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## Reverse Payment Agreements: Why a “Quick Look” Properly Protects Patents and Patients

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## REVERSE PAYMENT AGREEMENTS: WHY A “QUICK LOOK” PROPERLY PROTECTS PATENTS AND PATIENTS

### INTRODUCTION

Regulating the pharmaceutical industry has proven to be precarious because of the unique landscape of the market. On the one hand, pharmaceutical companies are encouraged and rewarded for developing innovative, and oftentimes, lifesaving drugs.<sup>1</sup> Yet, on the other hand, regulation is required to ensure that there is competition in the market to drive down prices and make prescription drugs affordable.<sup>2</sup> The sometimes-conflicting goals of encouraging innovation and ensuring competition to drive down prices have created difficulties for Congress, courts, and regulatory agencies in framing rules and regulations for the pharmaceutical industry.

Antitrust analysis concerning the pharmaceutical industry’s use of reverse payment agreements has become increasingly divided and complex. Congress, the Department of Justice (DOJ), the Federal Trade Commission (FTC), and numerous circuit courts have approached this issue and applied varied tests in analyzing the occurrence of reverse payments. When the Third Circuit threw its hat in with its decision in *In re K-Dur*, it provided yet another determination on the antitrust implications of reverse payments.<sup>3</sup> The holding in *In re K-Dur* created a significant divide among the circuit courts in considering what

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1. Jon Leibowitz, Comm’r of the Fed. Trade Comm’n, *Prepared Statement of the Federal Trade Commission Before the Special Committee on Aging of the United States Senate on Barriers to Generic Entry*, in 6 HEALTH CARE & ANTITRUST L. APPENDIX E142 (2013).

2. *See id.* (citing the necessity of addressing escalating drug expenditures as a reason behind Congress’s passage of the Hatch–Waxman Amendments).

3. *In re K-Dur*, 686 F.3d 197, 202 (3d Cir. 2012), *vacated sub nom.* Merck & Co., Inc. v. Louisiana Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013), and *Upsher-Smith Laboratories, Inc. v. Louisiana Wholesale Drug Co., Inc.*, 133 S. Ct. 2849 (2013). In *In re K-Dur*, Merck & Co., Inc. (Merck), Upsher-Smith Laboratories, Inc. (Upsher), and Louisiana Wholesale Drug Co., Inc., were named as parties to the litigation. Following the decision by the Third Circuit, Merck, as well as Upsher, filed a petition for writ of certiorari with the United States Supreme Court, which the Supreme Court granted. After issuing its opinion in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), the Supreme Court vacated the *In re K-Dur* decision and remanded the cases back to the Third Circuit, in light of its *Actavis* decision. The fact that the *In re K-Dur* decision was vacated does not affect my analysis of the decision, nor my conclusions in this Comment. In this Comment, the *In re K-Dur* decision is reviewed in the context of its importance in creating a circuit split in analyzing reverse payment agreements, which is not affected by the Supreme Court’s decision.

analysis is appropriate for reverse payments.<sup>4</sup> As such, in order to align the competing tests and provide the pharmaceutical industry with a more stable analysis, the U.S. Supreme Court was urged to consider the legality of reverse payments because of the issue's "exceptional importance to the national economy" and the well-defined circuit split.<sup>5</sup> The Supreme Court finally granted certiorari on this issue and ultimately considered whether reverse payment agreements are per se lawful or whether these agreements are presumptively anticompetitive and unlawful.<sup>6</sup>

In Part I of this Comment, I provide a brief introduction to the pharmaceutical industry, paying particular attention to the development of the Hatch–Waxman Act and its regulatory impact on the industry. Additionally, I provide an introduction to reverse payment agreements and their impact on the pharmaceutical industry. In Part II, I examine the development of the circuit split and explain how different circuits have analyzed reverse payment agreements. Then, in Part III, I briefly describe Congress's failed attempts at resolving this issue legislatively and discuss why further attempts are likely to fail as well. In Part IV, I explain why the circuit split and the failure of Congress to successfully legislate this issue ripened it for Supreme Court review, and I outline the Court's decision in *FTC v. Actavis*. In Part V, I discuss previous Supreme Court decisions relating to similar disputes and explain how they might have informed the Court's ruling. Finally, in Parts VI and VII, I present and justify what I believe is the most desirable test for "reverse payment" agreements, arguing that the Supreme Court should have adopted a "quick look" approach.

## I. BACKGROUND

### A. *Landscape of the Pharmaceutical Industry*

In the past decade, much attention has been given to the development of innovative, and oftentimes exorbitantly expensive, prescription drugs. While pharmaceutical innovations have benefited Americans and facilitated the treatment of some medical conditions in a more effective manner, the cost of pharmaceuticals has garnered some criticism. Prescription drug spending in

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4. Petition for Writ of Certiorari submitted by Merck & Co., Inc. at 17, *Merck & Co., Inc. v. Louisiana Wholesale Drug Co., Inc.*, 686 F.3d 197 (3d. Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013), *and sub nom.* *Upsher-Smith Laboratories, Inc. v. Louisiana Wholesale Drug Co., Inc.*, 133 S. Ct. 2849 (2013) (No. 12-245) [hereinafter Merck Petition for Writ of Certiorari].

5. Petition for Writ of Certiorari submitted by The Fed. Trade Comm'n at 10, *Fed. Trade Comm'n v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298 (11th Cir. 2012), *rev'd sub nom.* *Fed. Trade Comm'n v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416) [hereinafter FTC Petition for Writ of Certiorari].

6. *Fed. Trade Comm'n v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298 (11th Cir. 2012), *rev'd sub nom.* *Fed. Trade Comm'n v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

2010 totaled approximately \$260 billion—about ten percent of the nation’s total healthcare spending.<sup>7</sup> Significantly, the rate of increase for commonly used prescription drugs is higher than the rate of increase in the medical Consumer Price Index (CPI), averaging 6.6 percent compared to 3.8 percent from 2006–2010, respectively.<sup>8</sup> Additionally, although prescription drug costs make up only ten percent of health care spending, it receives considerable attention because expenditures have grown 114 percent from 2000 until 2010, with no end in sight.<sup>9</sup> The increase in prescription drug spending is attributable primarily to brand name drugs, as brand name drug spending increased at an average annual rate of 8.3 percent from 2006–2010, compared to generic drug spending, which decreased 2.6 percent over the same time period.<sup>10</sup> Prescription drug prices and the mechanisms that sustain them have garnered scrutiny in recent years because of the considerable amount of healthcare spending apportioned to the industry.

The stakeholders in the pharmaceutical industry are heavily dependent on patent protection. As an industry, billions are spent each year on research and development for new drugs, most of which will not develop into viable products.<sup>11</sup> The industry relies on patent protection for the drugs that ultimately are deemed effective in order to secure profits, recoup their initial investment, and funnel some of those profits toward research and development of new drugs.<sup>12</sup> In fact, as patent protections expire for such blockbuster drugs as Pfizer’s Lipitor, it is suggested that consumers will initially benefit as lower cost generics enter the market, but that they should also be wary because they may suffer over the long-term if these brand name manufacturers cut back on research and development because of a loss in profits.<sup>13</sup> Brand name drug manufacturers argue that patent protection is essential for the viability of the

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7. HENRY J. KAISER FAM. FOUND., HEALTH CARE COSTS: A PRIMER: KEY INFORMATION ON HEALTH CARE COSTS AND THEIR IMPACT 10 (May 2012), [http://www.kff.org/insurance/upload/7670\\_02.pdf](http://www.kff.org/insurance/upload/7670_02.pdf).

8. U. S. GOV’T ACCOUNTABILITY OFFICE, GAO-11-306R, PRESCRIPTION DRUGS: TRENDS IN USUAL AND CUSTOMARY PRICES FOR COMMONLY USED DRUGS 3 (2011). Significantly, the dramatic inflation of prescription drug prices is most concerning when compared to the consumer price index for all items. In 2012, the Consumer Price Index for all items less food and energy rose 1.9 percent, compared to the Consumer Price Index for medical care, which rose 3.2 percent. *News Release, Consumer Price Index—December 2012*, BUREAU OF LAB. STAT., U.S. DEP’T OF LAB. 3 (Jan. 16, 2012), [http://www.bls.gov/news.release/archives/cpi\\_01162013.pdf](http://www.bls.gov/news.release/archives/cpi_01162013.pdf).

9. HENRY J. KAISER FAM. FOUND., *supra* note 7, at 1.

10. U. S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 8, at 4.

11. Yuki Onoe, “Pay-For-Delay” Settlements in Pharmaceutical Litigation: Drawing a Fine Line Between Patent Zone and Antitrust Zone, 9 J. MARSHALL REV. INTELL. PROP. L. 528, 531 (2009).

12. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1562–63 (2006).

13. Duff Wilson, *Patent Woes Threatening Drug Firms*, N.Y. TIMES, Mar. 7, 2011, at A1.

pharmaceutical industry because, once a drug's formula is understood, it is fairly easy and cheap for others to manufacture it without incurring the expensive initial research and development costs.<sup>14</sup> Proponents of pharmaceutical patent protection argue that it is necessary in order to incentivize pharmaceutical companies to spend millions on research for the development of new and innovative drugs.<sup>15</sup>

Although patents are necessary to protect pharmaceutical innovations, these patents should not unduly prohibit competition or be free from antitrust scrutiny. Many characteristics of the pharmaceutical industry make it ripe for collusion and other anti-competitive tactics that require antitrust regulation.<sup>16</sup> First, pharmaceuticals developed by the industry often have a low elasticity of demand, meaning that increases in price will not greatly affect consumer demand for the product.<sup>17</sup> Because pharmaceuticals often mean the difference between pain and relief or life and death for consumers, they are unlikely to stop purchasing drugs based on an artificially high price.<sup>18</sup> Studies have indicated that the price elasticity of demand for pharmaceuticals may range from -0.05 to -0.08.<sup>19</sup> As a result, pharmaceutical manufacturers are able to charge prices that are above competitive levels.<sup>20</sup> Second, consumers are typically unaware of the actual cost of their drugs.<sup>21</sup> Most consumers have insurance companies that act as third-party payors and shield them from the full impact of their drug cost.<sup>22</sup> Thus, consumers may continue purchasing

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14. Hemphill, *supra* note 12, at 1563–65.

15. Pamela J. Clements, *The Hatch–Waxman Act and the Conflict Between Antitrust Law & Patent Law*, 48 IDEA 381, 383 (2008) (explaining that “[p]atents grant potential monopolies to innovators in an effort to encourage innovation by allowing them to charge higher prices to recoup money spent on research and development.”).

16. Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 11 (2004).

17. *Id.*

18. Joshua P. Davis & Steig Olson, *Efforts to Delay Competition From Generic Drugs: Litigation Along a Seismic Fault Between Antitrust and Intellectual Property Law*, 39 U.S.F. L. REV. 1, 1 (2004); Hovenkamp, *supra* note 16, at 11.

19. JEANNE S. RINGEL ET AL., NAT'L DEF. RES. INST., *THE ELASTICITY OF DEMAND FOR HEALTH CARE: A REVIEW OF THE LITERATURE AND ITS APPLICATION TO THE MILITARY HEALTH SYSTEM* 35 (2002). If a product is perfectly price inelastic, its price elasticity will be zero. In contrast, a product that is perfectly price elastic will be one. Thus, the closer a product's price elasticity is to zero, the less elasticity in price the product has. Compare the price elasticity of pharmaceuticals to the price elasticity of soda, which is approximately 0.80. This indicates that consumers are much more likely to change their spending habits if the price of soda increased than if the price of a pharmaceutical increased. Tatiana Andreyeva et al., *The Impact of Food Prices on Consumption: A Systematic Review of Research on the Price Elasticity of Demand for Food*, 100 AM. J. PUB. HEALTH 216, 217–18 (2010).

20. Hovenkamp, *supra* note 16, at 11.

21. *Id.*

22. *Id.*

drugs even when they are priced above their competitive level. Finally, although there are many different drugs available for a wide array of ailments, usually there are a very limited number of drugs available to treat a specific ailment.<sup>23</sup> Typically, a physician may only deem two or three drugs as viable options for a specific patient.<sup>24</sup> Thus, collusion within these small groupings of drugs is not only possible but also highly likely, as cartels with small numbers are always more threatening than cartels with large numbers.<sup>25</sup> Courts and antitrust regulators need to take these industry factors into consideration when analyzing agreements among and between pharmaceutical companies. Although innovation needs to be rewarded, collusion among manufacturers and other anticompetitive behavior should be prevented so as to maintain competitive pricing levels.

In analyzing the activities of pharmaceutical manufacturers, it is imperative to take into consideration the landscape of the industry. Regulations aimed at increasing competition and reducing anticompetitive behavior need to be tailored in such a manner so that they do not affect the patent rights of pharmaceutical innovators in an unfair or unduly way.

#### B. *Hatch–Waxman Act and Reverse Payments*

Pharmaceutical companies spend enormous sums in order to bring a new, viable product to market. As such, they fund a broad range of patents, casting their net wide to protect potentially viable products from competitors.<sup>26</sup> These pharmaceutical companies then have a possibility of a twenty-year exclusive patent on their brand name drug.<sup>27</sup> During this exclusivity period, the brand name pharmaceutical company can reap great, monopoly-level profits on the sale of the patented drug.<sup>28</sup> The patent protection for the pharmaceutical companies is intended to reward them for their time spent on research and development.<sup>29</sup> Yet, although these pharmaceutical manufacturers have a patent on certain brand name drugs, it does not protect the patent for life, nor does it protect the patent from being challenged by generic drug manufacturers.

The Hatch–Waxman Act encourages generic drug manufacturers to challenge the patents held by brand name drug manufacturers by certifying that

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23. *Id.*

24. *Id.*

25. Hovenkamp, *supra* note 16, at 11.

26. Onoe, *supra* note 11, at 531.

27. WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL30756, PATENT LAW AND ITS APPLICATION TO THE PHARMACEUTICAL INDUSTRY: AN EXAMINATION OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 (“THE HATCH–WAXMAN ACT”) 2 (2005).

28. Clements, *supra* note 15, at 383.

29. Hemphill, *supra* note 12, at 1562–65.

either the patent is invalid or will not be infringed by the manufacture, use, or sale of a new drug that the generic is planning on manufacturing.<sup>30</sup> These generic drug manufacturers must file an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA) in order to begin manufacturing and marketing of the new, generic version of the drug.<sup>31</sup> An ANDA allows the generic drug manufacturer to rely on the costly safety and efficacy studies done by the brand name manufacturer to assert that the active ingredients of the drug are safe and effective.<sup>32</sup> Furthermore, the generic manufacturer who submits the first ANDA receives an exclusive 180-day period to manufacture and sell the generic drug before the FDA will approve any subsequent ANDA applications.<sup>33</sup> The exclusive 180-day period is triggered when either the first ANDA applicant begins commercially marketing its generic drug or when there is a court decision ruling that the patent is either invalid or not infringed.<sup>34</sup> The 180-day exclusivity period is considered a “bounty worth hundreds of millions of dollars” and provides generic drug companies an estimated sixty percent to eighty percent of their potential profits for a product.<sup>35</sup> Once an ANDA is filed, the patent-holder of the drug has forty-five days to respond and file a patent infringement action against the generic drug manufacturer applicant.<sup>36</sup> If the patent-holder files suit, a thirty-month stay goes into effect.<sup>37</sup> During this time, the FDA cannot approve the generic drug unless, during this time, a court hearing the patent infringement case finds that the patent is either invalid or not infringed.<sup>38</sup>

After an ANDA is filed and challenged by a brand name drug manufacturer, the manufacturer of the patented drug may, as an alternative to patent litigation, pay an agreed-upon sum to the generic challenger.<sup>39</sup> Such agreements are deemed reverse payments or “pay-for-delay” settlements. These agreements typically stipulate that the brand name manufacturer will pay the generic manufacturer a large sum of money and, in return, the generic manufacturer will forgo entry into the generic market for the drug at issue.<sup>40</sup> The effect of these agreements is to remove early competition in the market for

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30. 21 U.S.C. § 355(b)(2)(A)(iv) (2012).

31. *Id.* § 355(j).

32. *See id.*

33. *Id.* § 355(j)(5)(B)(iv).

34. *Id.*

35. Michael R. Herman, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1797 (2011).

36. 21 U.S.C. § 355(c)(3)(C) (2012).

37. *Id.* § 355(j)(5)(B)(iii).

38. *Id.*

39. Hemphill, *supra* note 12, at 1568.

40. *Id.* at 1568–70.

the brand name drug and deny consumers the benefit of receiving a lower price.<sup>41</sup> In a recent report issued by the FTC, the agency found that reverse payment agreements are prevalent in the pharmaceutical industry, citing the occurrence of sixty-six such agreements from 2004–2009.<sup>42</sup> Additionally, the report indicated that such agreements delay entry of a generic competitor to the market for an average of seventeen months.<sup>43</sup> The FTC has acknowledged it will aggressively litigate against and condemn reverse payment agreements, estimating that these agreements will cost consumers an estimated thirty-five billion dollars over the next ten years.<sup>44</sup>

The anti-competitive effects of reverse payments were given much attention by Congress, regulatory agencies, and circuit courts. However, these entities struggled to agree on an appropriate test to apply to such behavior.<sup>45</sup> The continuing litigation of reverse payments in the last decade, coupled with the increasing division of the circuit courts in deciding these cases, prompted the Supreme Court to recently review a reverse payment agreement.<sup>46</sup>

## II. CIRCUIT COURT DECISIONS

In analyzing whether a reverse payment agreement is valid and legal, circuit courts tended to favor either antitrust and its regard for competition, or patent law and its regard for innovation. Antitrust law and patent law often have conflicting aims. The ultimate goal of the Sherman Act is to stimulate competition and innovation by prohibiting “[e]very contract, combination . . . or conspiracy, in restraint of trade” and “monopoliz[ation], or attempt[s] to monopolize, or combin[at]ions or conspir[acies] . . . to monopolize.”<sup>47</sup> Antitrust’s aims are to discourage collusion and increase competition. The ultimate aim of antitrust law is to protect competition, not competitors.<sup>48</sup> In contrast, the ultimate goal of patent law is to stimulate innovation.<sup>49</sup> In order to achieve its aims, patent law grants an innovator “the right to exclude others from making, using, offering for sale, or selling the invention.”<sup>50</sup> Throughout the last decade, the circuit courts were divided on what test to apply to

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41. *Id.*

42. FED. TRADE COMM’N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 4 (2010).

43. *Id.*

44. *Id.* at 6.

45. *See infra* Parts II–III.

46. Fed. Trade Comm’n v. Watson Pharmaceuticals, Inc., 677 F.3d 1298 (11th Cir. 2012), *rev’d sub nom.* Fed. Trade Comm’n v. Actavis, Inc., 133 S. Ct. 2223 (2013).

47. 15 U.S.C. § 1–2 (2012).

48. Brown Shoe Co. v. United States, 370 U.S. 294, 320 (1962).

49. *In re* Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187, 201–02 (2d Cir. 2006), *abrogated by* Fed. Trade Comm’n v. Actavis, Inc., 133 S. Ct. 2223 (2013).

50. *Id.*



instances of reverse payments. As such, the circuit courts generally applied either principles of antitrust (per se, rule of reason, or quick look analysis) or a “scope of the patent” test, initially articulated by the Eleventh Circuit.<sup>51</sup> In a more recent circuit court decision analyzing reverse payments, the Third Circuit explicitly rejected the “scope of the patent” test in favor of a “quick look rule of reason,” which created a clear division among the circuit courts, and made the issue ripe for Supreme Court review.<sup>52</sup>

A. *The Scope of the Patent Test*

*Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, decided by the Eleventh Circuit in 2003, considered a patent holder’s antitrust liability for making a reverse payment.<sup>53</sup> Notably, the Eleventh Circuit limited a patent holder’s antitrust liability by the terms of the patent.<sup>54</sup> The court determined that “[t]he precise terms of the grant[ed statutory rights] define the limits of a patentee’s monopoly and the area in which the patentee is freed from competition of price, service, quality or otherwise.”<sup>55</sup> As such, the Eleventh Circuit conceptualized, and applied, what is now known as the “scope of the patent test.” The scope of the patent test gives much deference to the brand name pharmaceutical manufacturer and its patent validity. Specifically, the scope of the patent test holds that “[w]hatever damage is done to competition by settlement is done pursuant to the monopoly extended to the patent holder . . . unless the terms of the settlement enlarge the scope of that monopoly.”<sup>56</sup> Thus, so long as the agreement between the brand name manufacturer and the generic manufacturer lies within the “scope of the patent” held by the brand name manufacturer, any anticompetitive conduct is protected pursuant to its lawful monopoly.<sup>57</sup> Importantly, courts applying the scope of the patent test do not concern themselves with evaluating the validity of the patent; rather, they merely discern whether the generic manufacturer is attempting to bring a product to market that is within the scope of the brand name manufacturer’s current patent.<sup>58</sup> Using this reasoning, it is assumed that the generic product is within the scope of the brand name manufacturer’s patent and that any

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51. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003).

52. *In re K-Dur*, 686 F.3d 197, 218 (3d Cir. 2012), *vacated sub nom. Merck & Co., Inc. v. Louisiana Wholesale Drug Co., Inc.*, 133 S. Ct. 2849 (2013), *and Upsher-Smith Laboratories, Inc. v. Louisiana Wholesale Drug Co., Inc.*, 133 S. Ct. 2849 (2013).

53. *Valley Drug*, 344 F.3d at 1294–97, 1309.

54. *Id.* at 1312.

55. *Id.*

56. *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 212–13 (2d Cir. 2006), *abrogated by Fed. Trade Comm’n v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

57. *See id.* at 213.

58. Michael A. Carrier, *Why the “Scope of the Patent” Test Cannot Solve the Drug Patent Settlement Problem*, 16 STAN. TECH. L. REV. 1, 6 (2012).

anticompetitive conduct arising pursuant to a reverse payment is valid and within the legal rights of the patent holder.<sup>59</sup> Thus, courts that invoke the scope of the patent test do not attempt to analyze any of the antitrust implications of reverse payments. Rather, these courts support the notion that “a patent is an exception to the general rule against monopolies and to the right to access to a free and open market.”<sup>60</sup>

In *In re Tamoxifen*, the Second Circuit considered an agreement between the brand name manufacturer of Tamoxifen and a generic competitor, Barr.<sup>61</sup> The agreement was spurred by Barr’s filing of an ANDA with the FDA requesting its approval for Barr to market a generic version of Tamoxifen.<sup>62</sup> The brand name manufacturer agreed to pay Barr \$21 million and, in exchange, Barr agreed that it would not market a generic version of the drug until the patent expired.<sup>63</sup> Although the court acknowledged that the agreement “almost certainly” resulted in less price competition, which would result in higher consumer prices for the drug, it refused to find the agreement invalid.<sup>64</sup> The court determined that the agreement was within the bounds of the patent that the brand name manufacturer had validly obtained.<sup>65</sup> Specifically, the court noted that the agreement did not extend the patent monopoly by restraining the introduction or marketing of unrelated, non-fringing products.<sup>66</sup> Thus, so long as the agreement restricted the generic manufacturer from marketing only Tamoxifen, the agreement was within the scope of the patent. Additionally, the court remarked that other generic manufacturers could challenge the patent.<sup>67</sup> Yet, the court failed to acknowledge that any other generic manufacturer who challenged the patent would be restricted from beginning its marketing or sale of the product until Barr began marketing its version of the product for 180 days. Thus, although a generic manufacturer may have filed to challenge the patent, this would be unlikely considering they could not begin selling the product.

The Second Circuit defended its utilization of the deferential scope of the patent test based on its analysis of the Hatch–Waxman Act and its “incentivizing” of reverse payment agreements.<sup>68</sup> The court explained that the structure of the Hatch–Waxman Act redistributes the relative risk of engaging in patent infringement litigation as it gave generic drug manufacturer

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59. *Id.*

60. Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945).

61. *In re Tamoxifen*, 466 F.3d at 190.

62. *Id.* at 193.

63. *Id.* at 193–94.

64. *Id.* at 216.

65. *Id.* at 213.

66. *In re Tamoxifen*, 466 F. 3d at 213.

67. *Id.* at 214.

68. *Id.* at 206.

challengers “considerable leverage” in patent suits.<sup>69</sup> Thus, the court appears to have adopted the scope of the patent test to redress some wrong it identified in the Hatch–Waxman Act. The court stated that there is “no sound basis” for “condemning” reverse payments when the purpose is merely to reduce uncertainty surrounding the patent’s validity and scope by way of the Hatch–Waxman Act.<sup>70</sup>

Following the lead of the Eleventh and Second Circuits, the Federal Circuit also expressly adopted the scope of the patent test. In *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, the Federal Circuit explained that, when all anticompetitive effects of a settlement agreement are within the lawful exclusionary power of the patent, it is protected from challenge.<sup>71</sup> Additionally, the court agreed with the Eleventh and Second Circuits, that, in the absence of fraud or sham, “the court need not consider the validity of the patent in the antitrust analysis.”<sup>72</sup> In holding that the reverse payment at issue was lawful and not subject to scrutiny, the court held that there is no basis for “restricting the right of a patentee to choose its preferred means of enforcement.”<sup>73</sup>

Ultimately, the courts that adopted the scope of the patent test favored the protections granted to patent-holders by the patent law even in the face of decreased competition and higher consumer prices.<sup>74</sup> The scope of the patent test gives patent holders broad discretion to engage in anticompetitive agreements so long as the agreements do not exceed the scope of the patent. As such, application of the scope of the patent test is outcome-determinative, with antitrust defendants typically, and uniformly, prevailing as a matter of law in these circuits.<sup>75</sup>

### B. Application of Antitrust Analysis

In contrast to the “scope of the patent test” applied by the Eleventh, Second, and Federal Circuits, some circuits have determined that “reverse payment” agreements must be subject to heightened antitrust scrutiny. Antitrust scrutiny lies on a continuum, with per se analysis being the strictest, and rule of reason the most lenient. The per se rule is reserved for conduct that is clearly anticompetitive.<sup>76</sup> In order to establish a per se case, a plaintiff must show that the conduct engaged in is of the type that is almost always

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69. *Id.* at 206–07.

70. *Id.* at 207.

71. *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323, 1336 (Fed. Cir. 2008), *abrogated by* Fed. Trade Comm’n v. Actavis, Inc., 133 S. Ct. 2223 (2013).

72. *Id.*

73. *Id.* at 1337.

74. *In re Tamoxifen*, 466 F.3d at 216.

75. FTC Petition for Writ of Certiorari, *supra* note 5, at 13–14.

76. Hovenkamp, *supra* note 16, at 19.

anticompetitive.<sup>77</sup> Courts have deemed per se treatment appropriate “[o]nce experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it.”<sup>78</sup> Thus, courts have reserved per se analysis for such blatant anticompetitive behavior as horizontal price fixing, horizontal market allocation, concerted refusals to deal, and most tying arrangements.<sup>79</sup> A showing of per se anticompetitive activities thus applies a “conclusive presumption” of illegality to certain types of agreements.<sup>80</sup> In these instances, the court need not consider any claimed procompetitive justifications or look at the restraint’s actual effect on competition.<sup>81</sup>

In contrast, rule of reason analysis affords a court significant flexibility in balancing the possible anticompetitive harms with any procompetitive benefits. Rule of reason requires a more searching analysis of the behavior engaged in. Courts will weigh the anticompetitive concerns with possible procompetitive benefits.<sup>82</sup> Specifically, the court must determine whether the questioned behavior “imposes an unreasonable restraint on competition.”<sup>83</sup> Courts will often consider a variety of factors, including information about the relevant business and industry, the condition of the industry before and after the alleged restraint was imposed, and the restraint’s history, nature, and effect.<sup>84</sup> Only after the plaintiff can show that the conduct produced an anticompetitive effect within the market does the burden shift to the defendant to show that the challenged conduct has a procompetitive purpose.<sup>85</sup>

The D.C. Circuit, as well as the Sixth Circuit, considered similar facts in determining that reverse payment agreements were subject to antitrust scrutiny and, as a result, were anticompetitive. In *In re Cardizem*, the Sixth Circuit considered an agreement between HMR, the entity that manufactured and marketed the brand name prescription drug Cardizem CD, and a generic competitor, Andrx.<sup>86</sup> The agreement was spurred by Andrx’s filing of an ANDA seeking approval to manufacture and sell a generic form of Cardizem

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77. *Id.* at 19–20.

78. *Arizona v. Maricopa Cnty. Med. Soc’y*, 457 U.S. 332, 344 (1982).

79. Hovenkamp, *supra* note 16, at 20.

80. *Maricopa*, 457 U.S. at 344.

81. *Nat’l Collegiate Athletic Ass’n v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 100 (1984).

82. Hovenkamp, *supra* note 16, at 20.

83. *In re K-Dur*, 686 F.3d 197, 209 (3d Cir. 2012), *vacated sub nom.* *Merck & Co., Inc. v. Louisiana Wholesale Drug Co., Inc.*, 133 S. Ct. 2849 (2013), *and* *Upsher-Smith Laboratories, Inc. v. Louisiana Wholesale Drug Co., Inc.*, 133 S. Ct. 2849 (2013).

84. *Id.*

85. *Id.*

86. *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 902 (6th Cir. 2003).

CD.<sup>87</sup> The agreement provided that Andrx would not market a generic version of Cardizem CD in the United States and, in return, HMR would pay Andrx forty million dollars per year beginning on the date Andrx received final approval from the FDA to market its generic drug.<sup>88</sup> Additionally, the agreement stipulated that HMR would pay Andrx \$100 million per year once it was determined that the patent was not infringed.<sup>89</sup> The court determined that the agreement constituted horizontal market allocation.<sup>90</sup> Specifically, the court found that the agreement intended to eliminate competition in the market for Cardizem throughout the entire United States,<sup>91</sup> as the agreement guaranteed HMR's exclusive access to the market for Cardizem CD throughout the United States until one of the end dates it stipulated in its agreement.<sup>92</sup> Furthermore, the court determined that the agreement had the effect of delaying any other generic competitors from entering the market.<sup>93</sup> Andrx had filed the first ANDA, and it was therefore guaranteed a 180-day exclusivity period that would not begin to run until it began to market its generic version of Cardizem CD.<sup>94</sup> The agreement effectively delayed the running of the 180-day exclusivity period for Andrx because it had agreed not to relinquish it or transfer it.<sup>95</sup> The court ultimately concluded that this was, on its face, horizontal market allocation. As such, it was deemed subject to per se antitrust analysis and found to be anticompetitive regardless of any pro-competitive effect it may ultimately provide. The court, however, failed to address whether per se analysis would apply to a settlement that did not require the relinquishing of the 180-day exclusivity period or a prohibition on marketing drugs that were not at issue in the underlying patent litigation.<sup>96</sup>

Similarly, the D.C. Circuit held in *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International* that an agreement between a brand name drug manufacturer and a generic competitor was of the type that "antitrust laws were designed to prevent" and indicated that the conduct was unlawful and subject to antitrust scrutiny.<sup>97</sup> The court in *Andrx Pharmaceuticals* was concerned with the agreement's effect on potential generic competitors.<sup>98</sup> The court found that the delay in competition would harm consumers by slowing

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87. *Id.*

88. *Id.*

89. *Id.* at 903.

90. *Id.* at 908.

91. *In re Cardizem*, 332 F.3d at 908.

92. *Id.* at 907.

93. *Id.*

94. *Id.*

95. *Id.*

96. Merck Petition for Writ of Certiorari, *supra* note 4, at 16.

97. *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 815 (D.C. Cir. 2001).

98. *Id.* at 813.

the introduction of lower-priced products into the market.<sup>99</sup> However, like the Sixth Circuit, the D.C. Circuit failed to address the validity of the agreement as a whole, focusing instead on the 180-day exclusivity provision.<sup>100</sup>

### C. *The Third Circuit Decision*

In its decision *In re K-Dur*, the Third Circuit explicitly rejected the “scope of the patent” test and held that reverse payments are subject to “quick look rule of reason” analysis.<sup>101</sup> In taking this position, the Third Circuit was the first federal appellate court to clearly indicate the presence of a circuit split on this issue.<sup>102</sup> In *In re K-Dur*, Upsher, a generic manufacturer, filed an ANDA to manufacture a generic version of *K-Dur*.<sup>103</sup> To prevent Upsher from engaging in the manufacture and marketing of the generic drug, Schering, the brand name manufacturer, agreed to pay Upsher sixty million dollars over three years.<sup>104</sup> The court regarded this agreement as suspect and prima facie evidence of an unreasonable restraint of trade.<sup>105</sup> Thus, applying the court’s reasoning, a “reverse payment” agreement is considered presumptively anticompetitive. The court noted that, under a “quick look rule of reason” analysis, once a plaintiff establishes a prima facie case, the defendant may rebut the presumption of illegality by showing that either the payment was for a purpose other than delayed entry or offered some pro-competitive benefit.<sup>106</sup> While the FTC indicated that the Third Circuit’s position “reflects the appropriate balance between the competing interests implicated by such agreements,”<sup>107</sup> others have remarked that this analysis would have a “chilling effect” on patent settlements between brand name and generic drug manufacturers.<sup>108</sup> Thus, the Third Circuit’s *In re K-Dur* decision clearly created a circuit split, and ripened the issue for Supreme Court review.

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99. *Id.*

100. *Id.*

101. *In re K-Dur*, 686 F.3d 197, 218 (3d Cir. 2012), *vacated sub nom.* Merck & Co., Inc. v. Louisiana Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013), *and* Upsher-Smith Laboratories, Inc. v. Louisiana Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013).

102. Merck Petition for Writ of Certiorari, *supra* note 4.

103. *In re K-Dur*, 686 F.3d at 205.

104. *Id.* at 205–06.

105. *Id.* at 218.

106. *Id.*

107. FTC Petition for Writ of Certiorari, *supra* note 5, at 21.

108. Merck Petition for Writ of Certiorari, *supra* note 4, at 21.

## III. CONGRESS'S CONTINUED FAILURE TO RESOLVE THE DISPUTE

A. *Past Congressional Efforts*

As the circuit split described above developed, members of Congress attempted to formulate a solution to reverse payment settlements that they deemed to be anticompetitive. Congress first attempted to pass legislation to deal with this issue during the 109th Congress in 2006, in the form of Senate Bill 3582, also known as the Preserve Access to Affordable Generics Act (Preserve Access Bill).<sup>109</sup> The Preserve Access Bill prohibited brand name drug companies from delaying the entry of generic drugs by providing the FTC with the ability to block a reverse payment settlement.<sup>110</sup> Specifically, it provided that agreements settling patent infringement claims between a brand name and generic drug manufacturer were per se illegal.<sup>111</sup> After being referred to the Committee on Commerce, Science, and Transportation, no further action was taken.<sup>112</sup> The Preserve Access Bill was again introduced in 2007, although no significant action was taken, and again in 2009.<sup>113</sup>

In 2009, the Preserve Access Bill was amended and, as a result, gained additional traction. The most significant amendment to the 2009 Preserve Access Bill was that agreements between brand name and generic drug manufacturers settling patent infringement claims were only presumed to be illegal, rather than deemed illegal per se.<sup>114</sup> Specifically, the 2009 Bill was amended to read that a reverse payment agreement, while presumptively illegal, may be deemed legal if the parties to the reverse payment agreement demonstrate by “clear and convincing evidence that the procompetitive benefits . . . outweigh the anticompetitive effects of the agreement.”<sup>115</sup>

In adopting this position, Congress was pushing for a resolution to reverse payments that was contrary to the holdings of the Second, Eleventh, and Federal Circuits.<sup>116</sup> As such, it was not necessarily a popular stance amongst all members of Congress.<sup>117</sup> Critics of the 2009 Preserve Access Bill found that the bill’s presumption of illegality actually “amount[ed] to a de facto per se ban on covered settlements—and would entail all of the evils attendant to a per

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109. S. COMM ON THE JUDICIARY, PRESERVE ACCESS TO AFFORDABLE GENERICS ACT, S. REP. NO. 111-123, at 6 (2d Sess. 2010).

110. *Id.* at 4.

111. *Id.*

112. *Id.* at 6.

113. *Id.* at 6–7.

114. S. REP. NO. 111-123, at 7.

115. *Id.* at 8 (quoting §3(a)).

116. 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, 597 (2012).

117. S. REP. NO. 111-123, at 18.

se ban.”<sup>118</sup> These critics determined that the “presumption of illegality” was in fact a per se ban for two reasons. First, for the legal presumption to work, they believed that the parties must be “afforded a forum in which they can quickly and fairly test whether they have overcome the presumption.”<sup>119</sup> However, they claimed that no such forum was available under the 2009 Preserve Access Bill because the issue would not be analyzed until the FTC brought an action, which could be years after the settlement was entered into.<sup>120</sup> Second, and most importantly, the 2009 Preserve Access Bill provided that parties to reverse settlements could only rebut a presumption of illegality by the presentation of “clear and convincing evidence that the procompetitive benefits of the agreement outweigh [its] anticompetitive effects.”<sup>121</sup> The critics explained that this is a “heavy burden,” inappropriate for commercial litigation, which “tilts the scales in a lawsuit sharply in the government’s favor.”<sup>122</sup> Generally, critics espoused that implementing what effectively was a per se presumption against all agreement where the ANDA filer receives “anything of value” overcompensates for the problem and hinders agreements that may have procompetitive effects.<sup>123</sup> Notably, these critics indicated they would support the creation of a legal presumption against drug patent settlements, but only if these issues were resolved and the presumption did not wholly favor the government.<sup>124</sup>

#### B. Recent Congressional Efforts—Different Year, Same Results

Recently, in 2013, a new version of the Preserve Access Bill was again introduced into the Senate.<sup>125</sup> Glaringly, what is deemed a new version of the Preserve Access Bill is, for all intents and purposes, almost the exact same, line by line, as the 2011 version that was already considered by Congress and failed.<sup>126</sup> Commentators have noted that because the 2013 bill is effectively the same as the 2011 version, “it does not address any of the ‘substantive concerns’ voiced by some Republicans and Democrats.”<sup>127</sup> These commentators suppose that because the substance of the 2013 Preserve Access

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118. *Id.*

119. *Id.*

120. *Id.*

121. S. REP. NO. 111-123, at 8.

122. *Id.* at 18.

123. Brown, *supra* note 116, at 603.

124. S. REP. NO. 111-123, at 18.

125. S. 214, 113th Cong. (1st Sess. 2013).

126. Compare S. 27, 112th Cong. (1st Sess. 2011), with S. 214, 113th Cong. (1st Sess. 2013) (showing nearly identical bills).

127. Kurt R. Karst, *Insanity? A Nearly Unchanged Preserve Access to Affordable Generics Act is Introduced in Congress*, MARTINDALE (Feb. 7, 2013), [http://www.martindale.com/litigation-law/article\\_Hyman-Phelps-McNamara-PC\\_1675802.htm](http://www.martindale.com/litigation-law/article_Hyman-Phelps-McNamara-PC_1675802.htm).



Bill has not been changed to address criticisms of the 2011 bill's legal presumption, it is unlikely that these criticisms will have changed.<sup>128</sup> Indeed, although commentators declined to speculate on exactly how the 2013 Congress would address the Preserve Access Bill, they asserted that much would be riding on the Supreme Court decision in this matter.<sup>129</sup>

#### IV. THE SUPREME COURT RULING IN *FEDERAL TRADE COMMISSION V. ACTAVIS, INC.*

After a decade of observing Congress, federal agencies, and the circuit courts struggle to analyze reverse payments and fail to provide pharmaceutical companies with a coherent, sound framework for determining what agreements may or may not be considered illegal, the Supreme Court, in 2013, granted certiorari on the issue. Although there had been speculation that legislation was the most appropriate manner in which to resolve reverse payment disputes, it appeared that any such legislation was unlikely to pass in the near future.<sup>130</sup> Additionally, the circuit courts had not been able to provide much clarity for pharmaceutical companies in the way of understanding how a reverse payment may be analyzed.<sup>131</sup> In fact, before the Supreme Court ruled on this issue, it appeared that an agreement may or may not be condemned depending on the circuit the case was brought in.<sup>132</sup> As the FTC explained, the divergence among the circuit courts was “outcome-determinative,” in that antitrust defendants in the Second, Eleventh, and Federal Circuits typically prevailed as a matter of law, while antitrust defendants in the Third, Sixth, and D.C. Circuits were ordered to further proceedings.<sup>133</sup> Thus, pharmaceutical companies were in a precarious position as they moved forward and structured agreements that could appear as though the brand name manufacturer were paying generic manufacturers to refrain from entering the market. At the urging of the FTC and various stakeholders in the pharmaceutical industry, the Supreme Court finally took up this issue and set forth a ruling in *Federal Trade Commission v. Actavis, Inc.*, on June 17, 2013, to provide courts across the country with a uniform analysis of “reverse payment” agreements.<sup>134</sup>

In its decision, the Court reviewed the Eleventh Circuit's dismissal of the Federal Trade Commission's complaint alleging that Solvay Pharmaceuticals

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128. *Id.*

129. *Id.*

130. *Id.* See also Shannon U. Han, *Pay-to-Delay Settlements: The Circuit-Splitting Headache Plaguing Big Pharma*, 15 VAND. J. ENT. & TECH. L. 913, 944–46 (2013) (discussing the need for a legislative solution and Congress's recent inability to pass such legislation).

131. See FTC Petition for Writ of Certiorari, *supra* note 5, at 10.

132. *Id.* at 10–11.

133. *Id.* at 13–14.

134. Fed. Trade Comm'n v. Actavis, Inc., 133 S. Ct. 2223 (2013), *rev'g sub nom.* Fed. Trade Comm'n v. Watson Pharm., Inc., 677 F.3d 1298 (11th Cir. 2012).

unlawfully restricted trade by paying its generic competitors to delay bringing their product to market.<sup>135</sup> The Court rejected the Eleventh Circuit's determination that patent holders have a lawful right to exclude others from the market.<sup>136</sup> The Court noted that paragraph IV litigation, used by generic competitors to challenge a patent's validity, necessarily "put[s] the patent's validity at issue."<sup>137</sup> As such, the Court found that it is "incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy."<sup>138</sup> Rather, the Court remarked that a reverse payment must be measured against both patent law policy and antitrust policy.<sup>139</sup>

In this vein, the Court held that "reverse payment" agreements must be analyzed using "rule of reason" analysis.<sup>140</sup> The Court asserted that "rule of reason" analysis is appropriate in this context because it appropriately weighs the considerations of both patent law and antitrust law.<sup>141</sup> Importantly, the Court declined to apply "quick look" antitrust analysis, which the FTC had argued was applicable.<sup>142</sup> The Court stated that "quick look" analysis is only appropriate where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets."<sup>143</sup> The Court supported its assertion by acknowledging that the likelihood of a reverse payment bringing about an anticompetitive effect depends upon its size, scale in relation to anticipated future litigation costs, and independence from other services.<sup>144</sup> In other words, the Court determined that there were circumstances in which a reverse payment settlement would not be considered anticompetitive. As such, the Court ultimately concluded that a more comprehensive look at the agreement's possible anticompetitive effects is required.<sup>145</sup> Glaringly, the Court failed to articulate how a lower court might structure antitrust litigation; it merely stated that courts should avoid applying antitrust theories that are too abbreviated and those that are too searching.<sup>146</sup>

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135. *Actavis*, 133 S. Ct. at 2227.

136. *Id.* at 2230.

137. *Id.* at 2231.

138. *Id.*

139. *Id.*

140. *Actavis*, 133 S. Ct. at 2236–37.

141. *Id.* at 2237.

142. *Id.*

143. *Id.* (internal quotation marks omitted).

144. *Id.*

145. *Actavis*, 133 S. Ct. at 2237.

146. *Id.* at 2238.

V. THE SUPREME COURT RULING IN CONTEXT: HOW THE COURT'S PREVIOUS DECISIONS FORETOLD ITS DECISION IN *FTC v. ACTAVIS*

Not surprisingly, the Court's ruling was an obvious attempt to placate competing views, and achieve a balance between antitrust concerns and patent protection concerns. The Supreme Court's previous rulings considering similar disputes foreshadowed its decision. In its recent rulings on patent disputes with antitrust implications, the Supreme Court tended to focus on the need to strike a proper balance between protecting a patent holder's monopoly rights and protecting competition—an issue that is fundamental to the reverse payment disputes. The proper balance, however, has oftentimes been difficult to determine—even for Supreme Court Justices. Justice Breyer's discussion during oral argument in *Bilski v. Kappos*<sup>147</sup> sheds light on how the Court would regard the competing interests at issue in “reverse payment” agreements. Justice Breyer stated:

There are actually four things in the patent law which everyone accepts. There are two that are plus and two that are minus. And the two that are plus is by giving people a monopoly, you get them to produce more [and] you get them to disclose.

The two minuses are they charge a higher price, so people use the product less; and moreover, the act of getting permissions and having to get permission can really slow things down and destroy advance[s]. So there's a balance.

. . . And if you ask me as a person how to make that balance in respect to information, if I am honest, I have to tell you: I don't know.<sup>148</sup>

Justice Breyer's discussion highlights the Supreme Court's concern at the intersection of antitrust and patent law—how much protection should be provided to a patent holder? Although this has been a difficult question to answer, a review of recent Supreme Court decisions in this area foretold that the Court might ultimately favor the protection of competition over the protection of patent holders in the case of “reverse payments.”

In recent years, the Supreme Court significantly increased the amount of patent law cases it addressed.<sup>149</sup> The Court's rulings, however, were generally not favorable to patent holders. Between 2006 and 2008, patent holders lost five consecutive patent cases reviewed by the Court.<sup>150</sup> Additionally, the

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147. *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

148. Transcript of Oral Argument at 19–20, *Bilski v. Kappos*, 130 S. Ct. 3218 (2010) (No. 08-964).

149. Peter O. Huang, *Recent Supreme Court Patent Decisions: The Trend to Limit the Power of Patent Holders*, 10 J. APP. PRAC. & PROCESS 393, 393 (2009).

150. *Id.* at 395. See also *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007); *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007); *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008).

opinions in these cases were not sharply divided; three of the five decisions were unanimous, with the others supporting only a lone dissenter.<sup>151</sup> Although the issues and holdings varied in these cases and none are particularly salient to the issue here, it is important to note this trend of disfavoring patent holders and their exclusive patents.

In a recent opinion that preceded *Actavis*, the Court had again reaffirmed traditional limits on patentability. In its opinion in *Bilski v. Kappos*, decided in 2010, the Court articulated a holding that reflected a conservative view of patent law, rejecting a patent application for a method of instructing how to hedge risk under its “precedents on the unpatentability of abstract ideas.”<sup>152</sup> Although the holding is fairly basic, the Court’s decision invoked two important concepts. First, it appeared that the Court was concerned about inflating the patent law beyond its original intent.<sup>153</sup> The Court’s position articulated a deflation, rather than inflation, of patent rights. Thus, it lent itself to the conclusion that the Supreme Court was concerned about providing patent holders too much monopoly power.<sup>154</sup> Second, the Court’s holding favored the arguments of those who were calling for a more certain application of the patent tests.<sup>155</sup> The principles illustrated by the Court’s holding indicated that it favored a clear and structured analysis of reverse payment agreements to provide more certainty to pharmaceutical companies attempting to protect their patents.<sup>156</sup> Additionally, it indicated that the Court was not necessarily inclined to protect a brand name manufacturer’s patent monopoly from any and all competitors.<sup>157</sup> It is unlikely that the principles articulated in *Bilski* will necessarily be furthered by the Supreme Court’s holding in *Actavis*.

## VI. SHORTCOMINGS OF THE SUPREME COURT’S APPROACH

In adopting a “rule of reason” approach to reverse payment agreements, the Supreme Court rejected the notion that such agreements are either presumptively legal or presumptively illegal. Rather, the Court held that such agreements may bring about anticompetitive effects, depending on their size, scale, and other factors.<sup>158</sup> As such, the Court proffered a view that has been criticized by many as being costly, time consuming, litigious, and arduous.

The Court squarely addressed its “rule of reason” critics, specifically stating that the FTC need not “litigate the patent’s validity, empirically

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151. Huang, *supra* note 149, at 398.

152. *Bilski*, 130 S. Ct. at 3231.

153. *Id.*

154. *See id.* at 3231; Huang, *supra* note 149, at 394.

155. *See Bilski*, 130 S. Ct. at 3231; Huang, *supra* note 149, at 397.

156. *See Bilski*, 130 S. Ct. at 3229; Huang, *supra* note 149, at 393.

157. *See Bilski*, 130 S. Ct. at 3228; Huang, *supra* note 149, at 393.

158. Fed. Trade Comm’n v. *Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013).

demonstrate the virtues or vices of the patent system, present every possible supporting fact or refute every possible pro-defense theory.”<sup>159</sup> Thus, the Supreme Court apparently lessened the burden placed on the FTC. However, it provided little direction on what the FTC, or any reverse payment challenger, would need to prove in order to make its case under “rule of reason” analysis. Additionally, it failed to provide a benchmark for what agreements may be reasonable and what agreements may be unreasonable. As such, the Court merely passed that buck to lower courts, stating that they could structure antitrust litigation to avoid making inquiries that were either too abbreviated to permit proper analysis or too unduly, considering every possible fact or theory irrespective of its relevance and applicability.<sup>160</sup> This approach does not provide a clear understanding of how courts will view such arrangements and what litigation may be anticipated to challenge and defend them. Thus, it fails to address the issues plaguing the pharmaceutical industry. Additionally, by stripping away the depth of inquiry required for “rule of reason” analysis, the Court’s approach appears confused and unclear—almost a reverse “quick look” approach in some respects.

#### VII. WHY THE “QUICK LOOK” IS THE MOST APPROPRIATE TEST

The “rule of reason” approach proffered by the Supreme Court does little to address the concerns of stakeholders in the industry and fails to provide clear guidance on what types of settlement agreements are acceptable. As such, the “quick look” approach articulated by the Third Circuit in *In re K-Dur* is superior to the “rule of reason” test, because it appropriately weighs the competing interests without placing an undue burden on either party to a dispute.<sup>161</sup> Generally, courts apply “quick look” to market restraints that appear to be facially anticompetitive, but occur in markets or contexts that are new or not fit for traditional antitrust analysis.<sup>162</sup> In the context of reverse payments, a quick look approach allows a plaintiff, most likely the Federal Trade Commission, to establish a prima facie case by showing that there was a reverse payment agreement made between a brand name drug manufacturer and a generic drug manufacturer that effectively delayed entrance of a generic drug onto the market.<sup>163</sup> The reverse payment in these instances represents conduct that is facially anticompetitive because it ultimately reduces output

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159. *Id.*

160. *Id.* at 2238.

161. *In re K-Dur*, 686 F.3d 197, 209 (3d Cir. 2012), *vacated sub nom.* Merck & Co., Inc. v. Louisiana Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013), and Upsher-Smith Laboratories, Inc. v. Louisiana Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013).

162. Max R. Shulman, *The Quick Look Rule of Reason: Retreat From Binary Antitrust Analysis*, 2 SEDONA CONF. J. 89, 89 (2001).

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

and keeps prices artificially high.<sup>164</sup> Once a prima facie case is established, the “quick look” approach shifts the burden to the defendant drug manufacturer to show that either the agreement was for a purpose other than to delay entry or that it fosters a procompetitive benefit that outweighs the anticompetitive conduct.<sup>165</sup> This shift provides the defendant drug manufacturer the opportunity to explain that the agreement was reached for a purpose other than to stifle competition or that it had procompetitive effects.<sup>166</sup> As such, the burden-shifting scheme of the “quick look” analysis reflects the proper balance between competition and patent protection that the Supreme Court appeared to be favoring in their recent decisions, such as *Bilski*, but is currently lacking in the other, alternative tests.

A. *Inadequacy of Per Se, Scope of the Patent, and Rule of Reason Tests*

Analysis under the per se test is too favorable to generic challengers, providing no deference to the lawful patent held by a brand name pharmaceutical company.<sup>167</sup> Although per se analysis provides for cost-effective litigation, it is too one-sided in the case of “reverse payments.”<sup>168</sup> Additionally, it would likely stem innovation as pharmaceutical companies may be less inclined to spend enormous sums on research and development if they cannot sustain monopoly-level profits for a reasonable period of time.<sup>169</sup> The per se test does not take the need to foster innovation into consideration. As such, it gives no deference to the purpose of patent laws and patent protections. Finally, courts are wary of relying on per se rules of illegality if there is “no justification other than the enhancement of predictability and the reduction of judicial investigation” for it may be viewed as abdicating their responsibility to tackle difficult economic problems.<sup>170</sup> In this instance, any per se rule would unduly burden the pharmaceutical industry and possibly reduce innovation and competition in the industry; thus, it is an inadequate response to reverse payment agreements. As such, the Supreme Court properly disregarded this approach for “reverse payment” agreements.

Application of the scope of the patent test is similarly one-sided and unfair to generic manufacturers and consumers. The framework for the scope of the

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164. Hovenkamp, *supra* note 16, at 11, 19–20.

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

166. *See* Hemphill, *supra* note 12, at 1573–77. The most common justification a defendant drug manufacturer is likely to make is that the agreement was reached in order to prevent an encroachment on a valid drug patent. The manufacturer would need to show that the drug manufacturer decided to enter into such an agreement because it felt that it would be cheaper than litigating over the patent’s validity.

167. *See* Hovenkamp, *supra* note 16, at 19–20.

168. *Id.* at 22–27.

169. Hemphill, *supra* note 12, at 1562–63.

170. *United States v. Topco Assoc., Inc.*, 405 U.S. 596, 622 (1972) (Burger, C.J., dissenting).

patent test first articulated in *In re Cardizem* is no longer recognizable as it has subtly shifted throughout the years.<sup>171</sup> In *In re Cardizem*, the Court condemned the reverse payment agreement as per se illegal in as far as it covered conduct lying outside of the valid patent.<sup>172</sup> The logic of the *Cardizem* test, however, was warped by the Eleventh Circuit to mean that any agreement dealing with a product within a patent is per se valid by way of the scope of the patent.<sup>173</sup> Thus, the current scope of the patent test gives brand name pharmaceutical companies' unbridled discretion to engage in anticompetitive behavior that may result in higher prices, so long as the agreement only deals with products mentioned in the brand name manufacturer's patent.<sup>174</sup> Courts that adopt the scope of the patent test prioritize patent law at the expense of unwisely diminishing antitrust law. The Supreme Court specifically rejected this approach in *Actavis*, finding that patent and antitrust policies are both relevant in determining the "scope of the patent monopoly."<sup>175</sup>

Finally, the rule of the reason test attempts to properly weigh anticompetitive concerns with concerns about bolstering innovation. However, this test is too arduous and demanding. Application of full-blown rule of reason analysis wastes not only the Court's time and resources, but also the time and resources of the litigants.<sup>176</sup> Additionally, the activity at issue is, on its face, anticompetitive.<sup>177</sup> Thus, it seems unnecessary to do a searching market analysis to determine whether this practice stifles competition.

#### B. "Quick Look" Strikes the Proper Balance

"Quick look" analysis is not unique to the issue of reverse payment agreements. It has been used in recent years in the context of collegiate and professional sports, as well as professional associations, to abbreviate the rule of reason inquiry and simplify its corresponding market analysis.<sup>178</sup> As such, it greatly diminishes the time that it takes to litigate a dispute.<sup>179</sup> However, "quick look" is more searching than a per se rule of illegality and provides pharmaceutical companies the opportunity to justify their reverse payment agreements.<sup>180</sup> In the cases where "quick look" developed, rule of reason analysis was unnecessary because the conduct at issue was plainly

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171. Carrier, *supra* note 58, at 5.

172. *Id.*

173. *Id.*

174. *See id.*

175. Fed. Trade Comm'n v. Actavis, Inc., 133 S. Ct. 2223, 2231 (2013).

176. Hovenkamp, *supra* note 16, at 20.

177. *Id.* at 24.

178. Shulman, *supra* note 162, at 89.

179. *See id.* at 89–90.

180. *Id.*

anticompetitive.<sup>181</sup> Yet, the conduct at issue in these cases was not so anticompetitive as to call for per se treatment.<sup>182</sup> “Quick look” analysis provides the appropriate inquiry, for it allows courts “interpreting . . . antitrust laws [to] make reasonable decisions under limited information.”<sup>183</sup> Similar to previous cases in which a version of “quick look” was used, reverse payment agreements involve obvious anticompetitive conduct, but may arguably offer some other purpose or procompetitive benefit.

Much like previous instances in which courts have applied “quick look” analysis, reverse payment agreements represent a practice that is new, unusual, and unfamiliar to traditional antitrust analysis. Reverse payment agreements pose an unusual difficulty for courts because of the unique characteristics present in the pharmaceutical industry. As explained above,<sup>184</sup> brand name pharmaceutical drug manufacturers depend on patents in order to recoup research and development costs.<sup>185</sup> The process of research and development results in innovation and ultimately more competition, as new drugs are developed and brought to market.<sup>186</sup> Therefore, proponents of reverse payment agreements argue that they are necessary to protect patents and, without this patent protection, there would be little incentive to innovate in the pharmaceutical industry. The Supreme Court has dealt with a similar issue in *National Collegiate Athletic Association v. Board of Regents*.<sup>187</sup> There, the Supreme Court considered a plan adopted by the NCAA that limited the televising of college football games.<sup>188</sup> The Court found:

While the plan constitute[d] horizontal price fixing and output limitation, restraints that ordinarily would be held “illegal per se,” it would be inappropriate to apply a per se rule . . . where it involves an industry in which horizontal restraints on competition are essential if the product is to be available at all.<sup>189</sup>

In industries such as this, courts may find that the restraints at issue actually widen consumer choice, and thus, can be viewed as procompetitive.<sup>190</sup> This analysis illustrates the Court’s understanding that although the Sherman Act prohibits restraints of trade, every contract is a restraint of trade, so the

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181. *Nat’l Collegiate Athletic Ass’n v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 109 (1984).

182. *Id.* at 100.

183. Hovenkamp, *supra* note 16, at 31.

184. *See supra* notes 11–15 and accompanying text.

185. Hemphill, *supra* note 12, at 1562–63.

186. *Id.*

187. *Nat’l Collegiate Athletic Ass’n v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 101 (1984).

188. *Id.* at 91–94.

189. *Id.* at 86.

190. *Id.* at 102.



Sherman Act must have been intended to prohibit only unreasonable restraints of trade.<sup>191</sup> It is in this vein that the Supreme Court should consider reverse payment agreements. “Quick look” analysis affords the opportunity to both the FTC and the defendant drug manufacturer to explain why or why not the reverse payment agreement unreasonably restrained trade, but without inundating courts with excessive information. Additionally, “quick look” analysis articulates what critics to the Congressional Preserve Access Bill have been espousing for the past few years.<sup>192</sup> It creates a rebuttable presumption that the reverse payment is illegal, but, unlike the 2013 Preserve Access Bill, it provides pharmaceutical companies with a more feasible way to rebut the presumption.<sup>193</sup> The following provides an outline of how a court would evaluate “reverse payment” agreements under “quick look.”

### C. Analysis Under “Quick Look”

#### 1. Alleged Anticompetitive Effects

The initial step in determining whether a reverse payment agreement is a reasonable restraint of trade pursuant to the Sherman Act is to determine if it adversely affects competition.<sup>194</sup> The FTC has clearly articulated its view on this matter. The FTC finds that reverse payment agreements support monopoly pricing of brand-name drugs by delaying the onset of generic competition.<sup>195</sup> They claim that this adversely affects consumers because once a generic drug is brought to market, it is sold, on average, for about fifteen percent of the price charged for its comparable brand-name drug.<sup>196</sup> Correspondingly, at this time, the brand-name manufacturer typically loses about ninety percent of its market share to generic competitors.<sup>197</sup> The implication of the FTC’s findings for purposes of “quick look” analysis is that a reverse payment agreement between a brand-name drug manufacturer and a generic competitor likely inhibits competition by keeping prices artificially high and reducing competition. Under “quick look” analysis, this establishes a prima facie case.<sup>198</sup> However, if a court does not find that this establishes a prima facie case, then its analysis may end without the defendant drug manufacturer

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191. *Id.* at 98.

192. S. COMM ON THE JUDICIARY, PRESERVE ACCESS TO AFFORDABLE GENERICS ACT, S. REP. NO. 111-123, at 18 (2d Sess. 2010).

193. *Id.*

194. *Law v. Nat’l Collegiate Athletic Ass’n*, 134 F.3d 1010, 1016–17 (10th Cir. 1998).

195. FTC Petition for Writ of Certiorari, *supra* note 5, at 16.

196. *Id.* app. at 5a n.2.

197. *Id.*

198. *In re K-Dur*, 686 F.3d 197, 218 (3d Cir. 2012), *vacated sub nom.* *Merck & Co., Inc. v. Louisiana Wholesale Drug Co., Inc.*, 133 S. Ct. 2849 (2013), *and* *Upsher-Smith Laboratories, Inc. v. Louisiana Wholesale Drug Co., Inc.*, 133 S. Ct. 2849 (2013).

having to justify its conduct. Assuming, *arguendo*, the FTC can establish a prima facie case and satisfy its burden of demonstrating that the agreement adversely affects competition, a court would continue its “quick look” analysis and shift the burden to the defendant drug manufacturer.

## 2. Procompetitive Benefits and Justifications for Reverse Payment Agreements

When the FTC satisfies its initial burden, “quick look” analysis shifts the burden to the defendant drug manufacturer to present the procompetitive benefits and justifications for the reverse payment agreement.<sup>199</sup> Unlike the 2013 Preserve Access Bill, a court should not require “clear and convincing” evidence of procompetitive justifications, but rather, should consider whether it is more likely than not that the procompetitive benefits outweigh the anticompetitive effects.<sup>200</sup> This is a standard that is more attuned to commercial litigation and reflects a better balance between the government’s interests and pharmaceutical companies’ interests.<sup>201</sup> Courts have discovered numerous procompetitive justifications for arrangements that might initially be determined to adversely affect competition.<sup>202</sup> The most pertinent to reverse payment agreements is the creation of new products.<sup>203</sup> Unlike cases of collegiate and professional sports, the new product at issue in reverse payment cases is not a byproduct of the restraint, but rather, a corollary of the restraint. For example, in *NCAA v. Board of Regents*, the Court found that the NCAA “enables [collegiate football] to be marketed,” by virtue of the restraints it imposes.<sup>204</sup> Thus, the Court thought its actions “widen[ed] consumer choice—not only the choices available to sports fans but also those available to athletes.”<sup>205</sup> Here, the pharmaceutical company would have to make a compelling argument that its ability to protect its patent from generic infringers ultimately “widen[s] consumer choice” by funding additional research and development for new products. The stark difference between reverse payments and the restraints in *NCAA* is the proximity reverse payment agreements have to the “new” product they are creating. In *NCAA*, the agreement directly affected the product and its marketability.<sup>206</sup> In the case of reverse payments, however, the reasoning is more attenuated. The Court would have to be

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199. *Law*, 134 F.3d at 1019.

200. S. COMM ON THE JUDICIARY, PRESERVE ACCESS TO AFFORDABLE GENERICS ACT, S. REP. NO. 111-123, at 18 (2d Sess. 2010).

201. *Id.*

202. *Law*, 134 F.3d at 1023.

203. *Id.*

204. Nat’l Collegiate Athletic Ass’n v. Bd. of Regents of Univ. of Okla., 468 U.S. 85, 102 (1984).

205. *Id.*

206. *Id.*

convinced that any monopoly-level profits would directly fund new products. Although this may be a challenging inference for a court to make, pharmaceutical companies should have the ability to justify their agreements and explain the procompetitive benefits those agreements may foster.

#### CONCLUSION

Reverse payment agreements between brand-name and generic drug manufacturers have confounded Congress and the courts for over a decade. Recently, the Supreme Court ruled that these types of agreements should be subjected to “rule of reason” antitrust analysis. However, the Supreme Court failed to provide lower courts with any direction on how to structure this analysis. Additionally, the Court appeared to limit the inquiry required for “rule of reason” analysis, indicating that proof of anticompetitive effect would vary with the circumstances. Because “rule of reason” in this context does not address the concerns of the industry and provide a clear framework for structuring and analyzing agreements, this Comment argues that “quick look” is a better approach. “Quick look” analysis reviews the claims from both sides and weighs both the anticompetitive conduct with its supposed procompetitive benefits. It does not, however, “stubbornly insist on strict and exhaustive proof.”<sup>207</sup> The Supreme Court should have adopted the “quick look” approach in order to provide pharmaceutical companies more certainty in forming their agreements and conducting their business and to protect consumers from anticompetitive conduct that will raise prices and diminish drug choices.

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207. Hovenkamp, *supra* note 16, at 31.

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