

6-2013

## Winning the War on Drug Prices: Analyzing Reverse Payment Settlements Through the Lens of Trinko

Alicia I. Hogges-Thomas

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### Recommended Citation

Alicia I. Hogges-Thomas, *Winning the War on Drug Prices: Analyzing Reverse Payment Settlements Through the Lens of Trinko*, 64 HASTINGS L.J. 1421 (2013).

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# Winning the War on Drug Prices: Analyzing Reverse Payment Settlements Through the Lens of *Trinko*

ALICIA I. HOGGES-THOMAS\*

*As drug prices continue to rise, many Americans are forced to choose between buying food or medicine. In 1984, Congress sought to address this issue by enacting the Hatch-Waxman Act. The purpose of the Act was to increase the availability of generic drugs by enabling the generic companies to challenge the brand companies' patents in litigation. But this purpose is frustrated when the brand companies pay the generic companies millions of dollars to settle the litigation and delay their market entry. These settlements, which are usually referred to as "pay-for-delay" or "reverse payment" settlements, benefit the pharmaceutical companies at the expense of consumers.*

*Reverse payment settlements have been challenged under the antitrust laws. In the last decade, the circuit courts have developed three approaches to analyzing reverse payment settlements. None of the courts considered whether the patent was valid or infringed. Furthermore, because courts favor settlement, the prevailing analysis has resulted in absolutely no antitrust scrutiny of reverse payment settlements.*

*Most recently, the Supreme Court granted a petition for certiorari in *FTC v. Watson Pharmaceuticals, Inc.* This Article argues that the Court's decision should be guided by the principles in *Verizon Communications v. Law Offices of Curtis V. Trinko*. Those principles will lead the Court to consider the particular circumstances of the pharmaceutical industry and how the Hatch-Waxman Act affects competition in that industry. After considering these factors, the Court should conclude that the policy favoring settlement should not be considered in this antitrust analysis and that the courts should decide the merits of the underlying patent claim.*

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## INTRODUCTION

For decades, Americans have struggled with the high cost of prescription drugs. As prices continue to rise, some consumers forego treatment completely. Others split their drugs in half or cross the Canadian border in search of lower prices. In 1984, Congress sought to remedy this issue by passing the Drug Price Competition and Patent Term Restoration Act (the “Hatch-Waxman Act” or the “Act”).<sup>1</sup> The

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1. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

purpose of the Act was to increase the availability of generic drugs through patent litigation. The price of generic drugs is significantly lower than the price of brand drugs.<sup>2</sup> As a result, when a generic drug enters the market, the brand company must lower its price to compete.

Unfortunately, the pharmaceutical companies are winning the drug price war. The Hatch-Waxman Act envisioned a regime wherein generic companies would challenge weak patents in litigation and then market their drugs after demonstrating that the patent was invalid or not infringed. Like many civil actions, these cases often settle. But these settlements are unusual in that the brand company pays the generic firm to delay its market entry. These payments are called reverse payment settlements because the money flows from the patent holder to the alleged infringer. In contrast, in an ordinary patent settlement, the payment flows from the infringer to the patent holder. By paying the generic company for delay, the brand company maintains its monopoly and the resulting ability to control prices. The drug companies split the monopoly profits of the brand company, which is a winning situation for both companies. The losers are the consumers, who continue to pay high prices because there is no competition for the drugs they need. According to the Federal Trade Commission (“FTC”), reverse payment settlements are costing consumers 3.5 billion dollars a year in the form of higher drug prices.<sup>3</sup>

Although they have been challenged under the antitrust laws, most courts have taken the position that reverse payment settlements are essentially immune from antitrust scrutiny, except in very limited circumstances. Any potential analysis must consider the fact that one of the parties holds a patent. As a result, the settlement will only violate the antitrust laws if the patent is invalid or if there is no infringement. If the generic drug is infringing a valid patent, the patent holder has a right to exclude the generic drug, and thus there is no antitrust violation.

In the last decade, the circuit courts have created three different approaches to analyzing reverse payment settlements. Unfortunately, none of these analyses address validity and infringement, the very issues that determine whether there is an antitrust violation in the first place. The fact that these agreements are litigation settlement agreements further complicates the analysis. Historically, courts have favored the settlement of litigation, and this policy is the primary justification for their reluctance to decide the issues of validity and infringement.

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2. Generic drugs cost 20–90% less than brand drugs. *FTC Staff Report Finds 60 Percent Increase in Pharmaceutical Industry Deals That Delay Consumers’ Access to Lower-Cost Generic Drugs*, FED. TRADE COMM’N (May 3, 2011), <http://www.ftc.gov/opa/2011/05/mmreport.shtm>.

3. FED. TRADE COMM’N, *PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS* (2010) [hereinafter *FED. TRADE COMM’N, PAY-FOR-DELAY*].

As the story continues, all eyes are now on the Supreme Court, which recently granted a petition for certiorari in *FTC v. Watson Pharmaceuticals, Inc.*<sup>4</sup> This Article argues that the Supreme Court's decision should be guided by the principles in *Verizon Communications v. Law Offices of Curtis V. Trinko*.<sup>5</sup> Those principles will lead the Court to consider the particular circumstances of the pharmaceutical industry and how the Hatch-Waxman Act affects competition in that industry. In doing so, the Court should compare reverse payment settlements to ordinary patent settlements and consider whether the Hatch-Waxman Act diminishes or increases antitrust harm.<sup>6</sup> Based on this industry-specific approach, the Court should conclude that when analyzing antitrust challenges to reverse payment settlements, courts should disregard the policy favoring settlement and decide the issues of patent validity and infringement.

## I. THE HATCH-WAXMAN ACT

### A. PURPOSE AND SUMMARY

Under the Federal Food, Drug, and Cosmetic Act, pharmaceutical companies must file new drug applications ("NDAs") with the Food and Drug Administration ("FDA") before marketing a new drug to the public.<sup>7</sup> In 1984, Congress enacted the Hatch-Waxman Act, which amended the Food, Drug, and Cosmetic Act to allow manufacturers of bioequivalent generic drugs to file abbreviated new drug applications ("ANDAs")<sup>8</sup> relying on the safety and efficacy tests of brand name drug manufacturers.<sup>9</sup>

When an ANDA is filed, the generic firm must certify, with respect to each patent that claims the brand name drug or a use thereof, either

(I) that [the] patent information has not been filed, (II) that [the] patent has expired, (III) . . . the date on which [the] patent will expire, or (IV) that [the] patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.<sup>10</sup>

When an ANDA filer certifies under Paragraph IV that the relevant patent is invalid or not infringed, it must notify the patent owner and the brand name drug manufacturer.<sup>11</sup> After the patent owner receives notice,

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4. 677 F.3d 1298 (2012).

5. 540 U.S. 398 (2004).

6. *Id.* at 411 (citing *Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990)).

7. 21 U.S.C. § 355(a) (2012).

8. H.R. REP. NO. 98-857(I) (1984); 21 U.S.C. § 355(j)(1)-(2).

9. H.R. REP. NO. 98-857(I); 21 U.S.C. § 355(j)(2).

10. 21 U.S.C. § 355(j)(2)(A)(vii).

11. *Id.* § 355(j)(2)(B)(iii).

it has forty-five days to initiate a patent infringement action.<sup>12</sup> If a patent infringement action is initiated, the FDA will not approve the ANDA for thirty months, or until a district court decides that the patent is invalid or not infringed, whichever is earlier.<sup>13</sup>

The primary purpose of the Hatch-Waxman Act was to increase generic drug competition by accelerating entry into the market.<sup>14</sup> When it files an ANDA, the generic drug company is not required to conduct the costly clinical trials that are necessary when filing the entire NDA.<sup>15</sup> Furthermore, if it is proven in litigation that the generic drug does not infringe the relevant patent, or that the patent is invalid, the generic drug can enter the market before the expiration of the patent term. To encourage patent challenges, the Hatch-Waxman Act provides a 180-day exclusive marketing period for the first generic company that challenges an invalid or non-infringed patent.<sup>16</sup> In this way, the Act provides an incentive for the testing of potentially weak patents through litigation.<sup>17</sup>

The Act also sought to increase innovation by restoring time lost on patent life while preparing for and awaiting FDA approval.<sup>18</sup> Although the statutory patent term in the United States was seventeen years, pharmaceutical products were marketed for less time, because the patents were obtained before FDA approval was granted.<sup>19</sup> To counteract this issue and encourage innovation, the legislature included a patent term extension for pharmaceuticals undergoing regulatory review.<sup>20</sup> Furthermore, brand name manufacturers received a three-year market exclusivity period for new forms and uses of previously approved drugs.<sup>21</sup>

Hence, the Hatch-Waxman Act strikes a balance between competition and innovation.<sup>22</sup> Within this legislation is Congress' judgment on the amount of competition and innovation that serves the public interest.

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12. *Id.* § 355(j)(5)(B)(iii).

13. *Id.*

14. H.R. REP. NO. 98-857(I), at 14.

15. *Id.*

16. 21 U.S.C. § 355(j)(5)(B)(iv).

17. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 61 (2009); see C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006) (noting that the 180-day "bounty" can be worth several hundred million dollars, inducing generic companies to challenge brand name drug patents).

18. H.R. REP. NO. 98-857(I), at 14.

19. *Id.* at 17-18.

20. 35 U.S.C. § 156(g)(6) (2012).

21. 21 U.S.C. § 355(c)(3)(E)(iii).

22. Carrier, *supra* note 17, at 45, 62 (arguing that the Hatch-Waxman Act created a "nuanced equilibrium between competition and innovation").

## B. THE NATURAL BY-PRODUCT OF THE HATCH-WAXMAN ACT

The first generic firm to file a Paragraph IV ANDA (“ANDA-IV”) alleging patent invalidity or non-infringement is entitled to 180 days of exclusive marketing after the application is approved. Until this 180-day period expires, no other ANDA-IVs will be approved.<sup>23</sup> But if a subsequent ANDA-IV filer demonstrates that the patent is invalid or not infringed, the exclusive marketing period of the first ANDA-IV filer is triggered, enabling subsequent ANDA-IV filers to enter after the 180-day period has ended.<sup>24</sup>

Despite this fact, subsequent ANDA filers have little, if any, incentive to select Paragraph IV and challenge the patent. A generic firm derives a significant portion of its profits during the 180-day exclusive marketing period.<sup>25</sup> Recognizing the value of exclusive marketing, Congress created the 180-day period to encourage generic firms to file ANDA-IVs that will ultimately challenge brand firm patents in litigation. But if the first ANDA-IV filer settles, the 180-day exclusive marketing period is not transferred to subsequent ANDA-IV filers, even if they prove lack of infringement or invalidity. This non-transferability of the 180-day reward is the primary reason why other generic firms will refrain from filing ANDA-IVs.<sup>26</sup> For the few generic firms that believe that filing an ANDA-IV may still be profitable without the exclusivity period, the requirement to wait 180 days to enter the market is an additional deterrent.<sup>27</sup>

Thus, when the brand company pays the first ANDA-IV filer to delay its entry, it essentially prevents all other generic companies from entering the market.<sup>28</sup> Given the regulatory structure, a reverse payment settlement is the best option for brand companies. The payment preserves the brand companies’ monopoly profits, whereas losing the litigation will cost them billions of dollars.<sup>29</sup> Generic companies also like the arrangement because

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23. Hemphill, *supra* note 17, at 1578 (noting that the “legal form” of the exclusive period is a delay in FDA approval of all other ANDA-IVs); *see* Carrier, *supra* note 17, at 47 (noting that the FTC cannot approve other ANDAs until the 180-day period expires).

24. Hemphill, *supra* note 17, at 1587.

25. *Id.* at 1590.

26. The 2003 Medicare Prescription Drug Improvement and Modernization Act created events that would cause a first ANDA-IV filer to lose its 180-day exclusive marketing period. 21 U.S.C. § 355(j)(5)(D). However, it appears that this modification has not reduced the number of reverse payment settlements, presumably because the 180-day reward is still not transferred to the next ANDA-IV filer. *See* C. Scott Hemphill, *Collusive and Exclusive Settlements of Intellectual Property Litigation*, 2010 COLUM. BUS. L. REV. 685, 708 (2010) (arguing that generic firm challenges are promoted by the 180-day period).

27. Carrier, *supra* note 17, at 47 (noting that the FTC cannot approve other ANDAs until the 180-day period expires).

28. Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1755 (2003) (noting that if the brand firm pays the generic firm to delay entry, this postpones the start of the 180-day marketing period, locking other generics out of the market).

29. By paying off the generic company, the brand company maintains its monopoly position. As a

the payment exceeds the profits they would have earned after winning the lawsuit and entering the market.<sup>30</sup>

Ironically, the Hatch-Waxman Act itself has provided the foundation for reverse payment settlements.<sup>31</sup> For this reason, reverse payment settlements have been described as the “natural by-product” of the Act’s 180-day exclusive marketing provision.<sup>32</sup>

## II. HOW REVERSE PAYMENT SETTLEMENTS HARM CONSUMERS

Reverse payment settlements have affected the prices of various popular drugs, such as Cipro and Plavix.<sup>33</sup> The drugs at the center of these lawsuits are used to treat common illnesses, such as hypertension and breast cancer. Others prevent strokes and heart attacks. In addition to individual consumers, lawsuits have been filed by wholesale drug companies, pharmacies, workers’ unions, and health plans.

The federal government has taken the position that reverse payment settlements harm consumers. According to the FTC, these agreements are presumptively anticompetitive,<sup>34</sup> costing consumers billions of dollars a year in higher prices.<sup>35</sup> Both the FTC and the Antitrust Division of the Department of Justice have filed amicus briefs in multiple private

monopolist, the brand company has the ability to control prices, which results in higher profits. But if the brand company continues the litigation and loses, the generic company can enter the market. Because generic drugs cost less, many consumers will switch to the generic drug, and the brand company will be forced to reduce its price to compete. As a result, losing the litigation would cost the brand company billions of dollars.

30. Carrier, *supra* note 17, at 39. When it delays entry by generic firms, the brand firm increases its monopoly profits. It then uses a portion of the profits to pay the generic firm more than it would have received through market entry. See Hemphill, *supra* note 17, at 1578 (concluding that the 180-day bounty ensures that a reverse payment settlement is an attractive option for both the brand and generic firms).

31. Hovenkamp et al., *supra* note 28, at 1755 (noting that it is generally accepted that the 180-day period of exclusive marketing provides the potential for collusive settlement agreements between brand firms and generic firms); see Hemphill, *supra* note 26, at 708. Hemphill argues that reverse payment settlements are encouraged by the fact that the generic firm retains the 180-day exclusive marketing period even if it settles. In his opinion, if the generic firm was required to give up the 180-day period when it settled, that would reduce the harm of reverse payment settlements.

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

33. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012); Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206–07 (2d Cir. 2006); *Andrx Pharm., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *Kroger Co. v. Sanofi-Aventis*, No. 1:06-cv-00263-HJW, 2006 WL 2503664 (S.D. Ohio July 31, 2006); *Biovail Corp. v. Mylan Labs, Inc.*, No. 1:01 CV66, 2002 U.S. Dist. LEXIS 6726 (N.D.W.Va. May 2, 2003); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002).

34. *Statement of the Federal Trade Commission Chairman Jon Leibowitz on the U.S. Court of Appeals for the Third Circuit Ruling in the K-Dur 20 Matter*, FED. TRADE COMM’N (July 16, 2012), <http://www.ftc.gov/opa/2012/07/kdur.shtm>.

35. *FTC Staff Report Finds 60 Percent Increase in Pharmaceutical Industry Deals*, *supra* note 2.

lawsuits.<sup>36</sup> According to a report from the Congressional Budget Office, eliminating these agreements would reduce federal government debt by \$4.8 billion over ten years.<sup>37</sup> And on four occasions, Congress has tried to pass legislation that would make these agreements illegal.<sup>38</sup>

The majority of scholars agree that a presumption of illegality is appropriate for these agreements<sup>39</sup> because they are anticompetitive and harm consumers.<sup>40</sup> There are two reasons why courts should view these settlements as atypical patent settlements that have harmful effects on consumers.

First, reverse payment settlements decrease competition. Because the 180-day exclusivity period is not transferable, reverse payment settlements prevent future patent challenges.<sup>41</sup> By removing all competitors, reverse payments force consumers to continue paying high prices.<sup>42</sup> In contrast, if there is a patent settlement in an unregulated industry, competing firms will still challenge the patent because they can market their product immediately if they win.<sup>43</sup> The patent holder has no incentive to pay for delay because the payment would not protect it from challenges from other competitors. Also, an ordinary patent case usually settles with a license agreement, which allows the infringing company to pay a royalty and sell its product.<sup>44</sup> In sum, an ordinary patent case in an unregulated industry results in more competition, not less.

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36. See, e.g., Brief for the United States, *Ark. Carpenters Health & Welfare Fund*, 604 F.3d 98 (Nos. 05-2851-cv(L), 05-2852-cv(CON)).

37. CONG. BUDGET OFFICE, CONGRESSIONAL BUDGET OFFICE COST ESTIMATE: S. 27 PRESERVE ACCESS TO AFFORDABLE GENERICS ACT (2011).

38. See Protecting Consumer Access to Generic Drugs Act of 2012, H.R. 3995, 112th Cong. (2d Sess. 2012); America's Affordable Health Choices Act of 2009, H.R. 3200, 111th Cong. (1st Sess. 2009); Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (1st Sess. 2009); Drug Price Competition Act of 2009, S. 1315, 111th Cong. (1st Sess. 2009).

39. See Carrier, *supra* note 17, at 38 (“[C]ourts should treat such settlements as presumptively illegal.”); Hemphill, *supra* note 26, at 708 (proposing that courts accord a presumption of illegality for agreements that contain a substantial payment); Hemphill, *supra* note 17, at 1561–62 (concluding that these settlements should be accorded a presumption of illegality); Hovenkamp et al., *supra* note 28, at 1720–21 (arguing that reverse payments that exceed litigation costs should be presumptively illegal).

40. Herbert Hovenkamp, *Patents, Property, and Competition Policy*, 34 J. CORP. L. 1243, 1251–52 (2009); see Carrier, *supra* note 17, at 75–76; Hemphill, *supra* note 26, at 703–05.

41. Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 RUTGERS L.J. 83, 84 (2009) (“[R]everse payment agreements . . . are not typical settlements. They are agreements that dispose of the validity and infringement challenges central to the Hatch-Waxman scheme.”).

42. Hemphill, *supra* note 26, at 704 (“[Reverse payment settlements are] bad . . . . A pay-for-delay settlement transfers wealth from consumers to drug makers in the form of continued high prices.”).

43. Carrier, *supra* note 17, at 61. Carrier notes that unlike pay-for-delay agreements, ordinary patent settlements do not prevent other competitors from challenging the patent. In ordinary patent cases, if a defendant settles and agrees not to challenge the patent, “many others often wait in the wings to do so.” *Id.*

44. Michael Carrier, *Innovation for the 21st Century: A Response to Seven Critics*, 61 ALA. L. REV. 597, 611 (2010); see Hovenkamp et al., *supra* note 28, at 1749–50.

Second, the payment size demonstrates that brand companies are purchasing a longer delay than their patents authorize.<sup>45</sup> If no payment is made, the length of the delay is a product of the strength of the patent and, therefore, indicative of the strength of the parties' litigation positions.<sup>46</sup> Thus, the larger the payment size, the greater the deviation from the monopoly period allowed by the strength of the patent. The large payment size also suggests that the patent is invalid.<sup>47</sup> If the brand company is likely to lose, it is more willing to pay for delay.<sup>48</sup> In that situation, there is no benefit that outweighs the competitive harm to consumers.<sup>49</sup> The enormous payments are even more disturbing when one considers the high success rate among generic companies. According to a recent FTC study, generic companies won seventy-three percent of cases between 1992 and 2000.<sup>50</sup>

Interestingly, between 2004 and 2009, seventy percent of Hatch-Waxman settlements did not contain reverse payments.<sup>51</sup> This suggests that reverse payment settlements are not necessary to settle patent infringement cases in the pharmaceutical context. But if reverse payments are not required to settle these cases, then why would Bayer pay \$398 million to settle the Cipro litigation?<sup>52</sup> The answer is obvious.

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45. See Carrier, *supra* note 44, at 612. Carrier argues that in most cases, payments that exceed the patent holder's litigation costs are being used to buy a later generic entry than the patent itself can provide. The general view is that payments that do not exceed the brand company's litigation costs do not raise a red flag. *Id.* See generally Hovenkamp et al., *supra* note 28, at 1758–60; Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 25 (2004) (noting that even a plaintiff who is sure of success would be willing to pay less than its litigation costs to settle the case).

46. Hemphill, *supra* note 26, at 703–04 (arguing that when a brand company makes a payment instead of relying solely on the strength of its case, it secures a later date of entry—one that is not warranted by the patent alone).

47. Carrier, *supra* note 44, at 612 (arguing that paying generics more than they would have earned had they entered the market raises a red flag of potential invalidity).

48. Hovenkamp et al., *supra* note 28, at 1758 (“[T]he size of the expected exclusion payments are inversely related to the strength of the patentee's case: the less likely the patentee is to win, the more it is willing to pay a generic to stay out of the market.”).

49. As Hovenkamp stated, “a larger payment suggests a more socially costly outcome—namely, preserving the exclusion power of the patent, at least vis-à-vis this particular defendant, even though the patent is likely to be invalid. The result is to deny the public the benefits of competition that it could otherwise obtain.” Hovenkamp, *supra* note 45, at 25.

50. See FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* 16 (2002); see also Paul M. Janicke & Lilan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 20 (2006) (noting that, according to a Federal Circuit survey, brand companies prevail in only thirty percent of cases).

51. See FED. TRADE COMM'N, *PAY-FOR-DELAY*, *supra* note 3.

52. The Cipro settlement totaled \$398.1 million and delayed all generic entry until the end of the patent term. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1329 n.5 (Fed. Cir. 2008).

The next Part summarizes the reverse payment cases that were decided between 2003 and 2012 and analyzes the three approaches that have emerged from those cases.

### III. A HISTORY OF THE CIRCUIT SPLIT

#### A. THE CASES

##### 1. *In re* Cardizem CD Antitrust Litigation<sup>53</sup>

Hoescht Marion Roussel, Inc. (“HMR”) sued Andrx Pharmaceuticals (“Andrx”) after Andrx filed an ANDA-IV for a generic version of Cardizem CD, which is used to treat angina and hypertension, and to prevent heart attacks and strokes.<sup>54</sup> In response to the ANDA-IV, HMR filed a patent suit, triggering the thirty month waiting period for FDA approval.<sup>55</sup> But when the FDA tentatively approved Andrx’s ANDA-IV (pending expiration of the thirty-month waiting period or a decision that the patent was not infringed), the parties formed an agreement.<sup>56</sup> Under this agreement, Andrx agreed to delay marketing its generic version of Cardizem CD. In addition, Andrx agreed to hold onto its 180-day period of marketing exclusivity.<sup>57</sup> In return, HMR agreed to pay Andrx \$40 million per year from the time that Andrx received FDA approval. Furthermore, HMR agreed to pay an additional \$100 million (less any interim payments) in the event that certain events transpired during the litigation.<sup>58</sup> After the thirty-month stay expired, the FDA approved Andrx’s ANDA-IV. HMR started to make its \$40 million payments to Andrx, and Andrx did not market its generic version of Cardizem CD.<sup>59</sup> About a year later, Andrx received FDA approval for a reformulated version of Cardizem CD.<sup>60</sup> On the same day, the parties settled the infringement lawsuit and terminated the aforementioned “pay-for-delay” agreement.<sup>61</sup> Shortly thereafter, Andrx started to market its generic version of Cardizem CD.<sup>62</sup> At the time of the settlement, HMR had paid Andrx a total of \$89.83 million.<sup>63</sup>

About a month after the parties signed their initial, pay-for-delay agreement, purchasers of Cardizem CD filed complaints in various courts

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53. 332 F.3d 896 (6th Cir. 2003).

54. *Id.* at 899, 901.

55. *Id.* at 902.

56. *Id.*

57. *Id.*

58. *Id.* at 903.

59. *Id.*

60. *Id.*

61. *Id.*

62. *Id.*

63. *Id.*

alleging violations of the federal antitrust laws and state antitrust and consumer protection statutes.<sup>64</sup> The plaintiffs alleged that the agreement prevented Andrx from selling its generic drug when it received FDA approval and prevented other generic firms from entering the market due to Andrx's postponement of the 180-day exclusive marketing period.<sup>65</sup> The district court concluded that the agreement (pursuant to which Andrx was paid \$40 million per year not to enter the market) was a per se illegal market allocation agreement, and it granted plaintiffs' motion for partial summary judgment.<sup>66</sup> Specifically, the court stated:

There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.<sup>67</sup>

Presently, the Sixth Circuit is the only circuit court to determine that a reverse payment agreement is per se illegal. However, in its opinion, the court noted that the agreement restrained generic firm Andrx from marketing other versions of Cardizem CD that were not covered by the patent litigation.<sup>68</sup> As a result, many believe that the Sixth Circuit did not intend to find all reverse payment agreements to be per se illegal, but rather only those agreements that restrict competition beyond the scope of the patent.<sup>69</sup>

## 2. Schering-Plough Corp. v. FTC<sup>70</sup>

Schering-Plough Corporation ("Schering") manufactures K-Dur 20, a potassium chloride product, which is used to treat high blood pressure and congestive heart disease.<sup>71</sup> In conjunction with K-Dur 20, Schering owns a formulation patent on the coating.<sup>72</sup> Upsher-Smith Laboratories ("Upsher") filed an ANDA-IV for its generic version of K-Dur 20, which is called Klor Con M20.<sup>73</sup> In response, Schering filed a patent infringement

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64. *Id.* at 903 n.7.

65. *Id.* at 904.

66. *Id.* at 905.

67. *Id.* at 908.

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

69. See *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1335 ("[A]lthough the Sixth Circuit found a per se violation in *In re* Cardizem, the facts of that case are distinguishable from this case and from the other circuit court decisions. . . . [in part because] the agreement provided that the generic manufacturer would not market non-infringing versions of the generic drug. Thus, the agreement clearly had anticompetitive effects outside the exclusion zone of the patent." (citations omitted)).

70. 402 F.3d 1056 (11th Cir. 2005).

71. *Id.* at 1058.

72. *Id.*

73. *Id.*

lawsuit.<sup>74</sup> On the eve of trial, the parties entered into a settlement agreement.<sup>75</sup> As part of the settlement, the parties agreed on an entry date for Upsher's generic drug, and Schering agreed to license Niacor and five other products from Upsher for an initial royalty fee of \$60 million.<sup>76</sup> Around the same time, ESI Lederle, Inc. ("ESI") filed an ANDA-IV for Micro-K 20, another generic version of K-Dur 20.<sup>77</sup> Schering sued ESI, and the parties settled.<sup>78</sup> ESI agreed that it would enter the market three years before Schering's patent expired.<sup>79</sup> In return, Schering agreed to pay \$5 million and an extra \$10 million if ESI received FDA approval by a specified date.<sup>80</sup>

About three years later, the FTC filed an administrative action against Schering, Upsher, and ESI, alleging that the settlement agreements violated the antitrust laws.<sup>81</sup> The administrative law judge dismissed the complaint, finding that the settlements were lawful.<sup>82</sup> The FTC staff appealed the decision to the full Commission, which reversed it.<sup>83</sup> The pharmaceutical defendants then appealed to the Eleventh Circuit.

On appeal, the Eleventh Circuit applied what is now known as the exclusionary scope analysis. Citing to its decision in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, the Eleventh Circuit examined: "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."<sup>84</sup> To apply this test, the court examined the language of the agreement and concluded that the language did not exceed the scope of the patent. The court did not examine the validity of the patent at issue. The judgment of the FTC was set aside.<sup>85</sup>

According to 35 U.S.C. § 282, a "patent shall be presumed valid."<sup>86</sup> The Eleventh Circuit relied on this presumption in finding that "Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products . . . did not infringe Schering's patent."<sup>87</sup> The court also believed that the exclusionary scope analysis reflected public policy:

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74. *Id.* at 1059.

75. *Id.* at 1060.

76. *Id.* at 1059–60.

77. *Id.* at 1060.

78. *Id.* at 1060–61.

79. *Id.*

80. *Id.*

81. *Id.* at 1061.

82. *Id.*

83. *Id.* at 1062.

84. *Id.* at 1066 (quoting *Valley Drug Co. v. Geneva Pharm.*, 344 F.3d 1294, 1312 (11th Cir. 2003)).

85. *Id.* at 1076.

86. 35 U.S.C. § 282 (2012).

87. *Schering-Plough*, 402 F.3d at 1066–67.

Given the costs of lawsuits to the parties, the public problems associated with overcrowded dockets, and the correlative public and private benefits of settlements, we fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and, in an ancillary transaction, pays for other products licensed by the generic.<sup>88</sup>

The court was concerned that a draconian rule would negatively impact settlement activity.

### 3. In re Tamoxifen Citrate Antitrust Litigation<sup>89</sup>

Zeneca, Inc. ("Zeneca") sued Barr Laboratories, Inc. ("Barr") after Barr filed an ANDA-IV for a generic version of Tamoxifen, a breast cancer treatment drug.<sup>90</sup> The district court declared that the patent was invalid, and Zeneca appealed.<sup>91</sup> While the appeal was still pending, the parties settled.<sup>92</sup> Under the terms of the settlement agreement, Barr received \$21 million and a license to sell Zeneca's Tamoxifen under the Barr label.<sup>93</sup> Furthermore, Barr's raw material supplier received \$9.5 million up front in addition to \$35.9 million over the next ten years.<sup>94</sup> In return, Barr agreed to refrain from marketing its generic version of Tamoxifen until Zeneca's patent expired.<sup>95</sup>

Consumer groups sued Zeneca and Barr, alleging that the settlement agreement violated the antitrust laws.<sup>96</sup> The district court granted Zeneca and Barr's motion to dismiss for failure to state a claim, and the plaintiff consumers appealed.<sup>97</sup>

On appeal, the Second Circuit applied the exclusionary scope analysis.<sup>98</sup> The court analyzed the language of the agreement and concluded that any exclusionary effects were within the scope of the patent.<sup>99</sup> Like the Eleventh Circuit, the Second Circuit did not examine the validity of the patent at issue.<sup>100</sup> Rather, the court presumed that the patent was valid, even though it was found to be invalid by the district

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88. *Id.* at 1076.

89. 466 F.3d 187 (2d Cir. 2005).

90. *Id.* at 190, 193.

91. *Id.* at 193.

92. *Id.*

93. *Id.* at 193–94.

94. *Id.* at 194.

95. *Id.*

96. *Id.* at 196–97.

97. *Id.* at 197.

98. *Id.* at 213.

99. *Id.* at 213–14.

100. *Id.* at 200.

court prior to Zeneca and Barr's settlement.<sup>101</sup> In reaching its decision, the court relied on the presumption of validity in 35 U.S.C. § 282.<sup>102</sup> The court also emphasized the public interest in the settlement of complex and expensive litigation.<sup>103</sup>

4. *In re Ciprofloxacin Hydrochloride Antitrust Litigation (Cipro)*<sup>104</sup>

Bayer manufactures the antibiotic Cipro and owns the patent that covers its active ingredient.<sup>105</sup> A few years after the patent issued, Barr filed an ANDA-IV for a generic version of Cipro, alleging that the relevant patent was invalid and unenforceable.<sup>106</sup> Bayer sued Barr for infringement, and Barr entered into a litigation-funding agreement with Rugby, a subsidiary of Hoechst Marion Roussel. Before trial, the parties entered into a settlement in which the generic companies agreed not to challenge the validity and enforceability of the patent until it expired.<sup>107</sup> In return, Bayer agreed to pay Barr \$49.1 million initially, in addition to quarterly payments, eventually totaling \$398.1 million.<sup>108</sup>

Direct and indirect purchasers of Cipro filed antitrust actions, claiming that the agreement between Bayer and the generic companies was an illegal market allocation.<sup>109</sup> The district court denied plaintiffs' motion for summary judgment and granted defendants' motion for the same.<sup>110</sup> Because the indirect purchasers added antitrust claims that are preempted by patent law, the case was bifurcated for appeal—the direct purchasers' appeal was heard by the Second Circuit, and the indirect purchasers' appeal was heard by the Federal Circuit.<sup>111</sup>

On appeal, the Federal Circuit applied the exclusionary scope analysis. In affirming the lower court's decision, the Federal Circuit found that it was within Bayer's rights as the patent holder to exclude the defendants from profiting from its patented invention.<sup>112</sup> Plaintiffs argued unsuccessfully that Bayer's "right to exclude competition is not defined by the facial scope of the patent, but rather is limited to the right to exclude others from profiting from the patented invention."<sup>113</sup>

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101. *Id.* at 209 n.22.

102. *Id.*

103. *Id.* at 202.

104. 544 F.3d 1323 (Fed. Cir. 2008).

105. *Id.* at 1327–28.

106. *Id.* at 1328.

107. *Id.* at 1329.

108. *Id.* at 1329 n.5.

109. *Id.* at 1329.

110. *Id.* at 1330.

111. *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 103 n.10 (2d Cir. 2010).

112. *Cipro*, 544 F.3d at 1333.

113. *Id.* at 1332–33.

The court also noted the “long-standing policy in . . . favor of settlements.”<sup>114</sup> According to the court, “[s]ettlement of patent claims by agreement between the parties—including exchange of consideration—rather than by litigation is not precluded by the Sherman Act even though it may have some adverse effect on competition.”<sup>115</sup> The court was not persuaded by plaintiffs’ argument that it should consider the public interest in removing invalid patents.<sup>116</sup> Rather, the court concluded that, “in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.”<sup>117</sup>

Like the Second and Eleventh Circuits, the Federal Circuit invoked the presumption of validity in support of its conclusion.<sup>118</sup> Citing *Tamoxifen*, the court stated that a “settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled—a monopoly over the manufacture and distribution of the patented invention.”<sup>119</sup>

After losing before the Federal Circuit, the indirect purchaser plaintiffs petitioned the Supreme Court for review, but their petition for certiorari was denied.<sup>120</sup>

##### 5. Arkansas Carpenters Health & Welfare Fund v. Bayer AG<sup>121</sup>

As was discussed above, the indirect purchasers’ appeal in *Cipro* was transferred to the Federal Circuit, but the direct purchasers’ appeal was heard by the Second Circuit. Following *Tamoxifen*, the Second Circuit applied the exclusionary scope analysis and determined that the language in the agreement did not exceed the scope of the patent.<sup>122</sup>

In its analysis, the court explicitly declined to address the validity of the patent:

The *Tamoxifen* majority urged against addressing the probability that a patent was invalid and deferred to a patent holder’s desire to settle patent challenges, concluding that a patent holder could reasonably decide to pay money, even more than a generic manufacturer would make on the market, to guarantee protection of its patent.<sup>123</sup>

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114. *Id.* at 1333.

115. *Id.* (citing *Standard Oil Co. v. United States*, 283 U.S. 163, 171 n.5 (1931)).

116. *Id.* at 1334.

117. *Id.* at 1336.

118. *Id.* at 1337.

119. *Id.*

120. See *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, No. 08-1194, 129 S. Ct. 2828 (June 22, 2009) (denying certiorari).

121. 604 F.3d 98 (2d Cir. 2010).

122. *Id.* at 104–06.

123. *Id.* at 108 (quoting *In re Tamoxifen Citrate Antitrust Litig.*, 446 F.3d 187, 210 (2d Cir. 2006)).

The court mentioned other policy considerations, but they were not addressed in the court's final analysis because it ultimately decided that it was bound to follow *Tamoxifen*.<sup>124</sup> However, the panel suggested that it might be willing to reconsider the standard in *Tamoxifen* and cited various reasons why the current case might be appropriate for reexamination by the full court.<sup>125</sup> In concluding, the panel invited plaintiffs to petition for rehearing by the full court.<sup>126</sup> Although plaintiffs complied with this request and petitioned for rehearing en banc, unexpectedly, their petition was denied.<sup>127</sup> Subsequently, plaintiffs petitioned the Supreme Court for review, but their writ of certiorari was also denied.<sup>128</sup>

#### 6. In re K-Dur Antitrust Litigation<sup>129</sup>

In this case, consumers of K-Dur 20 filed a lawsuit against Schering, Upsher, and ESI. The plaintiffs claimed that the companies' settlement of patent litigation was a reverse payment agreement that violated the antitrust laws. This case challenged the same agreement that the FTC challenged in *Schering-Plough*.<sup>130</sup> The district court utilized the exclusionary scope analysis and granted the pharmaceutical defendants' motion to dismiss. On appeal, the Third Circuit rejected the exclusionary scope test, finding that it failed to subject reverse payment agreements to any antitrust scrutiny and that it undermined the policies of the Hatch-Waxman Act.<sup>131</sup>

The Third Circuit opted to create its own analysis, which it referred to as a "quick look rule of reason analysis."<sup>132</sup> This analysis was based in part on the approach espoused by the FTC in its amicus brief.<sup>133</sup> Under this test, a reverse payment settlement is prima facie evidence of an unreasonable restraint of trade, incorporating the concept of presumptive illegality.<sup>134</sup> After evidence of a reverse payment has been proffered, the prima facie case can be rebutted.<sup>135</sup> The court provided two examples of how the prima facie case can be rebutted. First, the drug manufacturers can demonstrate that the payment was not for delay, but for another

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124. *Id.*

125. *Id.*

126. *Id.* at 110.

127. Ark. Carpenters Health & Welfare Fund v. Bayer AG, 625 F.3d 779, 779 (2d Cir. 2010).

128. La. Wholesale Drug Co. v. Bayer AG (2d Cir. 2011), *cert. denied*, 131 S. Ct. 1606 (2011) (No. 10-762).

129. 686 F.3d 197 (3d Cir. 2012).

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

131. *In re K-Dur*, 686 F.3d at 214.

132. *Id.* at 218.

133. See Brief of the Fed. Trade Comm'n as Amicus Curiae Supporting Appellants and Urging Reversal at 22-28, *In re K-Dur*, 686 F.3d 197 (Nos. 10-2077, 10-2078, 10-2079); see also Carrier, *supra* note 17, at 76-78 (advocating a similar approach to that proposed by the FTC in its amicus brief).

134. *In re K-Dur*, 686 F.3d at 218.

135. *Id.*

reason.<sup>136</sup> Second, defendants can demonstrate that the payment creates a procompetitive result that could not have been achieved absent the reverse payment, such as “a modest cash payment that enables a cash-starved generic manufacturer to avoid bankruptcy and begin manufacturing a generic drug.”<sup>137</sup>

The Third Circuit reversed the decision of the district court and remanded the case so it could apply the aforementioned analysis.<sup>138</sup> The pharmaceutical defendants petitioned the Supreme Court for review.<sup>139</sup>

#### 7. FTC v. Watson Pharmaceuticals, Inc.<sup>140</sup>

Besins Healthcare developed AndroGel, a gel that treats low testosterone.<sup>141</sup> Solvay Pharmaceuticals obtained a license to sell AndroGel in the United States. After it received FDA approval, Solvay obtained a patent.<sup>142</sup> Watson Pharmaceuticals and Paddock Laboratories filed ANDA-IVs in May 2003.<sup>143</sup> In response, Solvay filed patent infringement suits against both companies. Eventually, the defendants filed motions for summary judgment.<sup>144</sup> While those motions were pending, the thirty month stay for FDA approval expired in January 2006.<sup>145</sup> Faced with the possibility of losing \$125 million a year in profits, Solvay settled with Watson and Paddock before the motions for summary judgment were decided. Watson and Paddock agreed not to market their generic versions of AndroGel until August 31, 2015.<sup>146</sup> Solvay agreed to pay Paddock \$10 million per year for six years, plus \$2 million per year for back-up manufacturing assistance. Solvay also agreed to pay Watson between \$19 and \$30 million per year.<sup>147</sup>

When this agreement was reported to the FTC pursuant to statutory requirements, the FTC filed an antitrust claim against Solvay, Watson, Par,<sup>148</sup> and Paddock. The FTC argued that Solvay was not likely to prevail in the patent case because Watson and Paddock had strong evidence that their products did not infringe the patent and that the patent was invalid. As a result, the FTC argued, Solvay’s reverse payments extended a

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136. *Id.*

137. *Id.*

138. *Id.*

139. Petition for Writ of Certiorari, *FTC v. Watson Pharm., Inc.*, 133 S. Ct. 787 (2012) (No. 12-265).

140. 677 F.3d 1298 (11th Cir. 2012).

141. *Id.* at 1303–04.

142. *Id.* at 1304.

143. *Id.*

144. *Id.*

145. *Id.*

146. *Id.* at 1305.

147. *Id.*

148. Par entered into a litigation-sharing agreement with Paddock. *Id.* at 1304.

monopoly that is not authorized under the patent laws, unlawfully restraining competition.<sup>149</sup>

The defendants filed a motion to dismiss for failure to state a claim. The district court applied the exclusionary scope analysis and granted the motion.<sup>150</sup> Relying on its decisions in *Valley Drug* and *Schering-Plough*, the Eleventh Circuit also applied the exclusionary scope analysis and affirmed the district court's decision.<sup>151</sup> Significantly, the Eleventh Circuit concluded that "neither the rule of reason nor the per se test is an appropriate way to analyze the antitrust implications of a reverse payment settlement."<sup>152</sup> The court opined that these traditional analyses were inappropriate because "one of the signatories to the settlement holds a patent, and a patent conveys a right to 'cripple competition.'"<sup>153</sup>

The court rejected the rule advocated by the FTC: "that an exclusion payment is unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date."<sup>154</sup> According to the court, the "FTC's position equates a likely result (failure of an infringement claim) with an actual result, but it is simply not true that an infringement claim that is 'likely' to fail actually will fail."<sup>155</sup>

## B. ANALYZING THE THREE APPROACHES

### 1. *Per Se Illegality*

There is no escaping the fact that the Sixth Circuit's per se illegal approach is over-inclusive. Concluding that a reverse payment settlement is illegal without considering validity or infringement ignores the accepted view that a patent is a legal monopoly that gives the patent holder the legal right to exclude competitors. If there is a valid patent and the competing product infringes that patent, the patent holder can pay its competitor to stay out of the market.

### 2. *The Exclusionary Scope Analysis*

In contrast to the Sixth Circuit's approach, the exclusionary scope analysis accomplishes too little. In most cases, it results in a total absence of antitrust scrutiny. Appropriately criticized as a "rule of per se legality," this analysis assumes that a patent has a scope without first determining if

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149. *Id.* at 1306.

150. *Id.*

151. *Id.* at 1312.

152. *Id.* at 1309.

153. *Id.* at 1310 (quoting *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005)).

154. *Id.* at 1312.

155. *Id.*

the patent is valid.<sup>156</sup> But if a patent is invalid, then there is no scope at all.<sup>157</sup>

To justify this conclusion, the courts invoke the presumption of validity found in 35 U.S.C. § 282. But the presumption of validity is a procedural presumption that allocates the burden of proof between the parties. It is not substantive evidence of validity.<sup>158</sup> Furthermore, it is clear from the statute that this presumption was intended to be rebuttable: “The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.”<sup>159</sup>

Also, in cases where only infringement is disputed, the exclusionary scope analysis creates a presumption of infringement that has no basis in the law. In patent law, the burden of proof is on the patent holder to prove infringement. There is no presumption of infringement.

Because it fails to address validity and infringement, the exclusionary scope analysis ignores the very issues that determine whether an antitrust violation exists. The widespread use of the exclusionary scope analysis has resulted in an absence of antitrust scrutiny for reverse payment settlements.

To understand the exclusionary scope analysis, one needs to examine the policies that motivate it. First, the courts emphasize that a patent gives the patent holder the right to exclude competitors, which negatively impacts competition but increases innovation. Second, the courts rely on the policy favoring settlement. These policies will be addressed in turn.

*a. A Patent’s Right to Exclude Should Be Considered  
Alongside the Public Interest in Removing Invalid Patents*

The courts are correct that a patent is an exception to the rule that competition is always better. If a patent is valid, the public benefits produced by innovation outweigh the harm to competition. Thus, when dealing with a *valid* patent, a court should uphold its right to exclude competitors. But what if the patent is invalid? In this situation, there is no benefit that outweighs the harm to competition. If the holder of an invalid patent excludes all competitors through a reverse payment settlement, the anticompetitive effects are not outweighed by any public benefit. As a result, when dealing with an antitrust challenge to a reverse payment settlement, courts should also consider the public interest in removing invalid patents.

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156. See Hemphill, *supra* note 26, at 705–06 (“[Courts] have adopted a rule that verges on per se legality . . .”).

157. Carrier, *supra* note 17, at 66 (“[I]f the patent is not valid, there is no scope at all.”).

158. See Carrier, *supra* note 41, at 86; see also Carrier, *supra* note 17, at 64.

159. 35 U.S.C. § 282 (2012).

This policy has its roots in Supreme Court precedent. In *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery*, the Supreme Court noted:

The possession and assertion of patent rights are issues of great moment to the public. A patent by its very nature is affected with a public interest. . . . At the same time, a patent is an exception to the general rule against monopolies and to the right to access to a free and open market. The far reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.<sup>160</sup>

The public's interest in removing invalid patents was also upheld in *Lear, Inc. v. Adkins*: “[F]ederal law requires that all ideas in general circulation be dedicated to the common good unless they are protected by a valid patent.”<sup>161</sup>

It is clear that the public interest in removing invalid patents influenced the creation of the Hatch-Waxman Act. The purpose of the Hatch-Waxman Act was to increase the availability of low cost drugs by encouraging generic firms to challenge potentially invalid patents through litigation.<sup>162</sup> When a generic company files an ANDA-IV, it initiates a process that was intended to end with a judicial decision regarding validity and infringement. If the generic firm prevails in the litigation, it can enter the market. The entry of competing drug makers increases competition and pushes down prices.

The 180-day exclusive marketing period was created to encourage firms to challenge potentially invalid patents and enter prior to patent expiration. But in addition to encouraging litigation, it has provided the incentive for reverse payment settlements, which prevent future patent challenges. Through the Hatch-Waxman Act, Congress selected the amount of competition and innovation that serves the public interest.<sup>163</sup> Reverse payment settlements are private agreements that alter that balance, favoring more innovation over competition.<sup>164</sup>

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160. *Precision Instrument Mfg. Co. v. Auto. Maint. Mach.*, 324 U.S. 806, 815–16 (1945) (citation omitted) (internal quotation marks omitted).

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

162. *See Carrier*, *supra* note 17, at 60 (“[E]ven a cursory consideration of the statute underscores the importance of patent challenges.”); *see also Hemphill*, *supra* note 17, at 1614 (describing litigation as the instrument by which the Hatch-Waxman Act accomplishes its goals).

163. *Hemphill*, *supra* note 17, at 1614 (“[T]he [Hatch-Waxman] Act sets a particular balance between innovation and competition.”).

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

b. *If These Settlements Actually Harm the Public, Then Why Rely on the Policy Favoring Settlement?*

Turning to the policy favoring settlement, it is clear that the courts' reliance on this policy is completely misguided. The policy is premised on the idea that settlements benefit the public, reduce litigation expenses, and conserve judicial resources. Courts are increasingly promoting the settlement of patent cases, which produce large litigation expenses and are believed to consume a significant amount of judicial resources.<sup>165</sup> But as a society, we should be wary of assuming that all settlements benefit the public interest.<sup>166</sup> The courts consider the public interest when deciding a case.<sup>167</sup> But when parties enter into a settlement, the court is removed from the process. The goal of the settling parties is to maximize their private interests.<sup>168</sup> Reverse payment settlements do just that—they maximize the pharmaceutical companies' profits at the expense of consumers. Because research and data demonstrate that reverse payment settlements harm consumers, the policy favoring settlement should not be considered when analyzing reverse payment settlements.

Given the overwhelming evidence that reverse payments harm consumers, one should question whether the courts' reliance on this policy is really motivated by a desire to protect the public interest. It appears that the courts are hiding behind this policy to avoid the complex and difficult issues that arise in patent cases.<sup>169</sup>

3. *Quick Look Rule of Reason*

The Third Circuit's decision to reject the exclusionary scope analysis and create its own test is a positive step. In contrast to the courts that employed the exclusionary scope analysis, the Third Circuit refuses to hide behind the policy favoring settlement, observing that

the judicial preference for settlement, while generally laudable, should not displace countervailing public policy objectives or, in this case, Congress's determination—which is evident from the structure of the Hatch-Waxman Act and the statements in the legislative record—that

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

166. Owen Fiss, *Against Settlement*, 93 YALE L.J. 1073, 1075 (1984). Fiss disagrees with the position that settlement is always better than judgment. He argues that settlement should not be utilized "on a wholesale and indiscriminate basis." *Id.*

167. *Id.* at 1085.

168. *Id.* (arguing that parties may settle in a manner that leaves justice undone).

169. Hovenkamp argues that the courts' reluctance to examine the underlying merits of the patent claim is not due to the policy favoring settlement, but rather the difficulty inherent in determining patent validity and scope. Hovenkamp, *supra* note 40, at 1251.

litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers.<sup>170</sup>

The court further suggested that any analysis should also consider the public interest in removing invalid patents.<sup>171</sup>

The Third Circuit's analysis provides some antitrust scrutiny. In particular, their decision to treat reverse payment settlements as presumptively illegal was appropriate. But under the Third Circuit's test, it is very easy for pharmaceutical companies to rebut the prima facie case.

First, the court stated that the prima facie case can be rebutted by demonstrating that the payment was for a reason other than delay. But pharmaceutical companies are already hiding their exit payments in other transactions.<sup>172</sup> That is what the drug companies were allegedly doing in *In re K-Dur*.<sup>173</sup>

Second, the defendants can demonstrate that the payment creates a procompetitive result that could not otherwise have been achieved, such as "a modest cash payment that enables a cash-starved generic manufacturer to avoid bankruptcy and begin manufacturing a generic drug."<sup>174</sup> What qualifies as "cash-starved" is unclear. This phrase is sufficiently broad that most generic companies could fall into this category. Also, at what point does a company decide to file for bankruptcy? And how do we define a "modest cash payment"?

Although the Third Circuit suggested that the public interest in removing invalid patents should be a factor in the analysis, in the end, its quick look rule of reason analysis does not examine validity or infringement at all. Like the courts that have employed the exclusionary scope analysis, the Third Circuit has failed to consider the issues that determine whether an antitrust violation has occurred.

If the patent is valid and infringed, then the brand company can rely on the patent to exclude competition, and the reverse payment settlement is not considered a market allocation agreement.<sup>175</sup> But if the patent is invalid or not infringed, then the agreement is a market allocation, which is

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170. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 217 (3d Cir. 2012).

171. *Id.* at 215–16.

172. See Carrier, *supra* note 41, at 93. Carrier notes that the payments from brand firms to generic firms are often hidden in other transactions. For example, instead of giving the generic firm a simple cash payment for delay, the brand companies are paying generics for IP licenses, products and/or raw materials, and advertising assistance. *Id.*

173. Schering (the brand manufacturer) promised to pay Upsher \$60 million for three years to license Niacor-SR. *Shering-Plough Corp. v. FTC*, 402 F.3d 1056, 1060 (11th Cir. 2005). After the settlement agreement was signed and the board ratified the acquisition of the license, plans to make and market Niacor-SR were abandoned. *Id.* The antitrust plaintiffs argued that the license agreement payment was in fact compensation to Upsher in return for its agreement not to enter the market. *Id.* at 1068.

174. *In re K-Dur*, 686 F.3d at 218.

175. Carrier, *supra* note 41, at 91.

per se illegal.<sup>176</sup> If an agreement is per se illegal, the defendant is not entitled to argue that there is a procompetitive justification.<sup>177</sup> This rebuttal option is only available for agreements that are reviewed under the rule of reason. The Third Circuit's analysis incorrectly provides rule of reason treatment for agreements that could very well be per se illegal market allocation agreements. But we will only know if these agreements are per se illegal if we first decide the issues of validity and infringement. As a result, to rebut the presumption of illegality, defendants must demonstrate that the patent is valid and infringed.

#### IV. THE SOLUTION: AN ANALYSIS BASED ON THE GUIDING PRINCIPLES OF *TRINKO*

As the Eleventh Circuit noted in *Schering-Plough*, the “general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.”<sup>178</sup> Furthermore, settlements in patent infringement suits are not precluded by the antitrust laws.<sup>179</sup> Because settlement of patent litigation is generally favored, and the antitrust laws do not preclude such settlements, under normal circumstances, courts should consider the policy favoring settlement when analyzing antitrust challenges to patent litigation settlements. But we are not dealing with ordinary circumstances, and we are not dealing with ordinary patent settlements.

In December 2012, the Supreme Court granted the petition for certiorari in *Watson Pharmaceuticals*.<sup>180</sup> Before the Court are the three analyses discussed above. This Article argues that the Supreme Court's decision should be guided by the principles in *Verizon Communications v. Law Offices of Curtis V. Trinko*. Based on these principles, it is clear that all three approaches should be rejected.

*Trinko* involved an antitrust challenge brought by customers of AT&T against Verizon Communications Inc.<sup>181</sup> Pursuant to the Telecommunications Act of 1996, incumbent local exchange carriers, such as Verizon, were required to share their networks with competitors.<sup>182</sup> According to the complaint, Verizon failed to fill its rivals' customer

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176. See *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990); *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972); see also *Carrier*, *supra* note 17, at 72. *Carrier* notes that if a patent is invalid or not infringed, there is no legitimate justification for delaying competition, and the reverse payment agreement is a cover for market allocation.

177. *Topco*, 405 U.S. at 608.

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

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

180. *FTC v. Watson Pharm., Inc.*, 133 S. Ct. 787 (2012).

181. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 404 (2004).

182. *Id.* at 401.

service orders to discourage customers from using its rivals' services.<sup>183</sup> Plaintiffs argued that this behavior constituted a refusal to deal in violation of section 2 of the Sherman Act, which forbids monopolies or attempts to monopolize.<sup>184</sup>

To decide whether an antitrust violation existed, the Court first determined "what effect (if any) the 1996 Act ha[d] upon the application of traditional antitrust principles."<sup>185</sup> The Court further elaborated that antitrust analysis "must always be attuned to the particular structure and circumstances of the industry at issue. Part of that attention to economic context is an awareness of the significance of regulation."<sup>186</sup> The Court added that antitrust analysis "must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies."<sup>187</sup> This last statement is a quote from *Town of Concord v. Boston Edison Co.*, a First Circuit opinion that was written by then Chief Judge Breyer.<sup>188</sup>

The Supreme Court's approach in *Trinko* is based in part on *Boston Edison*.<sup>189</sup> The latter involved a claim brought by municipal distributors of electricity against a fully integrated investor-owned utility, whose rates are regulated by the Federal Energy Regulatory Commission.<sup>190</sup> The municipal distributors alleged that the defendant engaged in a price squeeze in violation of section 2 of the Sherman Act.<sup>191</sup> The court held that this type of price squeeze would not ordinarily violate the Sherman Act because the defendant's prices were regulated at both levels of production.<sup>192</sup> The court further explained: "[I]n light of regulatory rules, constraints, and practices, the price squeeze at issue here is not ordinarily exclusionary, and, for that reason, it does not violate the Sherman Act."<sup>193</sup> The court reached its conclusion by "(1) analyzing the ordinary price squeeze, (2) comparing it to the 'regulatory' price squeeze, and (3) noting that regulation makes a critical difference in terms of antitrust harms, benefits, and administrative considerations."<sup>194</sup> Adopting a portion of this analysis and applying it to the telecommunications industry, the *Trinko* court concluded that the regulatory framework demonstrated

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183. *Id.* at 404.

184. *Id.* at 407.

185. *Id.* at 405.

186. *Id.* at 411.

187. *Id.* (quoting *Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990)).

188. *Boston Edison*, 915 F.2d at 22.

189. *Trinko*, 540 U.S. at 411-12 (citing *Boston Edison*, 915 F.2d 17).

190. *Boston Edison*, 915 F.2d at 20-21.

191. *Id.*

192. *Id.* at 22.

193. *Id.*

194. *Id.* at 23.

“how, in certain circumstances, ‘regulation significantly diminishes the likelihood of major antitrust harm.’”<sup>195</sup>

Applying the foregoing analysis to reverse payment settlements results in a different conclusion. The circuit courts that utilize the exclusionary scope analysis are arguably stuck in part one of the *Boston Edison* analysis. They treat reverse payment settlements as ordinary patent settlements in an unregulated industry. But according to *Trinko*, in conducting their antitrust analysis, the courts need to consider “the particular structure and circumstances of the industry at issue.” They must be aware of “the significance of regulation.” In other words, they need to consider the particular circumstances of the pharmaceutical industry and how the Hatch-Waxman Act affects competition in that industry.

Under the framework laid out in *Trinko* and *Boston Edison*, we should first compare the ordinary patent settlement to the Hatch-Waxman reverse payment settlement. When settling a patent claim in an unregulated industry, the alleged infringer pays a royalty fee to continue selling its product. In other words, patent settlements in unregulated industries result in more competition, not less competition. In contrast, in the Hatch-Waxman context, when the parties settle and the brand company pays the generic company to delay its entry, it precludes all other generics from entering the market.

Next, we should consider whether the Hatch-Waxman Act makes a significant difference with respect to antitrust harms and benefits. Through the Hatch-Waxman Act, Congress sought to promote competition by encouraging patent challenges. It tried to promote these challenges by offering a 180-day exclusive marketing period. But the Hatch-Waxman Act is malfunctioning. The 180-day exclusivity period has encouraged the formation of reverse payment settlements, which harm consumers. Given the size of the payments and the high success rate of generic companies, it appears that reverse payment settlements are extending patents that are invalid and/or not infringed. As a result, the regulatory framework of the Hatch-Waxman Act is significantly increasing the likelihood of competitive harm. A reverse payment settlement in the pharmaceutical industry will normally constitute a market allocation agreement.

In reaching its decision in *Watson Pharmaceuticals*, the Eleventh Circuit relied on the presumption of validity and the policy favoring settlement. The exclusionary scope analysis is a perfect blend of these two principles. Thus, this test may be appropriate for ordinary patent

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195. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 412 (2004) (quoting *Boston Edison*, 915 F.2d at 25).

settlements in an unregulated industry. But it is the wrong test for reverse payment settlements in the pharmaceutical industry.

Because the regulatory structure of the Hatch-Waxman Act significantly increases the likelihood of antitrust harm, the general principal that courts should encourage settlement should not be a factor at all when analyzing reverse payment settlements. Because these settlements are more likely to extend patents that are invalid, the courts should focus on the public interest in removing invalid patents when creating their antitrust analysis. The presumption of illegality, which is utilized in *In re K-Dur*, is insufficient to uphold this public interest. Rather, the courts must decide the merits of the underlying patent claim.<sup>196</sup>

Other commentators have also advocated an industry-specific approach to reverse payment settlements. For example, in an article they co-authored, Hovenkamp, Janis, and Lemley voiced support for such an approach.<sup>197</sup> Relying in part on *Trinko*, Carrier has also advocated an industry-specific approach, arguing that the language of the Hatch-Waxman Act demonstrates the secondary relevance of the settlement-related policies on which the courts have focused their analysis.<sup>198</sup> I agree that the courts are wrong to focus on the policy favoring settlement in analyzing these settlements. But I think the error is clear from the effect that the Hatch-Waxman Act has on competition, not from the language of the Act itself. The courts did not err by failing to consider the policies advanced in the Act. The error is in their failure to recognize that the regulatory framework of the Act is hurting competition, and to tailor their antitrust analysis accordingly.

The aforementioned scholars do not support a full analysis on the merits.<sup>199</sup> It is easy to understand why. Patent litigation is complex and time consuming, and the courts are busy. But let us not forget that we are dealing with a regulatory regime that significantly increases the likelihood of major antitrust harm and provides absolutely no antitrust scrutiny. As the Supreme Court noted in *Trinko*, where there “‘is nothing built into the regulatory scheme which performs the antitrust function,’ the benefits of antitrust are worth its sometimes considerable disadvantages.”<sup>200</sup> In this context, the benefits to be gained are better health, freedom from pain, and in some cases, the chance to live.

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196. Specifically, the courts must decide the issues of validity and infringement.

197. Hovenkamp et al., *supra* note 28, at 1736–39.

198. Carrier, *supra* note 17, at 69.

199. *Id.* at 73; Hovenkamp et al., *supra* note 28, at 1759–61.

200. *Trinko*, 540 U.S. at 412 (citation omitted).

## CONCLUSION

This Article has argued that the Supreme Court's decision in *Watson Pharmaceuticals* should be guided by the principles in *Trinko*. During the last ten years, the circuit courts have developed three different approaches to analyzing reverse payment settlements. Unfortunately, none of these approaches fully complies with *Trinko*'s directive to consider the unique circumstances of the industry at issue. The Sixth Circuit's approach completely ignores the fact that these settlements involve a patent. The exclusionary scope analysis relies on the presumption of validity and the policy favoring settlement even though these settlements are more likely to involve an invalid patent, and have been shown to harm consumers. Lastly, the Third Circuit approach applies a quick look rule of reason analysis to agreements that may be per se illegal market allocation agreements.

The Hatch-Waxman Act itself has provided the foundation for reverse payment settlements. These settlements do not serve the public interest—they benefit the pharmaceutical companies at the expense of consumers. Based on the industry-specific approach mandated in *Trinko*, the Court should conclude that the general policy favoring settlement should not be a factor in this antitrust analysis and that the courts should decide the merits of the underlying patent claim.