

Inevitable Imbalance:  
Why *FTC v. Actavis* Was Inadequate to Solve the  
Reverse Payment Settlement Problem and Proposing a  
New Amendment to the Hatch–Waxman Act

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The law regarding reverse payment settlements is anything but settled. Reverse payment settlements are settlements that occur during a patent infringement litigation in which a pharmaceutical patent holder pays a generic drug producer to not infringe on the pharmaceutical patent.<sup>1</sup> Despite the recent decision by the United States Supreme Court in *FTC v. Actavis, Inc.*,<sup>2</sup> there are still unanswered questions about how the “full rule of reason” analysis<sup>3</sup> will be applied to reverse payment settle-

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\* J.D. Candidate, Seattle University School of Law, 2014. I want to dedicate this Comment to my family who has a not-so-secret pact to all become authors. To Mom and Dad, I was so blessed that you taught me to enjoy learning for its own sake. To Daniel and Aaron, our conversations about books and ideas continue to inspire me and help me think about things in new ways. And to Kefi, I cannot wait to read your first novel.

1. *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1301 (11th Cir. 2012). Other names for reverse payment settlements include “pay for delay” settlements and “exclusion payments.” See, e.g., Robert A. Skitol & Kenneth M. Vorrasi, *FTC v. Actavis: Inviting a More Nimble Rule of Reason*, ANTITRUST, Fall 2013, at 29, 51; Brief Amici Curiae of 118 Law, Economics, and Business Professors et al. in Support of Petitioners at 2, *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012) (No. 12-416) [hereinafter Amici Curiae Brief in Support of FTC], available at [http://www.americanbar.org/content/dam/aba/publications/supreme\\_court\\_preview/briefs-v2/12-416\\_pet\\_amcu\\_118-prof-et-al.authcheckdam.pdf](http://www.americanbar.org/content/dam/aba/publications/supreme_court_preview/briefs-v2/12-416_pet_amcu_118-prof-et-al.authcheckdam.pdf).

2. 133 S. Ct. 2223 (2013). This case was decided on June 17, 2013. *Id.*

3. The full rule of reason is the basic way to analyze antitrust suits. 58 C.J.S. *Monopolies* § 57 (2006). Explaining the rule of reason analysis further is beyond the scope of this Comment; however, a basic statement of the full rule of reason can be summarized as follows:

Under the Sherman Anti-Trust Act . . . the rule of reason . . . requires the fact finder to decide whether under all the circumstances the restrictive practice imposes an unreasonable restraint on competition. It requires a weighing of the relevant circumstances to decide whether the practice constitutes such an unreasonable restraint. The inquiry mandated by the rule is whether the agreement is one that promotes competition or whether it suppresses competition. A restraint is unreasonable if it has an adverse impact on competition and cannot be justified as a pro-competitive measure. A combination is not legal merely because some persons other than the members of the combination have profited by its operation.

ments.<sup>4</sup> Now, another legislative amendment regarding reverse payment settlements has been proposed in Congress,<sup>5</sup> and the *Actavis* decision fails to address both public and private concerns focused on by legal scholarship.<sup>6</sup>

To contextualize the issues underlying reverse payment settlements, *FTC v. Watson Pharmaceuticals, Inc.*<sup>7</sup>—the Eleventh Circuit decision reversed in *Actavis*—provides an instructive example. In *Watson*, a pharmaceutical patent holder sued two generic drug companies for infringing on its patent rights.<sup>8</sup> Responsively, the two generic drug producers challenged the validity<sup>9</sup> of the pharmaceutical patent.<sup>10</sup> Before the court entered judgment regarding the patent's validity, the patent holder and generic drug producers settled.<sup>11</sup> Thus, the parties avoided establishing a final judgment about the validity of the underlying patent.<sup>12</sup> By the terms of the settlement, the generic drug producers agreed to dismiss the suit, not produce the patented product until a certain date, and promote the patented product for the patent holder.<sup>13</sup> In exchange, the patent holder agreed to pay the generic producers between \$72 million and \$360 million over the course of six years.<sup>14</sup> The patent holder did this to protect its own profits, which were estimated at \$125 million per year (\$750 million over six years).<sup>15</sup> The size of the settlement payments by the patent holder has been criticized as anticompetitive because the patent holder is spending such a large portion of its yearly profits to avoid a

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*Id.* (internal citations omitted).

4. The holding was that “the Eleventh Circuit should have allowed the FTC’s lawsuit to proceed,” not that reverse payment settlements are per se valid or invalid. *Actavis*, 133 S. Ct. at 2227.

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

6. *See, e.g.*, Amici Curiae Brief in Support of FTC, *supra* note 1, at 1–2 (suggesting that they are seeking the right balance between innovation and competition when rejecting the scope of the patent test).

7. *Watson*, 677 F.3d 1298.

8. *Id.* at 1305.

9. Whether a patent is valid depends on many factors, which are not the focus of this Comment. *See generally* 35 U.S.C. §§ 101–103 (2012) (discussing respectively patentable subject matter, novelty, and non-obviousness requirements). Suffice it to say that if a patent dispute is litigated to a final judgment and the patent is found to be invalid, then the patent holder could no longer enforce the patent exclusivity.

10. *Watson*, 677 F.3d at 1305.

11. *Id.*

12. *Id.*

13. *Id.*

14. *Id.*

15. *Id.*

judicial decision regarding its patent's validity, which would potentially make the market more competitive.<sup>16</sup>

These settlements have been called antitrust violations by the Federal Trade Commission (FTC)<sup>17</sup> and legal scholarship;<sup>18</sup> meanwhile, the majority of the federal courts found the settlements near per se legal because the settlement was within the rights of the patent holder to negotiate prior to *Actavis*.<sup>19</sup> Reverse settlement payments occur in part because of the complex regulatory framework of the Drug Price Competition and Patent Restoration Act (the Hatch–Waxman Act or the Act).<sup>20</sup>

This Comment argues that despite the outcome in *Actavis*, the structure of the Hatch–Waxman Act will create repeated conflicts between antitrust law and patent law because it attempts to use private actors as proxies for the interests of externalities. Thus, the only long-term solution is to pass a legislative amendment and have the government assume responsibility for litigating the validity of weak patents in the reverse-payment settlement context.<sup>21</sup>

To support this thesis, Part I sets out the background of the unique regulatory scheme created in the Hatch–Waxman Act while also locating the stakeholders in a real world context. Part II discusses how pharmaceutical patent holders have responded to litigation stemming from the Act and the range of agreements that have arisen between patent holders and generic producers. Part III discusses the judicial history of the various reverse-payment settlement cases and explains why the Supreme Court's decision in *Actavis* does not resolve the anticompetitive potential of reverse-payment settlement. Part IV discusses previously proposed reverse-payment settlement legislation and why such legislation would

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16. See Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 TEX. L. REV. 283, 288 (2012) (stating that “even though patent holders get a presumption of patent validity, they lose 48%–73% of patent cases . . .”).

17. Richard A. Feinstein, *Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs*, FED. TRADE COMMISSION (June 3, 2009), [http://www.ftc.gov/sites/default/files/documents/public\\_statements/prepared-statement-federal-trade-commission-anticompetitive-pay-delay-settlements-pharmaceutical/p859910payfordelay.pdf](http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-anticompetitive-pay-delay-settlements-pharmaceutical/p859910payfordelay.pdf) (prepared statement before the Subcommittee on Courts and Competition Policy of the U.S. House of Representatives Committee on the Judiciary).

18. See, e.g., Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 491–92 (2007).

19. *Compare Watson*, 677 F.3d at 1308–09 (supporting the scope of the patent test which presumes patent validity), with *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 215 (3d Cir. 2012) (only circuit court case finding that antitrust violations occurred despite the reverse-payment settlement being within the exclusionary scope of the patent).

20. Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch–Waxman Act), 35 U.S.C. § 156 (codified in part in Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (2012)).

21. See *infra* Part V.B for specific language of the proposed amendment.

fail to solve the underlying issue of patent validity. Part V proposes (A) that the incentive structure of the Hatch–Waxman Act is inherently flawed; and (B) that a government body, potentially the FTC, should be given standing by Congress to directly litigate weak pharmaceutical patents after a reverse-payment settlement occurs. Part VI offers a brief conclusion.

## I. THE HATCH–WAXMAN ACT: THEORETICAL FORMATION AND UNANTICIPATED RESULTS

The Hatch–Waxman Act is, in part, an attempt to incentivize the discovery and invalidation of weak drug patents<sup>22</sup>—those issued patents that may not be valid.<sup>23</sup> This Part discusses both the formation as well as the technical mechanisms of the Act.

### A. Formation of the Hatch–Waxman Act

When it comes to pharmaceutical patent validity, consumers, the government, and generic producers have a naturally aligned interest in invalidation. When a generic drug enters the market because a drug is no longer patented, the drug price drops by approximately 80%.<sup>24</sup> The consumer has an interest in low-cost drugs.<sup>25</sup> The government, while trying to balance the public and private interests,<sup>26</sup> has favored the public good

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22. Although the Act is generally characterized as a balance between the interests of generic producers and patent holders, the former legislative scheme was highly favorable to the patent holders, and the pharmaceutical patent holder lobby group objected to the patent act changes throughout the Act's drafting and enactment. Compare H.R. REP. NO. 98-857(II) (1984) (the statement by the patent holder lobby group: "a group of drug companies opposed to the legislation in its current form articulated its reservations. They argue that the bill will hamper innovation and research, create unnecessary litigation and unconstitutionally take property from patent owners.") (original capitalization omitted), with *id.* ("Congressman Waxman engaged in extensive negotiations with interested parties. The primary participants were the generic pharmaceutical industry associations (GPIA) and the pharmaceutical manufacturers association (PMA).") (original capitalization omitted).

23. See Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents*, 98 AM. ECON. REV. 1347 (2008). As Farrell and Shapiro theorize, "The bigger issue [than blatantly invalid patents], . . . concerns patents that are not *clearly* invalid, but are weak—they may well be invalid, but nobody knows for sure without conclusive litigation." *Id.* (emphasis in original).

24. "Generally hundreds of millions and, not infrequently, billions of dollars are at stake for the brand company. If the generic company successfully defends against the infringement claim, competition occurs. The generic will quickly take as much as 80 percent of the brand's prescriptions in a matter of months." Michael Kades, *Whistling Past the Graveyard: The Problem with the Per Se Legality Treatment of Pay-for-Delay Settlements*, 5 COMPETITION POL'Y INT'L 143, 147 (2009).

25. One commentator noted, "On four blockbusters alone, consumers are expected to save over 16 billion dollars because of generic entry prior to patent expiration." *Id.*

26. See *Competition in the Pharmaceutical Marketplace: Antitrust Implication of Patent Settlements: Hearing Before the S. Comm. on the Judiciary*, 107th Cong. 10 (2001) [hereinafter *Senate Hearing*].

over the interests of the private parties in the pharmaceutical industry.<sup>27</sup> Also, the government itself is a customer of pharmaceutical drugs, which suggests that it has an interest in patent invalidity.<sup>28</sup> Finally, the generic drug producer's interests are financial. The generic drug companies make money by selling off-patent drugs to as many consumers as possible.<sup>29</sup> By doing this, the generic companies make their profits by avoiding research and development costs—which exponentially increase overhead costs—by selling formerly patented products.<sup>30</sup>

When drafting the Hatch–Waxman Act, Congress seemingly assumed that the consumer, governmental, and generic interests would remain aligned. So Congress had a stroke of brilliance: incentivize generic companies to challenge pharmaceutical patent validity,<sup>31</sup> and the consumers will vicariously benefit.<sup>32</sup> Thus, the theoretical negotiation of the Hatch–Waxman Act seemed to leave all of the stakeholders happy. All of the stakeholders, that is, except the pharmaceutical patent holders.<sup>33</sup>

Pharmaceutical patent holders were in a bind. For years the pharmaceutical companies had borne the almost prohibitively high costs of pioneer drug development.<sup>34</sup> The discovery of a new drug was costly and

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[The Act was] intended to balance two important public policy goals. First, drug manufacturers need meaningful market protection incentives to encourage the development of valuable new drugs. Second, once the statutory patent protection and market exclusivity for these new drugs has expired, the public benefits from the rapid availability of lower-price generic versions of the innovator drug.

*Id.* (statement of Sen. Hatch, Chairman, S. Comm. on the Judiciary).

27. See H.R. REP. NO. 98-857(II) (1984), *supra* note 22 and accompanying text.

28. In one FTC report on the costs of reverse payment settlements, the FTC points out that “[t]he federal government is particularly affected: Federal dollars accounted for an estimated 31 percent of the \$235 billion spent on prescription drugs in 2008, and that share is expected to rise to 40 percent by 2018.” Feinstein, *supra* note 17, at 3.

29. The generic producers avoid huge costs by not innovating new drugs. In one year, pharmaceutical patent holders spent a combined \$50 billion investment in life science research. *Senate Hearing, supra* note 26, at 10.

30. *Id.*

31. See generally 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2013) (companies could file drug applications based on the invalidity of a currently patented drug).

32. By 2009, after the enactment of the Hatch–Waxman Act, consumers had saved an estimated \$734 billion, at an estimated rate of \$121 billion a year, which outstripped the original estimate of \$1 billion in savings expected over the course of ten years. S. RES. 287, 111th Cong. (1st Sess. 2009) (resolution introduced in the Senate).

33. “A group of drug companies opposed to the legislation in its current form articulated its reservations. They argue that the bill will hamper innovation and research, create unnecessary litigation and unconstitutionally take property from patent owners.” H.R. REP. NO. 98-857(II) (1984) (original capitalization omitted); see also *Senate Hearing, supra* note 26, at 10 (statement of Sen. Hatch, Chairman, S. Comm. on the Judiciary).

34. Estimates of the cost of research and development for each new drug compound to the value on the day of market approval was roughly \$194 million in 1990; other estimates have been as

risky, but the patent holders continued to fund research because even one pharmaceutical patent was incredibly lucrative.<sup>35</sup> The lucrative nature of the business model was directly linked to the patent monopoly.<sup>36</sup> These monopolies were so lucrative that the pharmaceutical companies put in incredible lobbying efforts to extend and take advantage of the former legislative scheme.<sup>37</sup> Prior to the Hatch–Waxman Act, even after drug patents naturally expired, generic companies would not produce the off-patent drugs because the companies had to first duplicate all of the FDA tests.<sup>38</sup> The Hatch–Waxman Act changed all of that.

Part of the negotiation of the Act included allowing the generic producers to piggy-back on the FDA testing done by the pharmaceutical patent holders.<sup>39</sup> The Act also incentivizes generic companies to file applications to produce drugs because it gives the first generic company a short exclusivity period.<sup>40</sup> Thus, Congress made filing easier and cheaper, and enticed generic companies to take advantage of the deal. And it succeeded; the Act revolutionized the landscape of the pharmaceutical drug market.<sup>41</sup>

### *B. The Technical Mechanisms of the Act*

The most pro-generic change under the Hatch–Waxman Act was the creation of the abbreviated new drug application (ANDA).<sup>42</sup> Part of the incredible expense of patenting a new drug is the required new drug application (NDA).<sup>43</sup> In NDAs, the pharmaceutical patent holders have to show that the drugs meet the requirements of the FDA through drug test-

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high as \$802 million per drug. Shannon U. Han, Note, *Pay-to-Delay Settlements: The Circuit-Splitting Headache Plaguing Big Pharma*, 15 VAND. J. ENT. & TECH. L. 913, 919 n. 34 (2013).

35. Typical profit margins range from 90%–95%. Barbara Martinez & Jacob Goldstein, *Big Pharma Faces Grim Prognosis: Industry Fails to Find New Drugs to Replace Wonders Like Lipitor*, WALL ST. J., Dec. 6, 2007, at A1.

36. See Jessie Cheng, Note, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1476 n. 28 (2008).

37. See H.R. REP. NO. 98-857(II) (1984) (“A group of drug companies opposed to the legislation in its current form articulated its reservations. They argue that the bill will hamper innovation and research, create unnecessary litigation and unconstitutionally take property from patent owners.”) (original capitalization omitted).

38. The Hatch–Waxman Act was negotiated because of “[t]he inability of generics to obtain approval for these post-1962 drugs without enormous expenditures of money for duplicative tests.” *Id.* (original capitalization omitted).

39. Holman, *supra* note 18, at 510–11.

40. 21 U.S.C. § 355(j)(5)(B)(iv) (2013).

41. See generally S. Res. 287, 111th Cong. (1st Sess. 2009) (describing over \$700 billion in savings by American consumers since the enactment of the Hatch–Waxman Act, which far exceeded the expected savings of \$1 billion annually).

42. See 21 U.S.C. § 355(j) (2012).

43. See *id.* § 355(b).

ing.<sup>44</sup> Under the old system, the generic drug producers who wanted to sell an off-patent drug would have to duplicate these tests.<sup>45</sup> After the passage of the Act, generic producers are able to file an ANDA instead.<sup>46</sup> The ANDA simply verifies that the drug to be produced is a bioequivalent<sup>47</sup> to the previously approved drug.<sup>48</sup> This abbreviated process significantly reduces costs for the generic producers and significantly raises competition for the original patent holder.<sup>49</sup>

When filing an ANDA, the generic drug producer must cite one of four bases laid out in the Act for its application.<sup>50</sup> Paragraph IV—the fourth basis—justifies the application on the fact that the patented drug is “invalid or will not be infringed.”<sup>51</sup> All reverse-payment settlement litigation is an outgrowth of Paragraph IV litigation.<sup>52</sup> Paragraph IV requires that the applicant generic drug producers include information about the bioequivalence of their ANDA to a patent holder’s NDA.<sup>53</sup> The bioequivalence requirement leads to controversy because if the generic company successfully applies under Paragraph IV, the patent will become invalid earlier than the date of patent expiration, and the exclusivity rights of the patent holder will end.<sup>54</sup>

Several administrative steps take place before the patent is declared invalid. First, the patent holder is sent notice of the ANDA<sup>55</sup> because, technically, an ANDA is an act of patent infringement.<sup>56</sup> Then the patent holder has forty-five days to initiate an infringement suit against the ge-

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44. *See id.*

45. H.R. REP. No. 98-857(II) (1984).

46. 21 U.S.C. § 355(j) (2012).

47. Bio-equivalent essentially means that there is not a change to the chemical structure of the drug’s active ingredient. *See* Holman, *supra* note 18, at 491–92.

48. 21 U.S.C. § 355(j)(2)(A).

49. Cheng, *supra* note 36, at 1476 n. 30.

50. The four bases are “(I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV).

51. *Id.*

52. “Nearly all reverse payment settlements stem from patent-infringement litigation where the generic entrant certifies that the patent is either invalid or not infringed. This is known as paragraph IV certification.” Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 64 (2010); *see also* Holman, *supra* note 18, at 494 (2007); 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).

53. 21 U.S.C. § 355(j)(2)(A)(vii).

54. *See id.* § 355(j)(5)(B)(iv).

55. *Id.* § 355(j)(2)(B)(iii)(I).

56. 35 U.S.C. § 271(e)(2)(A) (2012).

neric producer, or it will passively concede validity.<sup>57</sup> Assuming that the patent holder initiates an infringement suit, an automatic stay is initiated, which stops the ANDA from being approved until either (a) thirty months pass; or (b) the court hearing the patent challenge finds the patent either invalid or not infringed.<sup>58</sup>

These mechanisms essentially require (1) the generic producer to constructively infringe on the patent; (2) the patent holder to file suit if it wants to retain its monopoly; and (3) the patent holder to either litigate, settle, or lose its patent monopoly. The cost of litigation is high for both parties, and the risk of patent invalidity is incredibly costly for patent holders.<sup>59</sup> The risk of infringement is similarly high for generic producers, and the value of the patent monopoly far outmatches the cost of settling the suit.<sup>60</sup>

In fact, pharmaceutical patents are so valuable that patent holders can settle Paragraph IV litigation for more than the generic producers would make by actually producing the drug.<sup>61</sup> Some studies even indicate that patent holders could pay settlements to over five generic challengers and still make a profit.<sup>62</sup> Furthermore, this level of profit would make it economically illogical and bad business for a patent holder to litigate even strong patents.<sup>63</sup>

On the other hand, if the generic producer's Paragraph IV ANDA was approved by the FDA—either through litigation or because the pa-

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57. 21 U.S.C. § 355(j)(2)(B)(iii).

58. *Id.* § 355(j)(2)(B)(iii)(I).

59. *See supra* note 24.

60. "Left to their own devices, both the incumbent monopolist and the entrant are better off if they eliminate competition and share the monopoly profits." Kades, *supra* note 24, at 148.

61. *Id.*

62. *Id.*

Assume that the brand product has yearly sales of one billion dollars. A single generic, assuming it takes 80 percent of the brand's sales and prices at a 30 percent discount, will earn roughly 560 million dollars in revenue. In contrast, if five generics enter, they drive the price down to 33 percent of the brand price. The total generic revenue will fall to 267 million dollars. In other words, if the brand has to pay the full revenue of the generics, it would actually cost more than twice as much to buy off one generic than five generics.

*Id.*

63. *Id.* at 150.

The important point is that, whether competition is certain . . . the patent is weak . . . or the patent is strong . . . [,] the brand and the generic are better off preserving the monopoly by having the branded firm pay the generic company not to enter. . . . The strength of the patent—how likely it is to block competition—would not determine when there is competition; rather, the profits the branded firm earns by eliminating the threat of generic competition and the brand's willingness to share those profits determines when competition would occur.

*Id.*



tent holder did not challenge the application—the generic producer would get a 180-day exclusivity period during which it would be the only competitor for the patent holder.<sup>64</sup> Prior to the expiration of this exclusivity period, other generic producers' applications would not be approved, thus giving the generic producer a short monopoly where it could charge a super-competitive price.<sup>65</sup> Furthermore, the 180-day period would not be triggered until the first-to-file generic drug producer began commercial marketing.<sup>66</sup> This strategy would allow the first-to-file generic producer to prevent other generic producers from entering the market.<sup>67</sup> All the first-to-file generic company would have to do is never begin commercial marketing.<sup>68</sup> This practice, called “bottlenecking,” meant that patent holders and first-to-file generic producers negotiated bottlenecking deals to extend the patent monopoly beyond its legal scope.<sup>69</sup> Bottlenecking deals, the first form of reverse payment settlements, were subsequently found to be per se illegal under antitrust law by the courts.<sup>70</sup> Thus, eliminating the provision that allows only one generic producer to gain first-to-file exclusivity would not help invalidate weak patents.<sup>71</sup>

## II. THE RANGE OF PARAGRAPH IV REVERSE-PAYMENT SETTLEMENT AGREEMENTS

After pharmaceutical patent holders failed to lobby to keep the Hatch–Waxman Act from being enacted, they tried to figure out how to regain lost ground under the new regulatory scheme. The pharmaceutical patent holders acted in their own profit maximizing self-interest—as is expected of rational actors in a competitive economic system—to find ways to make the new law beneficial to their businesses. One solution created by the patent holders was to make reverse payment settlements

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64. 21 U.S.C. § 355(j)(5)(B)(iv) (2012).

65. *Id.* § 355(j)(5)(B)(iv).

66. *Id.* § 355(j)(5)(B)(iv).

67. Seiko F. Okada, In re K-Dur *Antitrust Litigation: Pharmaceutical Reverse Payment Settlements Go Beyond the “Scope of the Patent,”* 14 N.C. J.L. & TECH. 303, 312 (2012) (“Accordingly, a subsequent filer of an ANDA is prohibited from marketing its generic drug until after the first-filer’s exclusivity period has ended. Therefore, the settling first-filer and innovator could effectively ‘bottle-neck’ the market by preventing any other generic from selling the drug.”).

68. *Id.*

69. Erica N. Andersen, Note, *Schering the Market: Analyzing the Debate over Reverse-Payment Settlements in the Wake of the Medicare Modernization Act of 2003 and In re Tamoxifen Citrate Litigation*, 93 IOWA L. REV. 1015, 1022 (2008).

70. See *infra* Part II.A.

71. See Kades, *supra* note 24, at 159 (“eliminating the 180-day exclusivity outright may have the unintended consequence of making pay-for-delay settlements more common”).

when generic companies challenged their patent validity.<sup>72</sup> These Paragraph IV litigation settlements have come under scrutiny because of their potentially anticompetitive effects.<sup>73</sup>

In Paragraph IV litigations, courts consider three potentially anti-competitive reverse payment settlements: (A) outside-the-scope patent settlements; (B) inside-the-scope patent settlements; and (C) potential sham exchanges that hide anticompetitive agreements. Both outside-the-scope settlements agreements and sham exchanges are clear violations of antitrust law.<sup>74</sup> But inside-the-scope agreements have split the circuits and caught the attention of the Supreme Court.<sup>75</sup>

### A. Outside-the-Scope Patent Settlements

Outside-the-scope patent settlement agreements were the FTC's first antitrust suits brought in response to Paragraph IV litigation.<sup>76</sup> Outside-the-scope reverse payment settlements effectively expand the patent rights beyond what a patent legally grants the patent holder.<sup>77</sup> One example of an outside-the-scope settlement is when a patent holder and a generic company agree to use the mechanisms of the Act to delay generic entry into the market in a settlement agreement *after* a court finds the patent invalid.<sup>78</sup> The patent holder and the generic producer agree that the generic would never begin commercial marketing, thus not triggering the first-to-file exclusivity period.<sup>79</sup> This agreement prevents other generic companies from entering the market and creates a potential perpetual monopoly.<sup>80</sup> This singular outside-the-scope settlement actually led to

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72. See Timothy A. Weil, Note, *Devising a Legislative Solution to the Reverse Payment Settlement Dilemma: How Congress Can Balance Competition, Innovation, and the Public Policy Favoring the Settlement of Disputes Without Litigation*, 55 ST. LOUIS L.J. 741, 759 (2011) ("[T]he complexity of reverse payment settlements has made it increasingly difficult for courts and the FTC to determine the reasonableness of reverse payments without launching a complex inquiry into the terms of the agreement and the business judgment of the settling parties.").

73. See *infra* Part III.

74. *Joblove v. Barr Labs., Inc.*, 466 F.3d 187, 203–04 (2d Cir. 2006); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001) (finding a reverse-payment settlement to be an antitrust violation because it extended patent rights beyond the exclusionary scope the patent rights granted to the patent holder); see also Elhauge & Krueger, *supra* note 16, at 286 ("[U]nless the patent was a sham or procured by fraud, reverse payment settlements were illegal only if the settlement exceeded the scope of the patent . . .").

75. See *infra* Part III.

76. Holman, *supra* note 18, at 547.

77. Jeff Thomas, Note, *Schering-Plough and In Re Tamoxifen: Lawful Reverse Payments in the Hatch-Waxman Context*, 22 BERKELEY TECH. L.J. 13, 43–44 (2007).

78. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 210 (3d Cir. 2012).

79. See *infra* Part III.

80. See *infra* Part III.

two different cases in which both courts found the settlement to be per se antitrust violations.<sup>81</sup>

In 2001, the D.C. Circuit Court of Appeals decided *Andrx Pharmaceuticals v. Biovail Corp. International*, setting the precedent for finding that an outside of the scope patent settlement constituted an anticompetitive antitrust violation.<sup>82</sup> In *Andrx*, a generic producer and a pharmaceutical patent holder agreed to a scheme that manipulated the structure of the Act to allow for delayed generic market entry.<sup>83</sup> First, the generic producer won its invalidity suit, which ended the patent holder's right to a monopoly on the drug.<sup>84</sup> Next, the patent holder agreed to pay the generic producer \$40 million a year for each year that the generic producer could produce the drug but did not do so.<sup>85</sup> This agreement was valuable to the patent holder because no other generic producer could enter the market until the first generic producer triggered and completed the first-to-file exclusivity period.<sup>86</sup> If the arrangement continued, then the (former) patent holder would have a continuing monopoly over the particular drug, despite a court finding that it had no right to the monopoly.

Because of the anticompetitive attributes of the settlement, the D.C. Circuit Court of Appeals found that it could "reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions."<sup>87</sup> Accordingly, the court rejected the validity of the post-judgment agreement between the patent holder and the first generic producer because it inappropriately extended the patent monopoly.<sup>88</sup> Furthermore, the court pointed out that "[a]lthough it is true that the first to file an ANDA is permitted to delay marketing as long as it likes, the statutory scheme does not envision the first applicant's agreeing with the patentholder [sic] of the pioneer drug to delay the start of the 180-day exclusivity period."<sup>89</sup>

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81. *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 908 (D.C. Cir. 2001).

82. *See generally id.*; *see also In re K-Dur*, 686 F.3d at 210 (discussing the importance of the precedent to reverse payment settlements).

83. James F. Ponsoldt & W. Hennen Ehrenclou, *The Antitrust Legality of Pharmaceutical Patent Litigation Settlements*, 2006 ILL. J.L. TECH. & POL'Y 37, 43.

84. *In re K-Dur*, 686 F.3d at 210 (discussing *Andrx*, 686 F.3d 197).

85. *See id.* Under the agreement, "[the former patent holder] would pay [the generic drug producer] \$40 million per year beginning on the date that [the generic drug producer] received final approval from the FDA and ending on the date that [the generic drug producer] either began selling [the generic drug] or was adjudged liable for patent infringement in the pending suit;" *see also* Michael A. Carrier, *Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem*, 16 STAN. TECH. L. REV. 1 (2012).

86. *Andrx Pharm.*, 256 F.3d at 809–10.

87. *Id.* at 811.

88. *Id.* at 809.

89. *Id.*

Thus, in *Andrx*, the requirements of antitrust prevention and the intention of the Act align to prevent extending the monopoly of an invalid patent.<sup>90</sup>

The next case, *In re Cardizem CD Antitrust Litigation*, established the original per se antitrust violation test as applied to Hatch–Waxman agreements.<sup>91</sup> The *Cardizem* case concerned the same settlement as *Andrx*.<sup>92</sup> The Sixth Circuit Court of Appeals also disfavored these types of agreements because of their anticompetitive effects.<sup>93</sup> The Sixth Circuit described the agreement as “a naked, horizontal restraint of trade that is per se illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers.”<sup>94</sup> The court concluded that this attempt to eliminate competition was a “classic example of per se illegal restraint of trade.”<sup>95</sup> This presumption acted as a strong deterrent of similar future agreements outside of the scope of the patent term.

Yet despite the strong language of the court regarding outside of the scope agreements, the court actually discussed how to legally take advantage of the patent monopolies. The court stated that “it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent’s effectiveness in inhibiting competitors . . . .”<sup>96</sup> This comparison is credited with inspiring the legal inside the scope reverse-payments settlements.<sup>97</sup>

### *B. Inside-the-Scope Patent Settlements*

Reverse payment settlements where the terms of the settlement do not go beyond the powers granted to the patent holder by the patent are within or inside the scope of the patent. These reverse payment settlements are where the legal battle rages. The scope of the patent case history is documented in Part III, but it is important to first understand why the issue is not easily resolved.

Reverse payment settlements exist between a rock and a hard place: antitrust and patent law. At what point does exercising patent monopoly rights cross over into violating antitrust laws?<sup>98</sup> “It is the tension between

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90. *Id.* at 799.

91. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 210–11 (3d Cir. 2012).

92. *Id.* at 210.

93. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

94. *Id.* at 911.

95. *Id.* at 908.

96. *Id.*

97. Carrier, *supra* note 85, at 1.

98. See generally THE SUPREME COURT AND PATENTS AND MONOPOLIES (Philip B. Kurland et al. eds., 1975).

restraints on anti-competitive [sic] behavior imposed by the Sherman Act and grants of patent monopolies under the patent laws, as complicated by the Hatch–Waxman Act, that underlies [a reverse-payment settlement] appeal.”<sup>99</sup>

Within the scope settlements also create theoretical problems, forcing the courts to assess difficult jurisprudential and practical considerations. First, jurisprudentially, the courts must consider the proper role of the judiciary in disputes and how to construe settlement agreements. Second, practically, the courts have to weigh the interests of a multitude of stakeholders, all of which stand to lose millions to billions of dollars if the “wrong” test is applied.

### 1. Jurisprudential Realities: Justice, Efficiency, Neutrality, and Presumptions

The courts are struggling with the competing jurisprudential values of neutrality, justice, and efficiency. Every opinion that held reverse payment settlements legal justified itself in part because of the policy in favor of settlements, which promote efficiency.<sup>100</sup> The settlements are considered efficient because they (1) “ease the burdens on courts”; (2) “decrease[] the expense and risk of litigation for parties”; and (3) “can result in a more satisfying resolution than would occur in litigation, because in negotiation the parties are free to consider the entire spectrum of relevant facts and principles . . . .”<sup>101</sup> But in the case of reverse payment settlements, the justifications for promoting settlements are not applicable to the intended beneficiaries of the Act.<sup>102</sup>

For example, one counterweight to efficiency is justice. In the particular realm of reverse payment settlements, the settlements themselves may not be legal.<sup>103</sup> Applying the policy of an efficient settlement to justify an illegal settlement is illogical, at best. In the case of reverse payment settlements, it is unlikely that either the “scope of the patent test” or

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99. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 202 (2d Cir. 2006).

100. For example, the *Ciprofloxacin* court said, “[T]here is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation.” *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008).

101. Margaret Meriwether Cordray, *Settlement Agreements and the Supreme Court*, 48 HASTINGS L.J. 9, 36–37 (1996).

102. “[Michael] Carrier suggests that the Hatch–Waxman regime reflects a policy in favor of patent challenges, that the regulatory regime is relatively ineffective in achieving this purpose, and that reverse payments are ‘uniquely concerning’ because they allow branded and generic manufacturers to limit competition.” David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch–Waxman Patent Litigation*, 98 GEO. L.J. 1303, 1322 (2010).

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

the per se antitrust test adequately aligns the courts' decisions with the most just result.<sup>104</sup>

Although courts and parties enjoy the certainty that presumptions provide, reverse payment settlements are an area where caution is appropriate. Presumptions should stem from a history of correlation or an expression of the general sense of courts' policy foundations.<sup>105</sup> And although presumption tests are efficient, the tests should not truncate justice.<sup>106</sup> While embodying their role as a neutral arbiter, courts should view both tests with a healthy dose of apprehension.<sup>107</sup> Any reverse-payment legislation should allow a court to act neutrally when considering reverse-payment settlement litigation.

## 2. Practical Consequences: Battle Between Private and Public Beneficiaries

Reverse payment settlements create a divide between interested parties. Generally, the parties to the original patent validity suit—patent holders and generic producers—seek “the scope of the patent” test for evaluating reverse payment settlements.<sup>108</sup> Conversely, the government and consumers favor the FTC test.<sup>109</sup> Although the patent holders and generic drug manufacturers are the parties to reverse-payment settlement agreements, the government and consumers also have a high stake in which test is adopted. In the Hatch–Waxman Act, the Legislature attempted to leverage private actions to benefit the public welfare.<sup>110</sup> Consequently, private actors' reasonable self-interest is pitted against the overall public good. Unfortunately, pharmaceutical companies cannot make maximum profits if the public pays minimal costs.

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104. Butler & Jarosch, *supra* note 52, at 120–21.

105. Thomas, *supra* note 77, at 16.

106. According to some scholars, the Court is moving away from a per se antitrust violation rule:

Beginning in the late-1970s . . . , the Supreme Court set out to place significant limits on the application of the per se rule and move ‘from a dichotomous categorical approach to a more nuanced and case specific inquiry.’ Accordingly, it began to ‘reframe antitrust rules around core economic concepts of anticompetitive effect, market power, and efficiencies,’ thereby eroding the long-standing analytical dichotomy.

Weil, *supra* note 72, at 759 (internal citations omitted).

107. Timothy Casey, *Electronic Surveillance and the Right to Be Secure*, 41 U.C. DAVIS L. REV. 977, 1031 (2008) (“In the traditional conception of the adversarial system, the court plays the role of neutral arbiter, deciding only the issues framed by the parties, based on the evidence provided by the parties.”).

108. See *infra* Part III.A.

109. See *infra* Part III.B.

110. See *Senate Hearings*, *supra* note 26.

The uncertainty linked to developing new life-saving medicines creates high stakes for patent holders. In one year, pharmaceutical patent holders spent a combined \$50 billion investment in life science research.<sup>111</sup> And even for only one drug, the risks and the costs are incredibly high: “When factoring in the costs of false starts and blind alleys, it can take literally several hundred million dollars to bring an effective new drug to market.”<sup>112</sup> As one court noted, “[o]nly one in every 5,000 medicines tested for the potential to treat illness is eventually approved for patient use, and studies estimate that developing a new drug takes 10 to 15 years and costs more than \$1.3 billion.”<sup>113</sup> Costs and timelines associated with developing new life-saving drugs demonstrate the incredible risks that pharmaceutical patent holders take. Accordingly, pharmaceutical patent holders argue that encouraging challenges to the validity of their patents would “hamper innovation and research, create unnecessary litigation and unconstitutionally take property from patent owners.”<sup>114</sup>

Meanwhile, the legislature tried to use generic drug manufacturers—another private actor—as a proxy for the government’s and consumers’ desired outcome: more generic drugs. This plan has backfired. While both the public and the generic manufacturers benefit when a patent is declared invalid, all of the costs and risks of proving invalidity are placed on the generic manufacturers. The costs and risks align patent holders’ interests with the generic producers’ interests.

If the generic manufacturers and patent holders settle invalidity suits for an amount higher than the expected profits for the generic producers but lower than the expected profits from maintained validity, both companies reduce all of the risks tied up in litigation proceedings. For example, three reverse payment settlements gave generic producers \$60 million,<sup>115</sup> \$49.1 million,<sup>116</sup> and \$21 million, respectively.<sup>117</sup> As self-interested private actors, it is only logical that generic producers would settle rather than litigate because settlement offers a higher monetary reward and lower relative risk.

For consumers—the intended beneficiaries of the Hatch–Waxman Act—reverse settlement payments have real and life changing effects.

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111. *Id.* at 3.

112. *Id.*

113. *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1300 (11th Cir. 2012), *cert. granted*, 133 S. Ct. 787 (2012), *rev’d sub nom.* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

114. H.R. REP. No. 98-857(II) (1984).

115. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 206 (3d Cir. 2012).

116. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1329 (Fed. Cir. 2008).

117. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193–94 (2d Cir. 2006).

The settlements externalize costs to the detriment of consumers. In one case, the court noted that “[t]hese settlements will delay generic entry, forcing consumers to pay substantially higher prices for prescription drugs. Already these deals are having an impact. A recent analysis by the FTC economists estimate that these types of deals cost consumers \$3.5 billion per year.”<sup>118</sup> Another commentator looking at the monetary incentives in reverse payment settlements noted, “On four blockbusters alone, consumers are expected to save over 16 billion dollars because of generic entry prior to patent expiration.”<sup>119</sup> Still, steep costs do not convey the reality of the issue for consumers. During a Senate hearing regarding proposed amendments to the Hatch–Waxman Act, one senator stated, “[W]e must never lose sight of the hard fact of life that an unaffordable medication may be the same as no medication at all.”<sup>120</sup> Thus, consumers have a collective monetary interest and health interests in invalidating weak pharmaceutical patents.

Meanwhile, the government is trying to balance the public and private interests while also having its own interest as a drug consumer. In one FTC report on the costs of reverse payment settlements, the FTC noted, “The federal government is particularly affected: Federal dollars accounted for an estimated 31 percent of the \$235 billion spent on prescription drugs in 2008, and that share is expected to rise to 40 percent by 2018.”<sup>121</sup> President Obama has supported the plan in his budget statements.<sup>122</sup> Furthermore, the FTC has consistently litigated reverse payment settlements as antitrust violations and campaigned Congress to revise the Hatch–Waxman Act to support this position.<sup>123</sup> Generally, the Executive Branch administrative agencies have been in support of patent invalidity.<sup>124</sup>

Critics of the scope of the patent test would characterize reverse-payment settlements as patent holders effectively paying generic companies not to challenge the validity of their pharmaceutical patents.<sup>125</sup> These settlements delay generic drugs from entering the market and manufacturers from selling the same product at a lower cost.<sup>126</sup> Essentially, the

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118. Kades, *supra* note 24, at 143.

119. *Id.*

120. *Senate Hearing, supra* note 26, at 3.

121. Feinstein, *supra* note 17, at 3.

122. Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch–Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 474 (2011).

123. *See, e.g.*, Feinstein, *supra* note 17, at 1–2.

124. The U.S. Department of Justice originally supported the Court’s outside the scope of the patent test, but later switched to support the FTC test. *See Butler & Jarosch, supra* note 52, at 61–62.

125. Feinstein, *supra* note 17, at 3.

126. *Id.*



effects of inside-the-scope settlements are the same as the effects of outside-the-scope settlements—only the certainty of invalidity has changed. And here, the implication is that the patent holders simply realized that their patents were invalid early enough to make an agreement with the generic drug company. The unknown answer to the underlying question is the key to resolving this issue: *Is the underlying patent valid?* This is the true conflict with which the federal courts have been grappling. Thus, the proposed legislation, discussed below, recommends a legislative change targeting the central underlying issue: weak patent validity.

### C. Sham Exchanges Creating Anticompetitive Agreements

Courts have alluded to one other type of reverse-payment settlement: sham consideration.<sup>127</sup> Some commentators consider sham exchanges to be the next evolution of the reverse-payment settlement problem.<sup>128</sup> Sham exchanges are reverse-payment settlement agreements that trade consideration—other than an agreement not to infringe on the patent—in exchange for the settlement money, but in reality the agreement is just legitimizing the high price of the reverse-payment settlement.<sup>129</sup>

For example, in *In re K-Dur Antitrust Litigation*, the Third Circuit implied that such fraud may exist in the reverse-payment settlement context.<sup>130</sup> In that settlement, the generic drug producer agreed to settle the dispute and turn over ownership of one of its own patents in exchange for \$60 million and a portion of the profits from that patent.<sup>131</sup> The pharmaceutical patent holder never subsequently used the generic company's patents.<sup>132</sup> This led the court to suggest that the unused patents may be merely a sham to help explain the excessive settlement payment.<sup>133</sup> Although the *K-Dur* court did not directly label the consideration as a sham,

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127. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 205–06 (3d Cir. 2012); *In re Tamoxifen*, 466 F.3d 187, 208–09 (2d Cir. 2006).

128. Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 RUTGERS L.J. 83, 93 (2009).

129. Or as Carrier notes,

No longer are brand firms making simple cash payments for generics not to enter the market. Instead, they are paying generics for IP licenses, for supplying raw materials or finished products, and for helping to promote products. They are paying milestones, up-front payments, and development fees for unrelated products. In many cases, they are guaranteeing that the settling generic will enjoy the exclusivity period. And in the latest trend . . . they are agreeing not to launch authorized, brand-sponsored, generics.

*Id.*

130. See *In re K-Dur*, 686 F.3d at 206.

131. *Id.* at 205.

132. *Id.* at 205–06.

133. *Id.* at 206.

it sided with the plaintiffs who did so expressly.<sup>134</sup> These sham exchanges may become more prevalent because they lend legitimacy to the otherwise suspicious reverse payment settlements.

### III. WHY THE SUPREME COURT'S DECISION IN *ACTAVIS* DOES NOT END THE CONFLICT

Recently, the Supreme Court granted certiorari and decided *Actavis*, a reverse-payment settlement antitrust case.<sup>135</sup> This much-anticipated decision resolved which test should be applied in the federal courts: the full rule of reason.<sup>136</sup> This decision effectively rejected both of the approaches adopted in the circuit courts.<sup>137</sup>

Until the summer of 2013, the consensus amongst circuit courts was that reverse payment settlements were presumptively valid unless the terms of the settlement went beyond the scope of the patent.<sup>138</sup> But then the Third Circuit in *K-Dur* became the first court to adopt the quick look rule of reason analysis<sup>139</sup>—an accelerated form of antitrust analysis that was later rejected in *Actavis*.<sup>140</sup> The advent of this circuit split is the likely reason for the Supreme Court granting certiorari in *Actavis* and deciding that all previously applied approaches were invalid.<sup>141</sup>

The Supreme Court's decision to apply the full rule of reason antitrust analysis was probably the best judicial response to reverse-payment settlement suits, but even so, the Court still does not require a determination of the patent's validity.<sup>142</sup> This is a wrong result, and it is up to Congress to correct the misstep. In order to understand why the Supreme Court's decision did not address the underlying problem of reverse-

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134. *Id.* In *K-Dur*, the court stated,

Plaintiffs contend that the license was a sham and that the \$60 million paid as royalties for Niacor-SR was actually compensation for Upsher's agreement to delay the entry of its generic extended-release potassium tablet. On the other hand, defendants contend that Schering's board valued the license deal separately and that \$60 million was its good faith valuation of the licenses at the time.

*Id.*

135. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

136. *Id.* at 2226.

137. *Id.* at 2227 (finding error in the Eleventh Circuit's presumptive approach—the “scope of the patent test”); *id.* at 2237 (declining to adopt the FTC's proposed quick-look rule of reason analysis).

138. *See, e.g., FTC v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012), *cert. granted*, 133 S. Ct. 787 (2012), *rev'd sub nom. FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

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

140. *Actavis*, 133 S. Ct. at 2237 (declining to adopt the FTC's proposed quick-look rule of reason analysis).

141. *See* sources cited *supra* note 137.

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

payment settlement suits, it is necessary to analyze what the Court was rejecting: the scope of the patent test and the FTC test.

#### A. *Watson and the Scope of the Patent Test*

The predominant test adopted by the federal circuit courts prior to *Actavis* was the scope of the patent test.<sup>143</sup> The Second,<sup>144</sup> Eleventh,<sup>145</sup> and Federal Circuit<sup>146</sup> adopted this particular test, whereas only one circuit, the Third Circuit,<sup>147</sup> adopted a different test. The scope of the patent test has a three-step analysis: (1) determine the scope of the exclusionary potential of the patent; (2) determine the extent to which the agreements exceed that scope; and (3) decide what the resulting anti-competitive effects are.<sup>148</sup>

The courts justified adopting the scope of the patent test for five main reasons. First, patent law is inherently designed to have anticompetitive effects.<sup>149</sup> Second, there is a strong policy in favor of settlements.<sup>150</sup> Third, settlements are the most fiscally logical solution for the parties involved in Paragraph IV litigation.<sup>151</sup> Fourth, the courts are concerned about funding future pharmaceutical innovation.<sup>152</sup> Fifth, the first-to-file status of the generic producer does not prevent other companies from challenging the validity of the patent.<sup>153</sup>

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143. *Id.*; *Watson*, 677 F.3d at 1309.

144. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).

145. *Watson*, 677 F.3d 1298; *Schering-Plough v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *Valley Drug v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

146. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008).

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

148. *Schering-Plough*, 402 F.3d at 1066.

149. *Id.* at 1064; *In re Ciprofloxacin*, 544 F.3d at 1333.

150. The *Tamoxifen* court justifies its decision based on the policy in favor of settlements. This is clear through its statements that courts are “‘bound to encourage’ the settlement of litigation.” *In re Tamoxifen*, 466 F.3d at 202; see also *In re Ciprofloxacin*, 544 F.3d at 1333; *Schering-Plough*, 402 F.3d at 1064 (citing *Valley Drug*, 344 F.3d at 1309).

151. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 209 (2d Cir. 2006).

152. Posited first by pharmaceutical lobbying groups during the creation of the Hatch-Waxman Act, “A group of drug companies opposed to the legislation in its current form articulated its reservations. They argue that the bill will hamper innovation and research, create unnecessary litigation and unconstitutionally take property from patent owners.” H.R. REP. NO. 98-857(II) (1984) (original capitalization omitted). Also, “[r]ules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation.” *In re Tamoxifen*, 466 F.3d at 203. Although the courts also questioned the underlying validity of the patent at question: “Perhaps it is unwise to protect patent monopolies that rest on such dubious patents. . . . Why, after all—viewing the settlement through an antitrust lens—should the potential competitor be permitted to receive such a windfall at the ultimate expense of drug purchasers?” *Id.* at 208, 210.

153. *In re Ciprofloxacin*, 544 F.3d at 1334.

The scope-of-the patent approach was characterized as the per se legality approach to reverse payment settlements.<sup>154</sup> The standard for finding the settlements to be anticompetitive is incredibly high: “[S]o long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.”<sup>155</sup>

*Watson*—the Eleventh Circuit case that the Supreme Court reversed—reaffirmed the scope of the patent test and added more certainty to how prior cases would be construed in that jurisdiction.<sup>156</sup> The court “clarified that its use in an earlier case of the phrase ‘strength of the patent’ referred to ‘the potential exclusionary scope of the patent,’ which means ‘the exclusionary rights appearing on the patent’s face and not the underlying merits of the infringement claim.’”<sup>157</sup>

The Eleventh Circuit—while implying that it was too complex for application—understood what would truly be required to know whether the settlement was valid:

[It] is worth emphasizing that what the FTC proposes is that we attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment. If we did that we would be deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task.<sup>158</sup>

Despite its satirical tone, this court accurately portrayed the complexity facing the court in reverse-payment settlement suits. This “turducken task,” as labeled by the Eleventh Circuit inspired the legislative solution proposed in Part V below.

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154. For example, the Federal Circuit first acknowledged the presumptive nature of the scope of the patent test through its statement that “a patent is presumed to be valid.” *Id.* at 1336. As one commentator notes, “Courts then imperceptibly shifted from punishing conduct ‘outside the scope’ of the patent to immunizing conduct ‘within the scope’ of the patent. In doing so, the test took a dramatic turn toward deference.” Carrier, *supra* note 85, at 3.

155. *In re Tamoxifen*, 466 F.3d at 208 (quoting *Standard Oil Co. v. United States*, 283 U.S. 163, 208 (1931)).

156. See *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1315 (11th Cir. 2012), *cert. granted*, 133 S. Ct. 787 (2012), *rev’d sub nom.* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013); Carrier, *supra* note 85, at 4.

157. Carrier, *supra* note 85, at 4 (quoting *Watson*, 677 F.3d at 1311 n.8).

158. *Watson*, 677 F.3d at 1315.

*B. K-Dur and the FTC Test*

Meanwhile, in *In re K-Dur Antitrust Litigation*, the FTC finally found a jurisdiction—the Third Circuit Court of Appeals—that approved of its approach to reverse payment settlements.<sup>159</sup> The Third Circuit test was an intentional departure from the doctrine set forth by the other circuits:

[T]he finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint on trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.<sup>160</sup>

This approach applied the quick-look rule of reason and therefore created a rebuttable presumption that reverse payment settlements were violations of antitrust law.<sup>161</sup>

The court justified its adoption of this test as an extension of the *per se* antitrust violation test created in *Andrx*—the outside-the-scope patent test.<sup>162</sup> It also noted that it “embrace[d] [the *Andrx*] court’s common sense conclusion that ‘[a] payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties entering the agreement.’”<sup>163</sup> The court also disdained the idea that “[the scope-of-the-patent] approach nominally protects intellectual property, not on the strength of a patent holder’s legal rights, but on the strength of its wallet.”<sup>164</sup> Essentially, this decision was based on the apparent facts of the case rather than a compilation of legal doctrines. The court suggested that reverse payment settlements, on their face, seem to be anticompetitive, unreasonable restraints on trade.<sup>165</sup>

This fact-based analysis is based on inherently incomplete information because the quick-look rule of reason does not assess whether the patent is valid, but rather presumes the patent’s invalidity. This approach would only be appropriate if it was correct to assume that all reverse payment settlements are near *per se* antitrust violations.

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159. See generally *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

160. *Id.* at 218.

161. *Id.*

162. *Id.*

163. *Id.* (quoting *Andrx Pharm., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 809 (D.C. Cir. 2001)).

164. *Id.* at 217.

165. *Id.* at 218.

*C. Actavis Wrongly Avoids the Turducken Task*

In the end, *Actavis* oversimplified the problem in reverse payment settlements to be primarily a question of antitrust law.<sup>166</sup> The Court initially decided that antitrust and patent law would be applied in each reverse-payment settlement case.<sup>167</sup> Then the Court's job became the simple question of determining which antitrust doctrine to apply, and the Court adopted the full rule of reason analysis.<sup>168</sup>

But the Court did not resolve two problems that will result in future litigation. First, the Court did not outline clear guidelines about how to assess the litigation for the lower courts; rather, it left the process for determining antitrust liability to the lower courts.<sup>169</sup> And second, the Court raised and dismissed the need to litigate the underlying patent validity in a full patent infringement suit.<sup>170</sup> In *Actavis*, the Court stated, “[T]he size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”<sup>171</sup> Rather, the structure of the lawsuit and the settlement size as a “surrogate for patent strength” are the core of the reverse-payment settlement problem. The settlement amount as a surrogate for patent strength is a problem because this ignores the scholarship suggesting that the size of the settlement may relate more to the profitability of the drug than the strength or weakness of the patent. The structure is a problem because of the remaining turducken task, which will lead the lower courts to resolve a question that many experts have not been able to answer: how do you assess whether a settlement is anticompetitive if you do not resolve whether the patent is valid?

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166. “And the basic question here is whether such an agreement can sometimes unreasonably diminish competition in violation of the antitrust laws.” *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013).

167. *Id.* at 2231. Or as the Court stated,

[I]t would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive [sic] antitrust policies as well. And indeed, contrary to the [c]ircuit’s view that the only pertinent question is whether ‘the settlement agreement . . . fall[s] within’ the legitimate ‘scope’ of the patent’s ‘exclusionary potential,’ . . . this Court has indicated that patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’—and consequently antitrust law immunity—that is conferred by a patent.

*Id.* (internal citations omitted).

168. *Id.* at 2238.

169. “We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.” *Id.*

170. *Id.* at 2236–37.

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

These problems were likely left unanswered because they need a congressional, not a judicial, solution.

*D. Inevitability of An Insufficient Judicial Outcome*

The scope of the patent test would have vindicated the interests of the patent holders and the generic manufacturers, and would have protected both parties' investments in new research. The FTC test would have furthered the interests of consumers and the government as a consumer. But the solution proposed by the Court answered only one question about the reverse-payment settlement analysis—which antitrust test to use—without resolving the conflict. The patent will not be held per se valid without any analysis of antitrust implications, but the full rule of reason is the most nuanced and time-consuming form of antitrust analysis. Moreover, the analysis is gutted of its central inquiry. The Court did not define the appropriate process for courts to use when deciding to accept or reject a reverse-payment settlement agreement, other than to dismiss the need to litigate the underlying patent validity. Therefore, the rule of reason analysis will require lower courts to assess the potential anticompetitive effects of the agreement without ever determining if the patent is actually weak.

The Court chose the full rule of reason analysis because neither presumption test was appropriate.<sup>172</sup> A decision in favor of the scope of the patent test would essentially decide the issue in favor of the patent holder.<sup>173</sup> A decision in favor of the FTC test would have trapped the patent holders, and potentially generic drug companies, in litigation and afforded a presumption in favor of the FTC and consumers.<sup>174</sup> It is not appropriate for the courts either to decide that the patent is presumptively valid or to presume that an antitrust violation occurred merely because a reverse-payment settlement exists.<sup>175</sup>

Despite being the best judicial solution, the Court's solution fails to directly address the question of patent validity, which is the key to reverse payment settlements. The full rule of reason analysis makes the

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172. See *infra* Part IV.

173. See *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012), *cert. granted*, 133 S. Ct. 787 (2012), *rev'd sub nom. FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

174. Scott A. Backus, Comment, *Reversing Course on Reverse Payment Settlements in the Pharmaceutical Industry: Has Schering-Plough Created the Blueprint for Defensible Antitrust Violations?*, 60 OKLA. L. REV. 375, 417 (2007).

175. See *Butler & Jarosch*, *supra* note 52, at 120 (“Selecting the wrong antitrust analysis may result in either prosecution of procompetitive [sic] or neutral business conduct (“Type I error”)—or failure to prosecute activity that is anticompetitive (“Type II error”).”). For further comparison of Type I and Type II errors, see *id.* at 120–21.

results of future litigation murky because it focuses on the reverse-payment settlement, not the patent.<sup>176</sup> Now, therefore, as future courts apply the full rule of reason analysis to reverse payment settlements, they will base their decisions on inherently incomplete information about the strength of the patent.

#### IV. INSUFFICIENCY OF PREVIOUSLY PROPOSED REVERSE-PAYMENT SETTLEMENT LEGISLATION

Since the original enactment of the Hatch–Waxman Act and the subsequent advent of reverse-payment settlement litigation, both the Senate and the House of Representatives have proposed bills that attempt to solve the reverse-payment settlement problem.<sup>177</sup> Thus far, no bill addressing the reverse-payment settlement issue directly has passed both houses of Congress.<sup>178</sup> And more importantly, none of the proposed legislation directly addresses whether the underlying patent is valid or invalid.<sup>179</sup>

Legislators are acting in response to the courts rather than analyzing the fundamental underlying problem: uncertainty about the strength of the underlying patent. All of the pieces of proposed legislation focus on defining reverse payment settlements as anticompetitive, which seemingly responds to the decisions of the majority of circuit courts.<sup>180</sup> For example, Senate Bill 214—the only current piece of legislation addressing the issue of reverse payment settlements—attempts to create a presump-

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

177. S. 214, 113th Cong. (1st Sess. 2013) (creating a presumption that reverse payment settlements are anticompetitive: “an agreement shall be presumed to have anticompetitive effects and be unlawful” if a reverse-payment settlement occurs); H.R. 3995, 112th Cong., (2nd Sess. 2012) (“Conduct Prohibited. It shall be unlawful for any person to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim in which” a reverse-payment settlement occurs); S. 369, 111th Cong. (1st Sess. 2009); Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009) (making reverse payments per se illegal under the FTC Act); *see Carrier*, *supra* note 128, at 90–97.

178. Senate Bill 214 is the only piece of legislation in the current Congress that addresses reverse payment settlements, and it has only been introduced into the Senate. *See* S. 214; *see also Carrier*, *supra* note 128, at 90–97 (2009) (discussing past reverse-payment settlement bills, all of which proposed presumption based approaches to the problem).

179. *See Carrier*, *supra* note 128, at 90–97.

180. For example,

The purposes of this Act are . . . (1) to enhance competition by stopping anticompetitive agreements between brand name and generic drug manufacturers that limit, delay, or otherwise prevent competition from generic drugs; and (2) to support the purpose and intent of antitrust law by prohibiting anticompetitive practices in the pharmaceutical industry that harm consumers.

S. 214 § (2)(b).



tion that reverse payment settlements are invalid.<sup>181</sup> This bill is problematic because it presumes that all reverse payment settlements are presumptively antitrust violations and does not account for reverse payment settlements with a valid underlying patent.<sup>182</sup> All other proposed bills regarding reverse payment settlements share the same fundamental problem.<sup>183</sup> And due to this fundamental problem, no bill proposing a presumption of antitrust has been enacted.<sup>184</sup>

The *Actavis* decision effectively rejected the assumption of validity adopted by the plurality of circuit courts.<sup>185</sup> The stated purpose of Senate Bill 369—the Preserve Access to Affordable Generics Act—was to “stop anticompetitive agreements between brand name and generic drug manufacturers that limit, delay, or otherwise prevent competition from generic drugs,” all to ensure that courts “do not make improper presumptions” when reviewing the agreements.<sup>186</sup>

Furthermore, none of the proposed bills directly address the issue of patent strength. Although Senate Bill 214 does list out “competitive factors” which might overcome the presumption that a reverse-payment settlement is invalid, the consideration of such factors is primarily within the discretion of the FTC.<sup>187</sup> Furthermore, nothing in the proposed legislation suggests that the FTC would then be empowered to litigate the validity of the underlying patent. The bill only allows the FTC to “initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling . . . a patent infringement claim, in connection with the sale of a drug product.”<sup>188</sup> And the remedy under this structure is not necessarily patent invalidity, but rather civil

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181. *Id.* §28(a)(2).

182. See the comparison of Type I and Type II errors in Butler & Jarosch, *supra* note 52, at 120–21.

183. See, e.g., H.R. 3995, 112th Cong., (2nd Sess. 2012) (“Conduct Prohibited. It shall be unlawful for any person to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim in which” a reverse-payment settlement occurs); H.R. 1706, 111th Cong. (1st Sess. 2009) (making reverse payments per se illegal under the FTC Act); see also Carrier, *supra* note 128, at 90–97.

184. S. 214, 113th Cong. (1st Sess. 2013) (introduced in Senate); H.R. 3995, 112th Cong., (2nd Sess. 2012) (introduced in the House of Representatives); S. Res. 287, 111th Cong. (1st Sess. 2009) (Resolution introduced in the Senate); S. 369, 111th Cong. (1st Sess. 2009) (reported in Senate); see Carrier, *supra* note 128, at 90–97.

185. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

186. Carrier, *supra* note 128, at 96 (quoting Substitute Amendment to S. 369 § 2(b)(1)(3), 111th Cong. (1st Sess. 2009)).

187. S. 214 § 28(e)(1) (“The Federal Trade Commission may issue . . . regulations implementing and interpreting this section.”).

188. *Id.* § 28(a)(1).

damages.<sup>189</sup> Thus, the proposed bill's remedies are activated by a presumption-based administrative process, not based on a full patent validity suit.<sup>190</sup>

The presumption-based approach to reverse payment settlements misses the nuance needed to address Paragraph IV settlements. The root of the problem is that some of the settlements may be legitimate—making a presumptive antitrust violation conclusion inappropriate<sup>191</sup>—while others may be anticompetitive—making per se legality inappropriate.<sup>192</sup> Congress needs an approach that allows the courts to weigh both options. The judge-based approach to this conundrum has been to advocate the adoption of the full rule of reason analysis.<sup>193</sup> But a rule of reason analysis under *Actavis* will still require a court to consider whether antitrust violations occurred without the court knowing whether the underlying patent is valid. The proposed legislation in Part V directly addresses the question of patent validity by realigning the ability to litigate patent validity with the correct stakeholders.

#### V. PROPOSED SOLUTION: REALIGN STAKEHOLDER INTERESTS TO THEIR ABILITY TO ACT THROUGH LEGISLATION

In this Part, section A explains the essential misalignment of stakeholders in the Hatch–Waxman regulatory scheme. Section B proposes new legislation and explains the advantages of an invalidity-based approach to reverse payment settlements. Section C anticipates criticism of the proposed legislation.

##### A. *The Hatch–Waxman Act's Misalignment of Stakeholders*

As is shown through the discussion of the current judicial and legislative battles, the Hatch–Waxman Act suffers from a structural design problem.<sup>194</sup> Congress attempted to align the private interests of generic drug producers with the public interests of consumers.<sup>195</sup> This choice made sense for several reasons. First, the direct market beneficiaries of non-patented drugs are generic drug producers. Second, Congress's decision to encourage generic drug producers to file Paragraph IV ANDAs

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189. *Id.* § 28(g).

190. *See id.* § 28(e)(1).

191. Butler & Jarosch, *supra* note 52, at 120–21 (describing prosecution of Type I errors as “condemning legitimate business conduct that is not anticompetitive”).

192. *Id.* at 121 (describing Type II Errors as failing to prosecute activity that is anticompetitive).

193. *Id.*

194. *See supra* Parts II–III.

195. *See supra* Part II.

externalized the cost of finding and invalidating weak patents. Third, when legislation requires pharmaceutical patent holders to respond by either instigating litigation or conceding patent invalidity, the legislation helps consumers by either testing or confirming patent invalidity.

Theoretically, the Hatch–Waxman regulatory scheme should vet out weak patents that should be challenged and, potentially, invalidated. The invalidation of weak patents would then benefit both the public sector consumers and the private sector generic producers. The generic producers would act as a proxy for the consumers, and all of these stakeholders—generic producers, government, and consumers—would benefit. But by externalizing the costs, Congress has also externalized control over the efficacy of the Hatch–Waxman Act in Paragraph IV litigations. Post-enactment, generic drug producers were empowered as the proxy litigators, and therefore proxy negotiators of the pro-invalidation position, despite being self-interested private actors.

This private actor self-interest was apparently the point of leverage that the pharmaceutical patent holders focused on in their negotiations for reverse payment settlements. The pharmaceutical patent holders found that if they could provide a financial benefit to the generic producers while simultaneously eliminating the risk of litigation, some generic producers would be willing to negotiate a settlement.<sup>196</sup> The courts found the first iteration of this settlement strategy to be per se antitrust violations: outside-the-scope patent settlements.<sup>197</sup> The second iteration of this settlement strategy is the reverse-payment settlement: within-the-scope patent settlements.<sup>198</sup> The third potential iteration of this settlement strategy is fraudulent business agreements, which include sham consideration as well as money in exchange for settlement.<sup>199</sup>

The settling parties' progressively subtle strategies to settle Paragraph IV litigations suggest that it is tempting for private actors to maintain patent validity, regardless of patent strength or weakness. Because of the nature of settlement negotiations between private actors, regulatory agencies—such as the FTC—are only able to collect circumstantial evidence of potential antitrust violations.

Still, the criticism set forth by the *Watson* court—the decision that *Actavis* reversed—is well-taken.<sup>200</sup> Congress created a structure where

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196. See, e.g., *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1305 (11th Cir. 2012), cert. granted, 133 S. Ct. 787 (2012), rev'd sub nom. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

197. See *supra* Part II.A.

198. See *supra* Part II.B.

199. See *supra* Part II.C.; *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

200. *Watson*, 677 F.3d at 1315. The court stated,

antitrust regulators are one step removed from executing the actual goals of the public. Congress also created a system that empowers self-interested parties, rather than parties working for the public interest, to act as proxies for consumer interests in pharmaceutical patent invalidity suits. Congress should not have created a system that encourages litigation, a context that makes anticompetitive behavior attractive, and subsequently fails to monitor or create disincentives to prevent antitrust violations.

*B. Proposed Legislation to Solve the Reverse-Payment  
Settlement Problem*

The government should be empowered to assume its proper role in advocating for consumers. In response to this regulatory mismatch, Congress should empower a regulatory agency—potentially the FTC—to bring patent invalidity suits directly. Currently, the U.S. government may not bring a patent validity suit unless an antitrust violation has been found and patent validity relates to relief.<sup>201</sup>

The key precedent to this doctrine is *United States v. Glaxo Group, Ltd.*<sup>202</sup> Here, the Supreme Court ruled that the Government could bring a patent validity suit after it had proven that the parties committed an antitrust violation if the relief in the case was related to patent validity.<sup>203</sup> In *Glaxo*, the Government brought and won an antitrust suit against a pharmaceutical patent holder for its anticompetitive licensing of its patented drug.<sup>204</sup> Along with the antitrust suit, the Government brought a patent invalidity suit against the patent holder.<sup>205</sup> But the lower court “struck the claims of patent validity from the Government’s complaint.”<sup>206</sup> The Su-

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In closing, it is worth emphasizing that what the FTC proposes is that we attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment. If we did that we would be deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task.

*Id.*

201. See, e.g., *United States v. Glaxo Group, Ltd.*, 410 U.S. 52 (1973).

[The Court] think[s] it would have been appropriate, if it appeared that the Government’s [antitrust] claims for further relief were substantial, for the court to have also entertained the Government’s challenge to the validity of those patents. In arriving at this conclusion, we do not recognize unlimited authority in the Government to attack a patent by basing an antitrust claim on the simple assertion that the patent is invalid.

*Id.* at 59.

202. *Id.*

203. *Id.* at 59.

204. *Id.* at 56.

205. *Id.*

206. *Id.*

preme Court remanded for consideration in part because “[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.”<sup>207</sup>

A proposed legislative amendment, in the spirit of *Glaxo*, may solve the reverse-payment settlement problem. A reverse-payment settlement may be an indicator that a patent would be found invalid. Legislators should take the patent’s potential invalidity and antitrust implications seriously, particularly in light of the outside-the-scope settlements that occurred early in Paragraph IV litigations.

To enable the government to act, this Comment proposes the following amendment, which has two main goals.<sup>208</sup> First, the amendment gives the government standing to litigate invalidity suits after a reverse-payment settlement has occurred. Second, assuming that the patent is found invalid, the amendment creates a rebuttable presumption that an antitrust violation occurred.

The proposed amendment:

- (a) Standing. The Federal Trade Commission [or another agency] shall have standing to sue a NDA holder to determine patent validity if:
  - (i) an ANDA filer receives anything of value from a NDA holder;
  - (ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time; and
  - (iii) what is received by the ANDA filer in (i) is valued over seven million USD.
- (b) Infringement. If (a) is satisfied, then the infringement requirements in the Patent Act are also satisfied.
- (c) Antitrust Presumption. If any suit is instigated under section (a) and the patent involved is found to be invalid, then:

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207. *Id.* at 58 (citing *Pope Mfg. Co. v. Cormully*, 144 U.S. 224, 234 (1892)).

208. The language of this proposed amendment is substantially taken from the language in Senate Bill 214, but the legislation outlined here functions differently. *See generally* S. 214, 113th Cong. (1st Sess. 2013). The proposed legislation bifurcates the reverse settlement suit into a patent invalidity suit and a subsequent antitrust challenge contingent on finding the patent invalid.

- (i) antitrust suit(s) may be instigated against the ANDA filer or the NDA holder by the Federal Trade Commission [or another agency]; and
  - (ii) the exchange described in section (a) shall be presumed to be anticompetitive behavior, placing the burden on the ANDA filer and the NDA holder.
- (d) **Competitive Factors.** In determining whether the parties to the original settlement can overcome the presumption that antitrust violations occurred under section (c), the fact finder shall consider:
- (i) the length of time remaining at the time of settlement, until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product;
  - (ii) the value to consumers of the competition from the ANDA product allowed under the agreement;
  - (iii) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim;
  - (iv) the revenue the ANDA filer would have received by winning the patent litigation;
  - (v) the reduction in the NDA holder's revenues if it had lost the patent litigation;
  - (vi) the type of underlying patent involved;
  - (vii) the time period between the date of the agreement conveying value to the ANDA filer and the date of the settlement of the patent infringement claim; and
  - (viii) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection.
- (e) **Penalties.**
- (i) Each person, partnership, or corporation that violates or assists in the violation of this section shall forfeit and pay to the United States a civil penalty sufficient to deter violations of this section, but in no event shall the penalty be greater than three times the value received by the party that is reasonably attributable to a violation of this section. If no such value has been received by the NDA holder, the penalty to the NDA holder shall be sufficient to deter violations, but in no event shall the penalty be greater than three times the value given to the ANDA

filer reasonably attributable to the violation of this section. Such penalty shall accrue to the United States and may be recovered in a civil action brought by the Federal Trade Commission [or another agency], in its own name by any of its attorneys designated by it for such purpose, in a district court of the United States against any person, partnership, or corporation that violates this section. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

- (ii) Civil penalty. In determining the amount of the civil penalty described in this section, the court shall take into account:
  - (A) the nature, circumstances, extent, and gravity of the violation;
  - (B) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the NDA holder, compensation received by the ANDA filer, and the amount of commerce affected; and
  - (C) other matters that justice requires.
  
- (f) Definitions.
  - (i) ANDA. The term “ANDA” means an abbreviated new drug application, as defined under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).
  - (iii) ANDA filer. The term “ANDA filer” means a party who has filed an ANDA with the Food and Drug Administration.
  - (iv) NDA. The term “NDA” means a new drug application, as defined under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).
  - (v) NDA holder. The term “NDA holder” means:
    - (A) the party that received FDA approval to market a drug product pursuant to an NDA;
    - (B) a party owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the “FDA Orange Book”) in connection with the NDA; or

- (C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and (B) (such control to be presumed by direct or indirect share ownership of 50% or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

If Congress enacts this proposed amendment, the new law would (1) align consumer interests to the party of the patent invalidity suit, essentially effectuating the original goal of the Hatch–Waxman structure; (2) empower the regulatory agency that monitors reverse payment settlements with the ability to prioritize which settlements seem to be protecting weak patents; (3) create a disincentive for generic drug producers to protect particularly weak patents along with patent holders; (4) break the potential for a code of silence amongst insiders; (5) have less dependence on the slow-moving decisions of the federal courts; (6) anticipate future issues with sham consideration; and (7) in some cases, eliminate the need to decide a patent case within an antitrust case by properly dividing the suit into stages to the benefit of consumers.

One of the government's unique roles is to protect citizens in situations where they cannot protect themselves—when citizens are externalities. By contrast, this is neither the role nor the expectation of private actors or businesses. In the case of the Hatch–Waxman Act, the government tried to turn private actors into proxies for consumers, but the application of the Act fell short of expectations. Still, the Act and the FTC's monitoring succeeded in discovering when these potentially anti-competitive agreements have been made. In light of the generic drug producer's potentially anticompetitive actions, it would not make sense to further delegate litigation to the private actors.

Instead, Congress should empower a government agency to exercise its discretion in bringing suits. This Comment proposes granting this ability to the FTC because it has spearheaded monitoring and scrutiny of reverse payment settlements thus far.<sup>209</sup> Thus, the agency already has practice at targeting suspicious reverse payments. The FTC is uniquely situated to exercise its discretionary power to bring invalidity suits. But ultimately, it does not matter which agency fulfills this role as long as it

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209. See, e.g., Feinstein, *supra* note 17, at 1–2.



is empowered to invalidate weak patents and prevent antitrust violations when reverse payment settlements occur.

Although generic drug producers may have colluded to help hide anticompetitive and weak patents, sufficiently high antitrust violation damages might deter generic drug producers from settling in future Hatch–Waxman litigation. By settling, the generic companies received significant benefits without exposing themselves to much risk. Because of reverse payment settlements, generic companies have been able to make higher profits by doing nothing, rather than by actually creating generic drugs.<sup>210</sup> If the proposed legislation was enacted, the generic producers would risk as much as they gain if they were eventually found to have wrongfully colluded in reverse payment settlements. This deterrent would help realign the generic companies' interests with the public.

At a minimum, the new legislation would divide the private interests, which could break the potential silence between insiders. While it might be impossible to convince the patent holders that they can benefit from invalidity and competition, it is possible to convince generic producers that they can benefit from off-patent drugs. The proposed amendment would re-divide the private interests and prevent the anticompetitive settlements between the parties. Furthermore, the bright-line settlement amount would allow both companies to plan and decide the relative strength of their suit. It would provide an incentive to settle early if the generic did not have a strong suit, and it would provide an incentive against settling if the generic producer expected to gain more than \$7 million net profit from producing the drug. This ability to plan around these incentives may keep these expensive patent and antitrust suits from clogging the courts with litigation. Thus, the legislation would also promote efficiency with regard to the courts.

The proposed amendment would formalize the goals of Congress such that the judiciary would not need to legislate from the bench. The decision in *Actavis* to apply the full rule of reason analysis arose to respond to the unique and unanticipated problems of reverse payment settlements. Furthermore, the decision in *Actavis* came ten years after the first Paragraph IV reverse settlements were litigated.<sup>211</sup> This slow-moving and backward-looking approach is not nimble enough to address the remaining problems with reverse-payments settlements.<sup>212</sup> Unlike the ultimate ruling in the courts, a legislative amendment would clarify and

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210. See *supra* note 60.

211. Compare *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001), with *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

212. See *supra* Part III.

solidify the government's expectations of the pharmaceutical patent holders and the generic companies. Also, because of the relative competencies of the legislature, it can address a broader scope of issues than the judiciary and actively advocate for the consumer–public interest by invalidating weak patents.

The amendment would also address the concerns of the *Watson* court in regard to deciding a patent case within an antitrust case—the turducken task.<sup>213</sup> First, the amendment intentionally stages litigation to consider validity before addressing whether antitrust violations occurred. In the first stage of litigation, the presumption of validity remains with the patent holder to satisfy the rights of the patent holder. The amendment only modifies the government's ability to bring a cause of action. Second, it is not a general grant of standing to the government. The agency would only be able to bring invalidity suits when a sufficiently large reverse-payment settlement occurs. Thus, the government would not have the unchecked ability to challenge pharmaceutical patents. Third, the government could win or lose this cause of action. If the government lost, then the matter would end. If the government won, the patent holder would still be able to defend itself from antitrust litigation and have the chance to prove the validity of the suit after the initial presumption had been satisfied. Lastly, the decision of the agency to move on and litigate the antitrust suit is also discretionary. If the patent was weak, then the agency could choose to proceed; but if the decision was close and the validity of the patent was a hard question, then the agency may opt to stop at finding the patent invalid. The shift in presumption in the second suit would allow the parties to defend the reasonableness of the patent claim, and any pro-competitive reasons for the reverse-payment settlement would make antitrust damages not necessarily a foregone conclusion.

Furthermore, the creation of stages within the litigation mirrors Congress's goals in creating the Hatch–Waxman Act. The Act was created to facilitate the entry of generics into the pharmaceutical market and get lower priced drugs to consumers.<sup>214</sup> In the proposed legislation, the government agency would be empowered to effectively complete the suit that the generic producer initiated. Regardless of how a patent might be invalidated, consumers will benefit if the patent monopoly is broken. If the agency feels that there was wrongdoing on the part of the parties to the settlement—that the agreement was an anticompetitive attempt to

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213. *See supra* note 200.

214. S. Res. 287, 111th Cong. (1st Sess. 2009) (resolution introduced in the Senate).

exercise a limited monopoly—then the government can pursue an anti-trust suit against the settlement parties. Thus, in descending order of importance, the priorities effectuated are first to benefit the public through generic entry, and second to punish and deter anticompetitive behavior.

In the end, providing a cause of action to a government agency better aligns the roles of the Executive Branch and the Judicial Branch in relation to reverse payment settlements. The Executive Branch's role is to effectuate the intended policies of Congress and protect the public through the execution of such laws. The proper role of the Judicial Branch is to act as a neutral arbiter between parties in conflict. Here, public and private interests are in conflict, and the decision of the Supreme Court in *Actavis* did not presumptively favor the private interests through the scope of the patent test, nor did it favor the public interests through the FTC test. Furthermore, the *Actavis* decision failed to provide clear guidance on how to apply the full rule of reason analysis. The first two options were not sufficiently neutral, and the final option left the private parties and the FTC unsure of how to conform their actions to the law.

Meanwhile, the proposed amendment would empower the government agency to act in a limited way. It would give guidance to private actors about how to conform their behavior because of the clear bright-line expectations within the amendment. And it would allow the court to maintain its proper role as a neutral arbiter when the interests of public and private actors come into conflict.

### *C. Response to Anticipated Criticism of the Proposed Legislation*

Just as the Hatch–Waxman Act has been criticized since its enactment, the proposed amendment will inevitably be criticized as imperfect as well. In an attempt to advocate for its enactment, this section addresses anticipated criticism of the proposed legislation. First, this section addresses concerns about how this action may harm innovation. Second, this section considers the practical consequences of the proposed litigation upon Paragraph IV filers.

First, the strongest policy defense of patent holders' rights to a monopoly is that those monopolies fund future innovation. While this is true, the patent holder should only be protected so far as it is actually innovating. As the court in *Glaxo* noted, "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monop-

oly. . . .”<sup>215</sup> Non-innovative patents do not serve innovation. Patents that are found invalid under the proposed legislation should logically be deemed fatally weak. Furthermore, under the proposed legislation the patent holder maintains its presumption of validity throughout the invalidity suit. Thus, the rights of a patent holder are maintained, but only protected so long as the new product is actually innovative.

The proposed litigation may also be criticized as a deterrent to litigation under Paragraph IV of the Hatch–Waxman Act, but this is the tradeoff that reverse payment settlements require. Generic producers may be more hesitant to file Paragraph IV ANDAs because patent holders may attempt to drive the cost above \$7 million to make the decision economically unsound. But this is the price of creating a bright-line rule. Generic producers who still believe that they may benefit more from filing than the company might lose by litigating the case will be able to make self-interested choices with clear fiscal margins in mind. The Act was created to facilitate generic drug entry; it was not created to give the generic companies leverage so that pharmaceutical patent holders would pay them to help protect their patents’ validity.<sup>216</sup>

Critics may suggest that the high costs of litigation would be a burden on the government in a time when federal funding is already limited. But the treble damages and the benefits to other government goals and programs will more than compensate the government and the consumers for the cost of litigating the patent validity or antitrust suits. The government is on many sides of this issue. Congress negotiated the Hatch–Waxman Act and would enact any future legislation. The FTC spearheaded the fight against the antitrust violations in reverse payment settlements. And the government is also a consumer in that it subsidizes medical care. These considerations should quell complaints that the government is spending money on litigation because of how many goals are accomplished through the litigation of fatally weak patents.

Admittedly, the proposed solution places most of the cost upon the pharmaceutical patent holder, but the property rights of the patent holders are not being arbitrarily challenged. Under the proposed legislation, there is a threshold requirement of a suspicious reverse-payment deal prior to FTC validity challenges. Patent holders may suggest that this will create unfair costs to the patent holders, but it seems reasonable for the patent holder to defend the patent’s validity in court for such a lucrative benefit. Perhaps the Hatch–Waxman Act and this amendment will

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215. *United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 58 (1973) (citing *Pope Mfg. Co. v. Cornully*, 144 U.S. 224, 234 (1892)).

216. *See supra* Part I.A.

decrease the profit margins of the pharmaceutical patent holders, but the historical expectations of profitability are partially based on the limited challenges to invalidity and criticized extension of monopolies beyond the patent term. The natural result of Congress's corrective action may be that the profits to the industry would shrink. Relevant questions include the following: Do the profit margins deserve to shrink? Was the high profitability of the pharmaceutical industry partially based on illegitimate, anticompetitive practices? If so, then Congress should continue to legislate so that private actors do not benefit wrongfully off of the legitimately earned wages of the public at large.

#### VI. CONCLUSION

The Supreme Court took over a decade to grant certiorari on a reverse settlement payment case. During that time, consumers may have lost billions of dollars due to reverse payment settlements. Congress should not allow the powerful self-interest of pharmaceutical patent holders to go unchecked. Although Congress created a uniquely litigious regulatory scheme in the Hatch–Waxman Act, this is not an excuse for private parties or the government to allow antitrust violations to be beyond review. It is true that we do not know if antitrust violations occurred or if the patents are invalid. But, if the government allows potential anticompetitive settlements to persist unquestioned, it would fail in its role of advocating for the interest of the consumers.

For these reasons, Congress should enact legislation that targets the source of the reverse-payment settlement problem: weak patent validity. The proposed legislation is not a sweeping standard that would allow the FTC to litigate in any circumstance. Rather, the language limits the scope of the standing granted to the specific context where the actions of the private parties indicate that anticompetitive behavior may have occurred. This has the added benefits of allowing the FTC to regulate the potentially anticompetitive behavior—reverse payment settlements—while simultaneously giving the private actors notice that the settlements may trigger a patent invalidity suit. Providing notice to the private actors allows them to plan in such a way so as to avoid litigation, or risk the FTC exercising its discretion to litigate.

Legislation is preferable to the decision of the Supreme Court in *Actavis* because the Court did not suggest that the FTC challenge the validity of a patent; now, only Congress can. Patent validity is the heart of the reverse-payment settlement problem. Pharmaceutical patent holders are not fighting for their right to settle Paragraph IV litigation, but to protect their patents' validity. The Hatch–Waxman Act was not created to force patent holders and generics into litigation, but to facilitate generic

market entry by invalidating weak patents. Antitrust damages will not benefit consumers, but invalidating weak patents that drive up consumer costs will. In the end, litigating the patents is the solution to the actual problem: fatally weak pharmaceutical patents.