursuing a Hatch-Waxman challenge.¹⁶¹ Reverse payment settlements must be allowed to continue providing parties with a method of resolution that allows for future pharmaceutical innovation, generic reinvestment, and long-term consumer welfare.¹⁶²

1. *Problematic, Short-Term Outlook of the Per Se Approach*

Supporters of the per se approach to reverse payment settlements look to consumer protection as their principal argument.¹⁶³ Congress enacted the Hatch-Waxman Act in order to drive pharmaceutical prices down by making generic alternatives widely available in the marketplace.¹⁶⁴ From an economic standpoint, the Act attempted to increase the elasticity of demand in the

158. *See id.* at 66–67 (explaining that per se approach creates irrebuttable presumption of illegality).

159. *See generally K-Dur*, 686 F.3d 197 (applying per se approach because of concerns for weak patents and high costs); *Cardizem*, 332 F.3d 896 (further affirming per se approach); *Andrx*, 256 F.3d 799 (applying per se approach).

160. *See Reverse-Payments Ban Dropped*, *supra* note 5 (discussing future concerns regarding pharmaceutical innovation and generic reinvestment).

161. *See id.* (explaining negative results derived from trying to end reverse payment settlements).

162. *See Butler & Jarosch*, *supra* note 6, at 125 (asserting concern for presumption of illegality putting burden on these settlements); *see also Reverse-Payments Ban Dropped*, *supra* note 5 (asserting strong need for reverse payment settlements to ensure continuing innovation and sustainability of generic companies).

163. *See K-Dur*, 686 F.3d at 217 (discussing Congress's intent to protect consumers from monopolistic activity). The court agreed with Congress that litigation is necessary to protect consumers from this unjustified monopolistic activity. *See id.* (explaining Congress's intent); *see also Liu & McNeill*, *supra* note 47, at 16 (explaining that opponents cite rising cost of prescription drugs as policy concern). "Opponents cite the ever-rising cost of prescription drugs as another important policy reason for banning the pay-for-delay practice." *Id.*

164. *See Dolin*, *supra* note 7, at 286–87 (explaining objectives sought to be accomplished through legislation of Act). "First, the Act sought to bring lower-cost generic equivalents of patented drugs to market on an expedited basis and thus make these drugs more widely available to the general public." *Id.* at 286; *see also Bagherian*, *supra* note 29, at 152 (asserting that objective of Act is to make more low-cost drugs available on market). Congress passed this act with the hope that there would be an increase in expenditures for research and development to bring generic alternatives to the market. *See id.* (explaining incentives meant to be created).

pharmaceutical market.¹⁶⁵ By offering an expedited procedural process to generic manufacturers, the legislature assumed more generic alternatives would flood the market and result in a higher volume of consumer options.¹⁶⁶ The mechanics of the Act have not produced the intended effect.¹⁶⁷ These faulty mechanics have developed a scenario in which a reverse payment settlement offers the greatest net utility to the parties involved.¹⁶⁸ In response, some courts have tried to vigorously inhibit the availability of this settlement structure.¹⁶⁹

The circuit courts employing this per se analysis attempt to force monopolistic activity out of the pharmaceutical marketplace by pushing Hatch-Waxman disputes to litigation.¹⁷⁰ The FTC and other opponents of reverse payments see judicial activism as the answer to the misguided Act.¹⁷¹ By coupling a push for more litigation with the FTC's analysis showing a high success rate in patent challenges, the proponents of a per se approach likely

165. See Dolin, *supra* note 7, at 286–87 (discussing intention to make generic alternative more widely available). Congress intended to increase the availability of other options in the pharmaceutical market, which would in turn lead to lower prices for consumers. See *id.* (explaining desired result).

166. See *K-Dur*, 686 F.3d at 204 (explaining Congress's intent in enacting Hatch-Waxman Act); see also H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647–48 (discussing intent to make more low-cost generic drugs available); Backus, *supra* note 29, at 380 (explaining Hatch-Waxman Act's intent to bring cheaper copies to market).

167. See Hemphill, *supra* note 9, at 1553–54 (discussing pay-for-delay settlements that have resulted from Hatch-Waxman disputes). “Over the past decade, drug makers have settled patent litigation by making large payments to potential rivals who, in turn, abandon suits that, if successful, would increase competition.” *Id.* at 1553. “[C]ertain features of the Act widen, often by subtle means, the potential for anticompetitive harm from pay-for-delay settlements.” *Id.*

168. See Buter & Jarosch, *supra* note 6, at 97–98 (discussing high cost of litigation lending itself to settlement). Any anti-competitive effects are offset by a net societal gain experienced through avoiding lengthy and expensive litigation. See *id.* at 97 (asserting benefits of these settlements). Aside from cost-saving benefits for parties involved, courts and society experience gains from settlement as well. See *id.* (explaining benefits to multiple parties).

169. See generally *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (reaffirming approach taken in *Andrx*); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001) (holding reverse payment settlements essentially per se illegal); see also Alyssa L. Brown, *Modest Proposals for a Complex Problem: Patent Misuse and Incremental Changes to the Hatch-Waxman Act as Solutions to the Problem of Reverse Payment Settlements*, 41 U. BALT. L. REV. 583, 595–96 (discussing Sixth Circuit's initial response making reverse payment settlements per se illegal).

170. See generally *Cardizem*, 332 F.3d 896 (reaffirming approach taken in *Andrx*); *Andrx*, 256 F.3d 799 (holding reverse payment settlements essentially per se illegal); see also Dolin, *supra* note 7, at 286–87 (asserting that objective of Act is more litigation). “Finally, the Act, through encouraging litigation over the patents that covered these drugs, sought to clear the landscape of invalid patents by providing a ‘bounty’ to generics firms that challenged the validity or enforceability of the patents covering brand-name drugs.” *Id.* at 286–87.

171. See *K-Dur*, 686 F.3d at 206–07 (discussing FTC action relating to *K-Dur* case). The FTC unanimously overruled the Administrative Law Judge's ruling that the agreements were not simply an attempt to preserve monopoly power in the market. See *id.* at 207 (explaining FTC action clearly showing strong restraint to reverse payment settlements).

believe their goals for the Hatch-Waxman Act can now be realized.¹⁷²

While this line of attack may result in more litigation, an alleged increase in generic alternatives, and initially lower consumer costs; severe consequences will likely arise in the pharmaceutical industry.¹⁷³ By increasing litigation and, in turn, possibly decreasing patent effectiveness, this per se approach will be detrimental to pharmaceutical innovation.¹⁷⁴ Without the certainty provided to intellectual property through patent law, pharmaceutical companies will find little economic incentive to continue the expensive research and development needed to generate new medications.¹⁷⁵

When surveying the effects of this per se approach, courts need to evaluate the general welfare of society.¹⁷⁶ Although consumer costs will possibly decrease in the interim, the general welfare of society will be negatively affected over time.¹⁷⁷ When analyzing the situation, decision-makers should consider the importance of continued medical innovation and the successes of new drug development in combating illness.¹⁷⁸

172. See Dolin, *supra* note 7, at 286–87 (discussing objective pushing for more litigation relating to pharmaceutical patents); cf. GENERIC DRUG ENTRY, *supra* note 106, at viii (explaining high statistical success rate for challenges that move forward to litigation).

173. See Hemphill, *supra* note 9, at 1562–63 (discussing relationship between innovation and patent policy). Pharmaceutical companies rely heavily on patent protection to ensure there will be a financial benefit to drug development. See *id.* (asserting patent necessity). “Drug companies, compared to innovators in other industries, cannot as easily rely upon a head start, complementary assets, and scale of production as means to preserve profits.” *Id.* at 1563.

174. See *id.* (discussing relationship between patent protection and innovation). “Partly as a result, pharmaceuticals have been associated with the case for strong patents.” *Id.* at 1564; see also Mark R. Patterson, *Leveraging Information About Patents: Settlements, Portfolios, and Holdups*, 50 HOUS. L. REV. 483 (2012) (explaining recent scholarship bringing much uncertainty to patent property rights). Uncertainty plays an important role in decision revolving around patent rights. See *id.* at 487–95 (discussing uncertainty and patent rights).

175. See Butler & Jarosch, *supra* note 6, at 90 (discussing relationship between patent value and future innovation). The brand name pharmaceuticals are able to use reverse payment settlements to add value to their patent rights and therefore, they are able to invest in further innovative projects. See *id.* (asserting strong reasoning for allowing branded pharmaceutical companies to strengthen patent rights).

176. See *id.* at 97–98 (asserting important role settlements play in promoting general welfare). A net societal gain outweighs anticompetitive results that may be a by-product of the settlement. See *id.* at 97 (asserting benefits of these settlements). Courts and society in general experience gains from settlement as well. See *id.* (explaining benefit to multiple parties); see also *id.* at 98 (discussing liquidity cash positions of generic and branded pharmaceutical companies). Some generic companies are small and have very limited cash, which results in an undesirable effect from litigation. See *id.* (describing how forcing litigation may hurt generic manufacturers).

177. See *Reverse-Payments Ban Dropped*, *supra* note 5 (explaining how innovation that is much needed will likely be negatively effected if reverse payment settlements are banned); see also Frank R. Lichtenberg, *Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-Income Countries, 2000-2009* 1–2 (Nat’l Bureau of Econ. Research, Working Paper Series No. 18235, 2012), available at http://www.nber.org/papers/w18235.pdf?new_window=1 (explaining direct correlation between pharmaceutical innovative and life expectancy).

178. See Lichtenberg, *supra* note 177, at 2 (asserting drug innovation being driving force in benefiting human life). “Life expectancy at all ages and survival rates above age 25 increased faster in countries with larger increases in drug vintage.” *Id.*

Moreover, courts should consider the liquidity of generic manufacturers, which is scarcely contemplated when analyzing the effects of reverse payment settlements.¹⁷⁹ Courts may believe that by prohibiting these settlements more generic alternatives will enter the market, but the effectual results will likely be quite contrary.¹⁸⁰ A chilling effect could result if litigation is the only option available for generic challengers.¹⁸¹ Due to a lack of financial reserves, along with the high cost of litigation, generic companies will likely have to risk everything in pursuit of obtaining FDA approval through a Hatch-Waxman challenge.¹⁸²

Considering long-term consumer welfare, the innovative response likely to result, and the high costs of litigation, a per se approach will be injurious to the entire pharmaceutical industry.¹⁸³ Furthermore, the per se approach will undermine the courts' preference for settlement.¹⁸⁴ By highlighting the problems with this method of analysis, it should be clear that another solution must be established.¹⁸⁵

2. *Settling Innovation Concerns Through Reverse Payment Settlements*

A strong concern for consumer costs leads many to view the high profit margins in the pharmaceutical industry as a problem that must be addressed.¹⁸⁶ It is often overlooked, however, that those high profit margins continue to drive

179. See Butler & Jarosch, *supra* note 6, at 98 (explaining liquidity cash position of generic companies). Forcing the high costs of litigation on generic challengers could lead to other indirect and undesired results. See *id.* (asserting opposing viewpoint to effects litigation will have on generic challenges and entry into market).

180. See *id.* (asserting likely precompetitive results of allowing reverse payments). "A prohibition on reverse payments in such situations would stifle generic entry." *Id.*

181. See Kevin E. Noonan, *Generic Defendant Petitions for Certiorari in K-Dur Litigation*, PATENT DOCS: BIOTECH & PHARMA PATENT LAW & NEWS BLOG (Sept. 18, 2012), <http://www.jdsupra.com/legalnews/generic-defendant-petitions-for-certiora-71606/> (asserting that generic defendant believes generic challenges will be chilled by this approach). The uncertainty produced by this recent Third Circuit decision will result in a chilling effect for generic challenges under the Hatch-Waxman Act. See *id.* (explaining how challenges will be chilled as result).

182. See Butler & Jarosch, *supra* note 6, at 97–99 (discussing high costs of litigation and weak cash positions for generic companies); see also *Reverse-Payments Ban Dropped*, *supra* note 5 (explaining change in economic positioning through pharmaceutical marketplace that will result from banning reverse payment settlement).

183. See *Reverse-Payments Ban Dropped*, *supra* note 5 (asserting how banning reverse payment settlements would be injurious to healthcare discovery at all levels). If litigation becomes the only option, generic companies will have less opportunity to challenge patents and pharmaceutical companies will be forced to expense large amounts to keep patent rights. See *id.* (explaining negative effects to all involved).

184. See *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056, 1072 (11th Cir. 2005) (asserting judicial policy concerns for favoring settlements). The general policy in law is to favor settlements to resolve litigation and this is true in patent infringement as well. See *id.* (asserting preference for settlement as point courts must address).

185. See Dolin, *supra* note 7, at 318 (explaining need for better resolution to this debate). "This lack of agreement in academia, Congress, the courts, and the Executive Branch leads me to conclude that a new approach is needed . . ." *Id.*

186. See *PAY-FOR-DELAY*, *supra* note 26, at 4 (asserting strong concern for consumer costs portrayed through statistical data collected).

pharmaceutical innovation.¹⁸⁷ With this critical realization in mind, courts should analyze reverse payment settlements using a method that enables the pharmaceutical industry to maintain the level of security offered through exclusionary patent rights.¹⁸⁸

Reverse payment analysis, prior to the *K-Dur* decision, migrated towards the scope of the patent test, which allowed courts to consider the exclusionary rights afforded to a patent holder.¹⁸⁹ This test, or some correlative substitute, would likely result in the most effective, long-term results.¹⁹⁰ The analysis should respect the level of exclusion provided by patent law, and courts should allow mutual settlements that reinforce patent strength.¹⁹¹ Although costs may not decrease, branded pharmaceutical manufacturers will be offered the reassurance needed to move forward with new drug research and development.¹⁹² By implementing a scope of the patent examination, courts will ensure general welfare continues to increase through new drug innovation and consequently a generic chilling effect will be avoided.¹⁹³

First, when addressing the general welfare of society, courts must reflect on the increased utility experienced due to the development of new medications.¹⁹⁴ The medical field has experienced numerous advancements

187. See Lichtenberg, *supra* note 177, at 2 (explaining high rate of increase in longevity of human life). Following an economic study, the only variable found to strongly correlate with an increase in life expectancy was drug vintage. See *id.* (asserting importance of new drug innovation). Drug innovation accounted for almost seventy-five percent of the increase in life expectancy throughout the studied countries. See *id.* (explaining strong statistical data supporting need for future drug innovation).

188. See Hemphill, *supra* note 9, at 1562–63 (asserting heavy reliance pharmaceutical companies have on patent policy). “Almost uniquely, in this industry a patent is considered necessary to recoup an initial investment.” *Id.* at 1562.

189. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) (affirming scope of patent test as current approach); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006) (asserting analysis to be whether agreement went beyond scope of patent protection); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1311 (11th Cir. 2003) (applying scope of patent test).

190. See Butler & Jarosch, *supra* note 6, at 120 (asserting rule of reason analysis as best approach). Other analyses, like the *per se* approach, abbreviate the examination and do not fully address the issue. See *id.* (explaining other approaches have errors that deem them intimately ineffective).

191. See Alison Frankel, *3rd Circuit Shocker: Pay-for-Delay Drug Settlements Are Illegal*, THOMSON REUTERS NEWS & INSIGHT (July 16, 2012), http://newsandinsight.thomsonreuters.com/Legal/News/2012/07_-_July/3rd_Circuit_shocker_Pay-for-delay_drug_settlements_are_illegal/ (asserting Judge Richard Posner’s reasons to enforce patent protection). Patent strength and protection is needed for pharmaceutical companies to recoup their investments in drug innovation. See *id.* (explaining importance of patent protections).

192. See PAY-FOR-DELAY, *supra* note 26, at 8 (discussing consumer cost differences between branded drugs and generic alternatives). *But see* Lichtenberg, *supra* note 177, at 2 (explaining major benefits to drug innovation and need to keep innovation driving forward).

193. See Lichtenberg, *supra* note 177, at 2 (explaining clear benefits seen by humanity in regards to life expectancy and its relation to pharmaceutical innovation); see also Noonan, *supra* note 181 (asserting concerns from generic companies regarding likely chilling response to denying reverse payment settlements).

194. See Lichtenberg, *supra* note 177, at 3 (discussing study regarding life expectancy). In the thirty countries studied, pharmaceutical innovation accounted for three-fourths of the increase to life expectancy. See *id.* at 2. (demonstrating major importance of

directly resulting from costly pharmaceutical innovation.¹⁹⁵ By allowing parties to settle Hatch-Waxman disputes through reverse payment agreements, courts will advance a judicial preference for settlement and ensure innovation for the future.¹⁹⁶

The harsh reality faced in the pharmaceutical industry is that without the certainty provided through patent protection, manufacturers will have little incentive to invest in future advancement.¹⁹⁷ The high cost of new drug development presents a serious risk that must be provided an equivalent reward when successful.¹⁹⁸ A scope of the patent analysis provides for further patent protection, while still examining the legality of the settlement.¹⁹⁹ In analyzing the restraint placed on trade, the scope of the patent test ensures that the reverse payment settlement does not reach beyond patent law protection.²⁰⁰ Through this approach, incentives remain in place that provide the certainty necessary for branded manufacturers to further pursue the development of new and better drugs.²⁰¹ Furthermore, allowing settlement to preclude litigation in Hatch-Waxman disputes will have positive effects on generic production as well.²⁰²

continuing pharmaceutical innovation).

195. *See id.* (explaining direct correlation between life expectancy advancement and pharmaceutical innovation); *see also* Frankel, *supra* note 191 (asserting Judge Richard Posner's position on patent protection). "He gave three reasons why drug companies need patent protection: New drugs cost millions of dollars to develop . . ." *Id.* at 1.

196. *See* Schering-Plough Corp. v. Fed. Trade Comm'n, 402 F.3d 1056, 1072 (11th Cir. 2005) (asserting judicial policy in favor of settlement); Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003) (discussing reasonable protections afforded through patent protection that should be respected).

197. *See* Frankel, *supra* note 191 (asserting reasons why pharmaceutical companies need strong patent protection); *see also* *Reverse-Payments Ban Dropped*, *supra* note 5 (discussing negative effects on future innovation that would be seen if reverse payment settlements were disallowed).

198. *See* Frankel, *supra* note 191 (explaining Judge Posner's support for strong patent protection). The three main reasons pharmaceutical innovation needs strong patent protection are the millions of dollars in costs, the inability to collect during the entire life span of the patent, and the low costs of copying a drug once it is developed. *See id.* (asserting Judge Posner's strongly supported argument for patent protection).

199. *See* Butler & Jarosch, *supra* note 6, at 114 (explaining traditional approach allowing for contextualized analysis of reverse payment settlements). This will allow courts to learn to differentiate between procompetitive agreements that should be allowed and anticompetitive agreements, which should not. *See id.* (asserting functionalism of this approach).

200. *See* In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1336 (Fed. Cir. 2008) (holding that inquiry is whether restriction goes beyond exclusionary scope of patent); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213 (2d Cir. 2006) (concluding that there is no injury to market as long as competition is restrained within scope of patent); Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1311–12 (11th Cir. 2003) (asserting that correct determination was whether settlements effects went beyond scope of protections offered through patent law).

201. *See* *Reverse-Payments Ban Dropped*, *supra* note 5 (explaining that pharmaceutical companies need protection of patents and reverse payments to ensure future pharmaceutical innovation). Reverse payment settlements allow for certainty in patent protection, which will result in continued innovation. *See id.* (asserting importance of allowing reverse payment settlements).

202. *See* Noonan, *supra* note 181 (asserting caution from generic companies because of possible chilling effect that would result from banning reverse payment settlements); *see also*

Turning to generic producers, courts have largely failed to address the possibility of a chilling effect.²⁰³ A per se approach to examining reverse payments may hamper the incentive for generic manufacturers to even pursue Hatch-Waxman challenges.²⁰⁴ By eliminating the option to agree to a structured reverse payment settlement, courts attempt to increase the likelihood of future litigation.²⁰⁵ Although this may be an objective of the Act, the high expenses incurred through litigation could nearly bankrupt a smaller generic manufacturer.²⁰⁶ By eliminating the option to settle the dispute through a reverse payment, courts will force generic manufacturers to essentially risk everything in pursuit of FDA approval through Hatch-Waxman litigation.²⁰⁷

Alternately, by allowing reverse payment settlements, generic manufacturers are provided financial gain that can later be reinvested into future drug development.²⁰⁸ The scope of the patent test allows both the branded pharmaceutical companies and the generic manufacturers to mutually achieve the greatest level of utility through settlement, while still ensuring the restraints placed on trade do not exceed the exclusionary patent rights.²⁰⁹ This

Reverse-Payments Ban Dropped, *supra* note 5 (explaining how reverse payment settlements provide for future generic entry into market).

203. *See Reverse-Payments Ban Dropped*, *supra* note 5 (discussing chilling effect likely to be experienced by generic manufacturers). With the high cost of litigation, generic manufacturers will likely bring less Hatch-Waxman challenges if reverse payment settlement is not an option. *See id.* (asserting concern for generic entry as well).

204. *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012) (asserting reverse payment as prima facie evidence of illegality, therefore ruling reverse payment settlements per se illegal); *cf. Reverse-Payments Ban Dropped*, *supra* note 5 (explaining that without option of settlements with reverse payment, risk of bringing Hatch-Waxman challenges increases and incentive to file ANDA decreases).

205. *See Dolin*, *supra* note 7, at 286–87 (explaining one objective of Act to be more litigation). The Hatch-Waxman Act was passed in order to encourage more litigation by providing incentives to generic challengers. *See id.* (asserting original objectives of Act).

206. *See Reverse-Payments Ban Dropped*, *supra* note 5 (examining negative effects that banning reverse payments would have on generic manufacturers' availability to bring Hatch-Waxman challenges); *see also Butler & Jarosch*, *supra* note 6, at 98 (explaining difficult position generic manufacturers with poor cash positions would be put in if reverse payment settlements were not available).

207. *See Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003), *dismissed*, 104 F. App'x 178 (Fed. Cir. 2004) (explaining how banning settlements would reduce generic manufacturers' option to settle and result in less incentive to bring challenges); *cf. Hemphill*, *supra* note 9, at 1575 (explaining that assertion made by Judge Posner has become relevant in other courts when discussing incentive effects resulting from disallowing reverse payment settlements).

208. *See Butler & Jarosch*, *supra* note 6, at 98 (discussing cash positions of both parties involved). The generic company often times has less liquidity and the settlements provide the generic manufacturers with money they need to stay afloat, and also to ensure they can continue to put drugs into the market. *See id.* (explaining why reverse payment settlements help generic manufacturers).

209. *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1311–12 (11th Cir. 2003) (discussing scope of patent test). The court suggests that only the portions of the agreement that reached beyond the protections offered by the patent were to be subjected to antitrust analysis. *See id.* (explaining what triggers antitrust analysis for reverse payment settlements); *cf. Hemphill*, *supra* note 9, at 1574–75 (explaining that allowing reverse payment settlements to continue benefits both parties involved).

conclusion will lead to the most effective and beneficial outcome for society.²¹⁰

VI. A CONCLUSION OF SUPREME COURT INTERVENTION

If the Supreme Court affirms this per se approach as the precedent for analyzing reverse payment settlements, our pharmaceutical industry will experience detrimental consequences.²¹¹ The conflict among circuit courts has come full circle with the decision in *K-Dur*.²¹² After analyzing the contradictory policy concerns advanced by opposing circuit courts, the need for Supreme Court intervention has become clear.²¹³

In order to appropriately consider all the implications of a judicial resolution, it is imperative that the long-term results are addressed.²¹⁴ By allowing reverse payment settlements to serve as a proper resolution to Hatch-Waxman Act disputes, the Court will ensure future development in the pharmaceutical industry.²¹⁵ After considering innovative incentives, the general welfare of society, and rights afforded through our essential patent system, the proper conclusion becomes evident.²¹⁶ There is a significant need

210. See *Reverse-Payments Ban Dropped*, *supra* note 5 (asserting concern for banning reverse payment settlements). If courts ban reverse payment settlements through a per se approach, not only will innovation for branded pharmaceuticals be affected, but generic alternatives will likely be negatively affected because such a ban will result in less challenges and a weak position for generic manufacturers. See *id.* (explaining in detail issues with banning reverse payment settlements).

211. See *id.* (discussing harmful effects on all parties if reverse payment settlements are banned). The branded pharmaceuticals will refrain from further innovation, while the generic companies will be forced to face lengthy and expensive litigation in order to pursue a Hatch-Waxman challenge. See *id.* (describing concerns about banning reverse payment settlements).

212. See generally *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) (concerning claims brought against settling parties to Hatch-Waxman disputes).

213. See *id.* at 210–14 (analyzing most recent reverse payment settlement under scrutiny); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1337 (Fed. Cir. 2008) (holding patent to be presumptively valid when analyzing reverse payment settlements); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 194 (2d Cir. 2006) (affirming scope of patent test for analyzing reverse payment settlements); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (concerning same reverse payment settlement in *Andrx*); *Valley Drug*, 344 F.3d 1294 (turning analysis of reverse payment settlements away from per se approach); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001) (discussing first relevant reverse payment agreement).

214. See *Reverse-Payments Ban Dropped*, *supra* note 5 (discussing detrimental long term effects of banning reverse payment settlements). There is a strong concern for both pharmaceutical innovation and future generic challengers when considering a ban of reverse payment settlements. See *id.* (explaining need to refrain from ban).

215. See *Butler & Jarosch*, *supra* note 6, at 90 (asserting that reverse payment settlements directly affect incentives to innovate). Reverse payment settlements extend patent benefits; therefore, pharmaceutical innovators have more incentive to continue investing in new drug development. See *id.* (explaining direct economic relationship); see also *Reverse-Payments Ban Dropped*, *supra* note 5 (condemning idea of banning these valuable reverse payment settlements).

216. See *Reverse-Payments Ban Dropped*, *supra* note 5 (expressing strong belief in allowing reverse payment settlements). A ban on reverse payment settlements, which the per se approach essentially casts, would be harmful to the future of our entire pharmaceutical industry. See *id.* (asserting strong concern with moving in this direction).

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for resolution, and that resolution is to substantiate the scope of the patent test as the clear and absolute precedent for analyzing pay-for-delay settlements.²¹⁷

217. See Ry Ellison, *Reverse Payment Settlement Agreements Likely Headed for Supreme Court Showdown*, WASHINGTON LEGAL FOUNDATION (July 23, 2012), <http://wlflegalpulse.com/2012/07/23/reverse-payment-settlement-agreements-likely-headed-for-supreme-court-showdown/> (discussing likelihood that Third Circuit's *K-Dur* decision could result in Supreme Court resolution). The Supreme Court is faced with a decision to choose between the views of the Third Circuit and the more reasoned and free-market approach of the other three circuits. See *id.* (expressing decision to be made).