

# Michigan Telecommunications and Technology Law Review

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Volume 20 | Issue 2

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2014

## Pay-For-Delay Settlements in the Wake of Actavis

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### Recommended Citation

Michael L. Fialkoff, *Pay-For-Delay Settlements in the Wake of Actavis*, 20 MICH. TELECOMM. & TECH. L. REV. 523 (2014).

Available at: <http://repository.law.umich.edu/mttlr/vol20/iss2/7>

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## NOTE

# PAY-FOR-DELAY SETTLEMENTS IN THE WAKE OF ACTAVIS

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Cite as: Michael L. Fialkoff, Note, *Pay-for-Delay Settlements  
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20 MICH. TELECOMM. & TECH. L. REV. 523 (2014).

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*“Pay-for-delay” settlements, also known as reverse payments, arise when a generic manufacturer pursues FDA approval of a generic version of a brand-name drug. If a patent protects the brand-name drug, the generic manufacturer has the option of contesting the validity of the patent or arguing that its product does not infringe the patent covering the brand-name drug. If the generic manufacturer prevails on either of these claims, the FDA will approve its generic version for sale. Approval of a generic version of a brand-name drug reduces the profitability of the brand-name drug by forcing the brand-name manufacturer to price its product competitively. Thus, under a typical pay-for-delay arrangement, the brand-name manufacturer avoids the risk of competition by paying the generic manufacturer to keep its product off the market, often for the remainder of the brand-name drug’s patent term. The FTC estimates that this practice costs consumers billions of dollars in the form of increased prescription drug prices. In June of 2013, the Supreme Court rendered its decision in *FTC v. Actavis, Inc.*, which addressed whether this type of arrangement violates federal antitrust law. In *Actavis*, the Court held that pay-for-delay settlements should be scrutinized under rule of reason antitrust analysis to determine whether a particular settlement unreasonably diminishes competition. This Note argues that the *Actavis* holding will not effectively address anticompetitive settlements in the pharmaceutical industry, and proposes a regulatory solution to the problem of pay-for-delay settlements.*

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\* J.D., University of Michigan Law School (expected 2015); B.A., University of Michigan (2011); Articles Editor, Vol. 21, *Michigan Telecommunications and Technology Law Review*. I would like to thank Professor Eisenberg for her helpful feedback on an earlier draft of this Note. I would also like to thank Helen Ji, Carly Williams, Daniel Zwick, Jason Wong, and the *MTTLR* Volume 20 editorial board for their hard work in bringing this Note to publication. Finally, I would like to thank my parents for their love and support, and for their valuable feedback and proofreading assistance.

## INTRODUCTION

In June of 2013, the Supreme Court rendered its decision in *FTC v. Actavis, Inc.*<sup>1</sup> The decision focused on the legality of “pay-for-delay” settlements in drug patent litigation. Pay-for-delay settlements, also known as reverse payments, arise when a generic manufacturer pursues FDA approval of a generic version of a brand-name drug (also known as a “pioneer” drug). If a patent protects the brand-name drug, the generic manufacturer has the option of contesting the validity of the patent or arguing that its product does not infringe the patent covering the pioneer drug. If the generic manufacturer prevails on either of these claims, the FDA will approve its generic version for sale. Approval of a generic version of a brand-name drug reduces the profitability of the brand-name drug by forcing the brand-name manufacturer to price its product competitively. Thus, under a typical pay-for-delay arrangement, the brand-name manufacturer avoids the risk of competition by paying the generic manufacturer to keep its product off the market, often for the remainder of the brand-name drug’s patent term.

The Federal Trade Commission (FTC) estimates that pay-for-delay settlements cost consumers \$3.5 billion per year, in the form of increased costs for prescription drugs.<sup>2</sup> As a result, the FTC has made opposition to such settlements one of its top priorities—initiating lawsuits against parties to pay-for-delay settlements and encouraging Congress to legislate against such arrangements.<sup>3</sup>

*Actavis* arose out of an FTC challenge to a pay-for-delay settlement between Solvay Pharmaceuticals, Inc. (now owned by Abbot Laboratories) and several generic manufacturers. Solvay paid the generic manufacturers millions of dollars to keep generic versions of its drug, AndroGel, off the market until 2015.

In *Actavis*, the Supreme Court addressed the issue of whether this type of arrangement violates federal antitrust law by “unreasonably diminishing competition.”<sup>4</sup> Prior to *Actavis*, the circuits were split on this question. On one end of the spectrum, the Court of Appeals for the D.C. Circuit and the Sixth Circuit had held that such arrangements were per se violations of antitrust law.<sup>5</sup> On the other end of the spectrum, the Federal Circuit, Second Circuit, and Eleventh Circuit had held that pay-for-delay agreements were a

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

2. FED. TRADE COMM’N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, 2 (2010).

3. *Pay-For-Delay: When Drug Companies Agree Not To Compete*, FED. TRADE COMM’N, <http://www.ftc.gov/news-events/media-resources/mergers-and-competition/pay-delay> (last visited Mar. 24, 2014).

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

5. JOHN R. THOMAS, CONG. RESEARCH SERV., R42960, PHARMACEUTICAL PATENT SETTLEMENTS: ISSUES IN INNOVATION AND COMPETITIVENESS, 10 (2013).

permissible exercise of patent rights, provided that any settlement did not extend exclusivity beyond the “scope of the patent.”<sup>6</sup>

Ultimately, the Supreme Court in *Actavis* chose an intermediate position. The Court declined to label such arrangements as either presumptively valid or presumptively violative of antitrust law. Instead, the Court held that courts examining pay-for-delay settlements should apply rule of reason analysis to determine whether a particular settlement unreasonably diminishes competition.<sup>7</sup>

This Note examines the ramifications of this decision and suggests that modifying the FDA regulatory regime may prove more effective than the *Actavis* Court’s antitrust approach in reducing the prevalence of pay-for-delay settlements. Part I explores the legal and economic framework that has given rise to pay-for-delay settlements in the pharmaceutical industry. Part II focuses on the events leading up to *Actavis* and on the Supreme Court’s decision itself. Part III contends that the antitrust analysis proposed by the Court in *Actavis* will not, by itself, effectively address the anticompetitive concerns raised by pay-for-delay settlements. In particular, Part III explores the possibility of pay-for-delay settlements that do not involve an overt exchange of money through a post-*Actavis* case arising out of the District of New Jersey. Finally, Part IV proposes modifying the FDA regulatory regime to more effectively deter pay-for-delay settlements and promote generic competition without trampling on the rights of pharmaceutical patent-holders.

## I

The rise of pay-for-delay settlements has been swift. FTC enforcement actions effectively deterred such arrangements until 2005, when the Eleventh Circuit held that pay-for-delay settlements were generally immune from antitrust scrutiny.<sup>8</sup> As several other Circuits followed suit, the number of pay-for-delay settlements increased dramatically. According to the FTC, there were only three pay-for-delay settlements in fiscal year 2005.<sup>9</sup> In 2006, the number jumped to fourteen,<sup>10</sup> and in fiscal year 2012, 40 out of 140 final resolutions of patent disputes between a brand-name and generic manufacturer involved possible pay-for-delay payments.<sup>11</sup> Interestingly, pay-for-delay settlements appear to be unique to the pharmaceutical indus-

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6. *Id.* at 10.

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

8. FED. TRADE COMM’N, *supra* note 2, at 1, 11 n.3.

9. *Id.* at 1.

10. *Id.*

11. THOMAS, *supra* note 5, at 9.

try.<sup>12</sup> This section explains how the legal framework and economics of the pharmaceutical industry incentivize pay-for-delay arrangements.

### A. Legal Framework

The interplay between brand-name drugs and their generic counterparts is governed by two sources of law: U.S. patent law and FDA regulatory law. Patent law gives brand-name manufacturers the right to exclude others from the market for a patent-protected drug. The FDA regulatory regime, by contrast, dictates whether a given manufacturer (brand-name or generic) is able to market a particular drug in the U.S. With respect to patent law, pioneer drugs are treated much the same way as any other invention. A valid patent covering a brand-name drug gives the manufacturer a lawful right to exclude competitors (i.e., generic versions of its drug) from the market for the term of the patent.<sup>13</sup> FDA regulatory law, however, modifies the standard patent regime, giving generic manufacturers additional incentives to seek approval of generic versions of brand-name drugs and to challenge the patents covering these drugs.

These two sources of law reflect countervailing concerns. Patent protection spurs innovation by giving brand-name manufacturers a *de facto* monopoly in the market for a given drug for the duration of the patent term. As a corollary, the brand-name manufacturer may charge a “higher-than-competitive” price during this period, allowing it to recoup the high cost of drug development.<sup>14</sup> By contrast, many aspects of the FDA regulatory regime are designed to foster generic competition in order to lower the cost to consumers of prescription drugs. In particular, the Hatch-Waxman Act, passed in 1984, contains a number of provisions designed to facilitate generic competition, and as a result, lower prescription drug prices.

First, the Hatch-Waxman Act provides a streamlined approval process for generic drugs, making it easier for generic manufacturers to obtain FDA approval of their drugs. Typically, to obtain approval of a new drug, a brand-name manufacturer must file a New Drug Application (“NDA”) with the FDA. The brand-name manufacturer must demonstrate through extensive testing that the new drug is safe and effective for use.<sup>15</sup> In addition, the brand-name manufacturer must file with the FDA “the patent number and the expiration date of any patent which claims the drug . . . or which claims a method of using such drug.”<sup>16</sup> The Hatch-Waxman Act allows a generic manufacturer to file an Abbreviated New Drug Application (“ANDA”) in

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12. *Actavis*, 133 S. Ct. at 2227 (“[M]ost if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation. . . .”)

13. *See* *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948).

14. *See infra* Part I.B.

15. 21 U.S.C. § 355(b)(1)(A) (2012).

16. *Id.* § 355(b)(1)(G).

lieu of a complete NDA.<sup>17</sup> To satisfy the requirements for ANDA approval, a generic manufacturer need not independently evaluate the safety and effectiveness of its version of the drug. Instead, the generic manufacturer need only demonstrate bioequivalence—a similar rate and extent of absorption—between its drug and the pioneer drug.<sup>18</sup>

Second, the Hatch-Waxman Act modifies standard patent law, making it easier for generic manufacturers to challenge the patents covering pioneer drugs. Recall that a patent holder has a legal right to exclude competitors from selling the patented product. Consequently, when a generic manufacturer applies for FDA approval under the abbreviated process, it must certify that the proposed generic drug will not violate any patents covering the brand-name drug. The generic manufacturer has several options as to the type of certification it can make. It may certify that: (I) there is no patent information on file for the pioneer drug, (II) the patent(s) covering the pioneer drug have expired, (III) the generic manufacturer is not seeking approval until the patent(s) covering the pioneer drug have expired, or (IV) the patent(s) covering the pioneer drug are invalid or will not be infringed by the generic manufacturer. A generic manufacturer making a so-called Paragraph IV certification is effectively challenging the validity and the scope of the pioneer drug's patents. Filing an ANDA with a Paragraph IV certification is automatically considered an act of infringement.<sup>19</sup> The generic manufacturer must notify the brand-name manufacturer that it is making a Paragraph IV certification.<sup>20</sup> If the manufacturer does not bring an infringement suit within 45 days, the generic version is approved.<sup>21</sup> If a suit is brought, the FDA will stay approval of the generic for 30 months, or until the court overseeing the patent litigation terminates the stay (the court has discretion to either increase or decrease the length of the stay).<sup>22</sup>

The automatic infringement effect of a Paragraph IV certification, coupled with the notice requirement, incentivizes generic proliferation by reducing the costs to generic manufacturers of challenging the patents of brand-name drugs. In standard patent law, patent infringement occurs only when an unauthorized party “makes, uses, offers to sell, or sells any patented invention.”<sup>23</sup> By making the filing of a Paragraph IV certification an act of infringement, and forcing the brand-name manufacturer to respond within 45 days of receiving notice of the certification, the Hatch-Waxman Act spares generic manufacturers the cost of committing an actual act of infringement—making, selling, or using their drug. Put another way, the generic

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17. *Id.* § 355(j).

18. *Id.* § 355(j)(2), (8)(b).

19. 35 U.S.C. § 271(e)(2)(A) (2012).

20. 21 U.S.C. § 355(j)(2)(B).

21. *Id.* § 355(j)(5)(B)(iii).

22. *Id.*

23. 35 U.S.C. § 271(a).

manufacturer need not invest in producing and selling its drug before it is able to challenge the brand-name manufacturer's patent. This provision also has the effect of shielding generic manufacturers from damages liability. Without any product on the market, the generic manufacturer would not be held liable for damages (in the form of lost profits for the brand-name manufacturer) even if a court were to hold the pioneer drug patent valid and infringed.

Finally, the Hatch-Waxman Act gives generic manufacturers an incentive to challenge brand-name drug patents by giving the first generic manufacturer to file a Paragraph IV certification a 180-day period of generic exclusivity—a 180-day period during which its generic version will be the only generic version approved for sale by the FDA.<sup>24</sup> This 180-day window commences upon the first commercial marketing of the first-filer's generic version of the brand-name drug.<sup>25</sup> Once the 180 days has expired, any other generic manufacturer may receive FDA approval of its version of the brand-name drug.

The 180-day exclusivity accomplishes two key goals with respect to promoting generic competition. First, the 180-day period of exclusivity gives generic manufacturers a strong incentive to initiate challenges to brand-name patents as early as possible. The Hatch-Waxman exclusivity provision rewards the first-to-file generic manufacturer with the ability to price its product at duopolistic levels for a limited time. This can be exceptionally lucrative for the first Paragraph IV ANDA filer, potentially producing hundreds of millions of dollars in revenue.<sup>26</sup> Second, when this period of exclusivity expires, other generic manufacturers are generally able to obtain approval based on the first-filer's successful patent challenge. Thus, the duopoly created by the 180-day exclusivity window relatively quickly gives way to a fully competitive market.

It is important to note that the period of generic exclusivity attaches only to the first-filer.<sup>27</sup> The first-filer may forfeit its generic exclusivity, such as by failing to bring its generic version to market under certain circumstances,<sup>28</sup> but in the event that it does so, no other ANDA filer will be entitled to the period of exclusivity.<sup>29</sup> Furthermore, settlement of Paragraph IV litigation does not in itself trigger forfeiture, even where the generic manufacturer agrees to delay entry into the market and drops its patent chal-

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24. 21 U.S.C. § 355(j)(5)(B)(iv).

25. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013).

26. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006).

27. *Id.* at 1560-61.

28. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

29. Hemphill, *supra* note 26, at 1583.

lenge.<sup>30</sup> In this context, only a final appellate judgment that a proposed settlement violates antitrust law will result in forfeiture.<sup>31</sup> The issue of forfeiture is critical to the solutions proposed by this Note and will be discussed further in Parts III and IV, *infra*.

The Hatch-Waxman provisions favoring generic competition have rendered challenges to pioneer drug patents commonplace.<sup>32</sup> Since 1984, there have been challenges to the validity of patents covering more than 200 drugs, and the rate of these challenges has increased over time.<sup>33</sup> In 2000, generic manufacturers challenged patents covering nine of the top ten best-selling drugs.<sup>34</sup> It seems clear that the Hatch-Waxman Act has been effective in promoting generic manufacturer challenges to pioneer drug patents, resulting in increased proliferation of generic drugs.

### B. Economic Framework

Pay-for-delay settlements arise from a confluence of regulatory and economic factors. The discussion in the preceding section explains how the regulatory framework surrounding the pharmaceutical industry—particularly the Hatch-Waxman Act and its effect on patent law—incentivizes generic manufacturers to seek approval of generic drugs and to challenge the validity of pioneer drug patents. Faced with such a challenge, a brand-name manufacturer appears to have two options in preserving the market exclusivity of its pioneer drug: 1) see the litigation through and hope that the patent at issue is found valid and infringed; or 2) pay the generic challenger to stay off the market. This section addresses how the economics of the pharmaceutical industry affect brand-name manufacturers' choice between these two alternatives. To do so, it is first necessary to address the role of market exclusivity in the pharmaceutical industry.

Brand-name manufacturers rely on monopolistic pricing to recoup the high cost of bringing a new drug to market and to realize a profit on the drug. Developing a pioneer drug is expensive. Estimates of the cost to bring a new drug to market vary significantly, but a 2003 study relying on confidential data submitted by pharmaceutical companies found that brand-name manufacturers spent an average of \$802 million per approved drug.<sup>35</sup> This figure only reflects the capitalized cost of clinical and preclinical investigation of new drugs, divided by a brand-name manufacturer's overall clinical success rate—the percentage of researched drugs that are actually

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30. C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 963 (2011).

31. *Id.* at 971.

32. Hemphill, *supra* note 26, at 1567.

33. *Id.*

34. *Id.*

35. Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003).



approved for sale by the FDA.<sup>36</sup> Higher estimates, such as the oft-cited figure of \$1 billion<sup>37</sup> may reflect additional costs such as advertising. By contrast, it costs about \$1 million to bring a generic drug to market.<sup>38</sup>

Generic competition prevents the brand-name manufacturer from monopolistically pricing its drug, making it more difficult for the brand-name manufacturer to profit from its investment in drug research and development. The FTC estimates that by the end of the first year of generic availability, the generic penetration rate is 90%.<sup>39</sup> In other words, after one year of generic availability, 90% of prescriptions for the drug are filled with a generic version.<sup>40</sup> Furthermore, the generic price may be as much as 85% less than the pre-generic price of the branded drug.<sup>41</sup> Using the generic penetration rate and price reduction figures above, a brand-name drug initially earning \$1 billion a year would quickly drop to earnings of only \$15 million one year after generics are introduced into the market (assuming the brand-name manufacturer reduces its price to the market-level). These figures underscore that market exclusivity is crucial to brand-name manufacturers' profitability.

It is through this economic lens that brand-name manufacturers evaluate the two options presented at the beginning of this section. Option 1, litigating the patent challenge, is appealing in that if the brand-name manufacturer prevails, it is able to realize the full benefit of monopolistic pricing for the remainder of the pioneer drug's patent term. However, it seems that quite often, the brand-name drug does not prevail. A 2002 FTC study found that between 1992 and 2002, generic manufacturers prevailed in 73% of patent disputes resolved by a court decision.<sup>42</sup> Thus, brand-name manufacturers have been increasingly resorting to the second option, pay-for-delay settlements.<sup>43</sup>

## II

Having examined the regulatory and economic framework of the pharmaceutical industry, and its impact on the rise of pay-for-delay settlements, this Note now turns to the *Actavis* case itself. This Part first examines the facts of the *Actavis* case, providing a concrete example of a standard pay-

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36. *Id.* at 158-61.

37. See Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, FORBES (Feb. 10, 2012, 7:41 AM), <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/>. Herper actually estimates the minimum cost of bringing a new drug to market at \$4 billion, but this figure appears to be somewhat of an outlier because it takes into account the cost of failed attempts.

38. Hemphill, *supra* note 26, at 1565.

39. FED. TRADE COMM'N, *supra* note 2, at 8.

40. *Id.*

41. *Id.*

42. *Id.* at 3.

43. See *id.* at 1.

for-delay arrangement. This Part next turns to how such arrangements were treated under antitrust law prior to *Actavis*. This Part concludes by summarizing the key components of the *Actavis* decision.

#### A. *The Facts of Actavis*

The *Actavis* decision itself arose out of a dispute between Solvay Pharmaceuticals, Inc. and several generic manufacturers.<sup>44</sup> The dispute centered on the drug AndroGel, which was developed by Besins Healthcare, S.A. and exclusively licensed to Solvay for U.S. distribution.<sup>45</sup> The drug received FDA approval in 2000.<sup>46</sup> In 2003, Solvay notified the FDA that it had obtained a patent covering specific formulations of AndroGel,<sup>47</sup> and the FDA published the new patent information as required by statute.<sup>48</sup>

Later in 2003, Actavis, Inc. (then known as Watson Pharmaceuticals) filed an ANDA for a generic version of AndroGel.<sup>49</sup> In its ANDA, Actavis made a Paragraph IV certification, asserting that Solvay's 2003 patent was invalid or not infringed.<sup>50</sup> Subsequently a second generic manufacturer, Paddock Laboratories, filed an ANDA with a Paragraph IV certification.<sup>51</sup> A third manufacturer, Par Pharmaceutical, did not file an ANDA, but agreed with Paddock to split the cost of patent litigation in exchange for a share of Paddock's profits from its generic version if the patent challenge succeeded.<sup>52</sup>

Pursuant to the Hatch-Waxman Act, Solvay initiated a patent infringement suit and the FDA stayed generic approval for the requisite 30-month period.<sup>53</sup> When the 30-month stay expired, the FDA approved Actavis' first-filed ANDA.<sup>54</sup> At this point, however, all parties to the litigation settled.<sup>55</sup> Solvay paid \$12 million to Paddock, \$60 million to Par, and an estimated \$19-30 million annually for nine years to Actavis. In exchange, the generic manufacturers agreed to keep their generic versions of AndroGel off the

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44. *Actavis*, 133 S. Ct. at 2229.

45. Lyle Denniston, *Argument Preview: Is "Pay for Delay" of Drugs Illegal?*, SCOTUSBLOG (Mar. 22, 2013, 12:19 AM), <http://www.scotusblog.com/2013/03/argument-preview-is-pay-for-delay-of-drugs-illegal/>.

46. *Actavis*, 133 S. Ct. at 2229.

47. *Id.*

48. *Id.*

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.*

53. *Id.* at 2229, 2246.

54. *Id.*

55. *Id.* at 2229.

market until August 31, 2015.<sup>56</sup> At least one generic manufacturer (Actavis) also agreed to promote AndroGel to urologists.<sup>57</sup>

On January 29, 2009, the FTC filed an antitrust action against Solvay and the three generic manufacturers.<sup>58</sup> The FTC alleged that the settling parties violated the Federal Trade Commission Act, which renders unlawful “unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce . . . .”<sup>59</sup> The District Court held that the settlement did not violate the Act and dismissed the FTC’s complaint.<sup>60</sup> The Court of Appeals for the Eleventh Circuit affirmed.<sup>61</sup>

### B. Antitrust Analysis of Pay-for-Delay Settlements Prior to Actavis

The Supreme Court granted certiorari upon the FTC’s request to resolve a circuit split regarding antitrust scrutiny of pay-for-delay settlements.<sup>62</sup> In antitrust law, there are essentially two tests a court might apply to determine whether a particular arrangement violates antitrust law. First, the “per se” approach asks whether a violating act occurred.<sup>63</sup> If so, the actor is liable under antitrust law in spite of any arguments the defendant might make that the behavior was reasonable or necessary. Second, the “rule of reason” approach requires the court to consider the circumstances surrounding the accused activity.<sup>64</sup> This is a more fact-intensive inquiry and generally considers whether the activity was reasonable and therefore permissible.

Within this second rule of reason approach, courts may choose one of two paths to determine whether the activity was reasonable. Sometimes, courts decide to apply a quick look analysis for the rule of reason. This quick look test is applicable when the experience of the market is so clear as to indicate that a given act will be anticompetitive or the court can confidently conclude that the principle tendency of the restriction is to be anticompetitive.<sup>65</sup> This analysis is similar to the per se approach, but it gives the defendant the opportunity to present a procompetitive rationale support-

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56. *Id.* It is worth noting that unlike many pay-for-delay arrangements, this settlement does not keep generic versions of the pioneer drug off the market for the remainder of the pioneer’s patent life (the 2003 AndroGel patent is not set to expire until 2020). However, Solvay plans on releasing a new version of AndroGel in 2015 and the settlement prevents generic competition until the new version is released. Denniston, *supra* note 45.

57. *Actavis*, 133 S. Ct. at 2229.

58. *Id.* at 2229-30.

59. *Id.*; Federal Trade Commission Act (FTC Act), 15 U.S.C. § 45(a)(1) (2012).

60. *Actavis*, 133 S. Ct. at 2230.

61. *Id.*

62. *Id.*

63. *See, e.g.*, *U.S. v. Topco Assocs.*, 405 U.S. 596, 609-10 (1972) (discussing per se violations of antitrust law).

64. *See, e.g.*, *Nw. Wholesale Stationers, Inc. v. Pac. Stationery & Printing Co.*, 472 U.S. 284, 296-98 (1985) (discussing distinction between rule of reason and per se scrutiny).

65. *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 781 (1999) (discussing applicability of quick look scrutiny).

ing a contested arrangement. Alternatively, courts may apply a standard rule of reason analysis, the typical fact-intensive approach.

The rule of reason and per se approaches are only applicable when a court has reason to believe an antitrust violation occurred. Prior to *Actavis* several courts espoused the view that a pay-for-delay settlement could not constitute an antitrust violation. These courts took a broad view of patent rights, finding that the monopoly conveyed by a patent precludes antitrust analysis into patent litigation settlements.

Prior to *Actavis*, courts ran the gamut of these options in their antitrust analysis of pay-for-delay settlements. At one end of the spectrum were the Court of Appeals for the D.C. Circuit and the Sixth Circuit Court of Appeals, which applied the per se approach to their antitrust analysis of pay-for-delay settlements.<sup>66</sup> In *Louisiana Wholesale Drug Co. v. Hoechst Marion Roussel, Inc.*, the Sixth Circuit Court of Appeals affirmed the district court's grant of summary judgment on the issue of the illegality of a pay-for-delay settlement.<sup>67</sup> The court ruled that such settlements are horizontal agreements between businesses at the same level of competition, and thus presumptively anticompetitive.<sup>68</sup>

At the other end of the spectrum were the Second, Eleventh, and Federal Circuit courts. These courts held pay-for-delay settlements immune from antitrust attack provided that any such agreement did not exceed the "scope of the patent."<sup>69</sup> In *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, the Eleventh Circuit first articulated the so-called "scope of the patent test," holding that only those "provisions of the [a]greements found to have effects beyond the exclusionary effects of Abbott's patent" should be subjected to traditional antitrust analysis.<sup>70</sup> The Eleventh Circuit explicitly rejected the idea of using the reverse payment amount as an indicator that the brand-name manufacturer was not confident in the validity of its patent and thus was not entitled to the exclusionary benefits conferred by the patent.<sup>71</sup> The court noted that, "[g]iven the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement."<sup>72</sup> The Eleventh Circuit followed

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66. *Louisiana Wholesale Drug Co. v. Hoechst Marion Roussel, Inc.* (*In re Cardizem CD Antitrust Litig.*), 332 F.3d 896, 900 (6th Cir. 2003); *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 814 (D.C. Cir. 2001) (discussing application of per se rule).

67. *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 900.

68. *Id.* at 908.

69. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212 (2d Cir. 2004); *Valley Drug Co. v. Geneva Pharm.*, 344 F.3d 1294, 1310-12 (11th Cir. 2003).

70. *Valley Drug Co.*, 344 F.3d at 1312.

71. *Id.* at 1310.

72. *Id.*

this precedent in affirming the dismissal of the FTC's complaint in *Actavis* (then captioned as *FTC v. Watson Pharms., Inc.*).<sup>73</sup>

In 2012, the Third Circuit had its opportunity to rule on the legality of pay-for-delay settlements in the *K-Dur Antitrust Litigation*.<sup>74</sup> The Third Circuit rejected the "scope of the patent" test and held that pay-for-delay settlements were subject to quick look analysis.<sup>75</sup> The court instructed that the fact-finder in a pay-for-delay antitrust case should treat the settlement as "*prima facie* evidence of an unreasonable restraint of 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>76</sup>

### C. The *Actavis* Decision

It was against this backdrop that the Supreme Court rendered its decision in *Actavis*. The Supreme Court held that pay-for-delay settlements should be evaluated under the standard rule of reason approach. The Court's decision proceeded in three parts. First the Court rejected the "scope of the patent" test described above. Next the Court described five factors contributing to its determination that pay-for-delay settlements may run afoul of antitrust law. Finally, the Court explained that the quick look approach taken by the Third Circuit was inappropriate, and instructed courts to apply standard rule of reason analysis.

#### 1. Rejection of the "Scope of the Patent" Test

The *Actavis* Court soundly rejected the "scope of the patent test" the Eleventh Circuit had applied in affirming the dismissal of the FTC's complaint in *Actavis*.<sup>77</sup> The majority noted that while a "*valid* patent (emphasis in the original) excludes all except its owner from the use of the protected process or product . . . an invalidated patent carries with it no such right."<sup>78</sup> The majority asserted that Paragraph IV litigation places a patent's validity at issue and thus calls into question the monopoly conferred by the patent.<sup>79</sup>

The majority found no support in U.S. patent law for the proposition that a patent owner may "simply pay a competitor to respect its patent and quit its patent invalidity or noninfringement claim without any antitrust scrutiny."<sup>80</sup> The majority cited multiple precedents in support of the contention

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73. *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1313, 1315 (11th Cir. 2012) (following its *Valley Drug* holding).

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

75. *Id.* at 218.

76. *Id.*

77. *See* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2231 (2013).

78. *Id.* at 2231 (citing *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948)) (internal citation omitted).

79. *See id.*

80. *Id.* at 2233 (internal quotation marks omitted).

that improper use of a patent monopoly may violate antitrust law.<sup>81</sup> The majority further refused to accept the dissent's contention (which would have upheld the Eleventh Circuit's analysis) that pay-for-delay arrangements are a "well-known feature of intellectual property litigation."<sup>82</sup> And the majority rejected the suggestion that any patent litigation settlement in which an alleged infringer settles for less than the full amount requested by the patent-holder involves an implicit reverse payment (the supposed implicit reverse payment being the difference between the settlement amount and the amount initially demanded by the patent-holder).<sup>83</sup> The majority noted that this species of settlement is well established; a party with a claim for damages may agree to settle its case for less than the full amount of damages requested.<sup>84</sup> But the majority distinguished pay-for-delay arrangements on the ground that in a typical pay-for-delay arrangement, a party with no claim for damages (the generic manufacturer) receives money to drop its patent challenge.<sup>85</sup>

The majority also looked to the underlying policy of the Hatch-Waxman Act in rejecting the Eleventh Circuit's reasoning. In light of the "procompetitive thrust of the statute," and its requirement that all pharmaceutical patent litigation settlements be reported to the FTC and the Antitrust Division of the Department of Justice, the majority concluded that the statutory policy of the Act was clearly contrary to the Eleventh Circuit's analysis.<sup>86</sup>

In rejecting the Eleventh Circuit's "scope of the patent" test, the majority adopted the view that pay-for-delay settlements might run afoul of antitrust laws even where the terms of the agreement fall within the preclusive scope of the patent. The majority conceded that the Eleventh Circuit view was supported by a general legal policy favoring the settlement of disputes.<sup>87</sup> The majority also acknowledged (though later dismissed) the Eleventh Circuit's concern that subjecting pay-for-delay settlements to antitrust scrutiny would force courts to examine the validity of the underlying patent as part of their antitrust inquiry.<sup>88</sup> Having invalidated the "scope of the patent" test, the Court described five factors that it believed warranted closer scrutiny of pay-for-delay arrangements.

## 2. The Court's Five Factor Analysis

The majority noted that "five sets of considerations" lead to the conclusion that the FTC should have had the opportunity to prove its antitrust case.

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81. *Id.* at 2231-33 (internal quotation marks omitted) (citing cases).

82. *Id.* at 2233.

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.* at 2234.

87. *Id.*

88. *Id.*

First, the majority pointed to the potential for “genuine adverse effects on competition.”<sup>89</sup> The majority noted that although the patent-holder in a pay-for-delay arrangement claims an exclusive right to market its product, that right would be lost were the patent found invalid or not infringed.<sup>90</sup> The majority did not find it significant that the *Actavis* settlement itself would have permitted generic competition prior to the expiration of the 2003 patent, noting that the patent-holder could simply raise prices to realize its expected patent-derived revenue.<sup>91</sup>

The majority also addressed the argument that when a patent-holder reaches a pay-for-delay agreement with one generic competitor, it signals to other generic competitors that the patent-holder believes its patent is weak, thereby incentivizing further challenges.<sup>92</sup> The majority noted that only the first generic manufacturer to file an ANDA with a Paragraph IV certification receives the benefit of the 180-day period of generic exclusivity. As noted above (and highlighted by the majority), this period of generic exclusivity may be worth hundreds of millions of dollars to the first Paragraph IV ANDA filer. Subsequent would-be generic challengers, the majority contended, have significantly less incentive to incur the costs of patent litigation.<sup>93</sup> Although the majority did not address the *Actavis* settlement specifically in making this argument, it is worth noting that the facts of *Actavis* provide strong support for the majority’s position. Under the *Actavis* settlement, Solvay would pay Actavis somewhere between \$171 and \$270 million total.<sup>94</sup> The other two generic competitors would receive a combined \$72 million.<sup>95</sup> These figures bolster the majority’s argument that the existence of multiple, subsequent generic filers does not render a pay-for-delay settlement untenable for the patent-holder. This is a crucial point that will be explored in greater detail in Part IV, *infra*.

Second, the majority noted that in at least some cases the anticompetitive effects of a pay-for-delay settlement will not be justified by legitimate settlement concerns.<sup>96</sup> While the majority noted that in some cases legitimate concerns such as offsetting the cost of litigation or providing compensation for services might warrant a reverse payment, it found the potential existence of such justifications insufficient to completely shield such settlements from antitrust scrutiny.

Third, the majority noted that pharmaceutical patent-holders have market power substantial enough to allow them to charge prices well above the

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89. *Id.*

90. *Id.*

91. *Id.* at 2234-35.

92. *Id.* at 2235.

93. *Id.*

94. *See id.* at 2229.

95. *See id.*

96. *Id.* at 2235-36.

competitive level.<sup>97</sup> This market power makes it feasible for a patent-holder to make large reverse payments to exclude others from the marketplace.<sup>98</sup>

Fourth, the majority asserted that contrary to the Eleventh Circuit's suggestion, it would not be necessary to litigate the underlying patent validity as part of an antitrust inquiry into a pay-for-delay settlement.<sup>99</sup> The majority suggested that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival."<sup>100</sup> The majority held that even where the risk of patent invalidation is low, a large payment designed to "prevent the risk of competition" constitutes an anticompetitive harm.<sup>101</sup>

Fifth, and finally, the majority noted that subjecting pay-for-delay settlements to antitrust scrutiny would not run completely counter to the policy favoring the settlement of disputes.<sup>102</sup> The majority acknowledged that the litigating parties were free to settle their dispute by allowing generic competition at some point prior to the expiration of the underlying patent without the patent-holder making a reverse payment.

### 3. The Appropriate Level of Scrutiny

Although the majority held pay-for-delay settlements subject to antitrust scrutiny, it declined to label such arrangements presumptively or per se unlawful. In doing so, the majority rejected the quick look analysis proposed by the Third Circuit in the *K-Dur Antitrust Litigation*. The majority held that such quick look analysis was appropriate only where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets."<sup>103</sup> Thus, the majority adopted the standard rule of reason approach for evaluating pay-for-delay settlements, placing the burden of proof on the FTC in proving an antitrust violation.<sup>104</sup>

Ultimately the majority in *Actavis* took an intermediate approach in resolving the circuit split surrounding the legality of pay-for-delay settlements. The majority, although critical of the Eleventh Circuit's "scope of the patent" analysis, acknowledged that certain circumstances might render some form of reverse payment appropriate. As a result, the FTC, in bringing an antitrust suit related to a pay-for-delay settlement, must be prepared to prove that an antitrust violation has in fact occurred. However, the Court in *Actavis* suggested that the FTC could satisfy this burden by focusing on the

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97. *See id.* at 2236.

98. *See id.*

99. *Id.*

100. *Id.*

101. *Id.*

102. *See id.* at 2237.

103. *Id.* (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999)).

104. *Id.*



reverse payment amount, rather than the underlying patent validity. The question to be addressed in the next section is whether this state of affairs effectively addresses the antitrust concerns raised by pay-for-delay settlements.

### III

*Actavis* eliminated confusion regarding the antitrust inquiry to be applied to pay-for-delay settlements. The Court rejected the Eleventh Circuit's "scope of the patent" test, electing instead to subject pay-for-delay agreements to standard rule of reason analysis. The Court emphasized that the size of an "unexplained reverse payment" may evince a brand-name manufacturer's intent to curb competition. And further, the Court explicitly rejected the contention that the risk of invalidation was a valid justification for a large reverse payment. The Court encouraged brand-name and generic manufacturers to settle in other ways, such as by allowing the generic manufacturer to enter the pioneer drug's market prior to the patent's expiration, without the brand-name manufacturer making a reverse payment.

This would seem to suggest that the Supreme Court in *Actavis* imposed significant limitations on the ability of brand-name manufacturers to enter into anticompetitive arrangements with generic competitors. In fact, many commentators (and the FTC itself) were quick to call the *Actavis* decision a victory for the FTC.<sup>105</sup> However, a closer analysis of the decision's impact suggests that a more tempered reaction is appropriate. In emphasizing the size of the reverse payment in determining whether a given settlement is impermissibly anticompetitive, the Court failed to recognize that there may be forms of pay-for-delay settlement—not involving any ostensible monetary reverse payment—that threaten to work similar anticompetitive harm. This section first examines a recent case arising in the District of New Jersey, *In re Lamictal Direct Purchaser Antitrust Litigation*, which demonstrates how brand-name manufacturers may be able to skirt the antitrust scrutiny described by the Court in *Actavis* by engaging in forms of anticompetitive settlement involving more subtle pay-for-delay arrangements. This section then describes how the parties to a potentially anticompetitive agreement may be able to direct antitrust litigation to a favorable forum where such an agreement is likely to pass antitrust scrutiny.

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105. E.g., David Sell, *Pharma Takes Some Comfort From 'Pay-to-Delay' Ruling*, PHILLY.COM (June 20, 2012), [http://articles.philly.com/2013-06-20/business/40072451\\_1\\_patent-settlements-hatch-waxman-act-ftc](http://articles.philly.com/2013-06-20/business/40072451_1_patent-settlements-hatch-waxman-act-ftc); see, e.g., Alan Morrison, *Commentary: Subjecting Reverse Payments in Patent Cases to Antitrust Scrutiny: Sounds Like a Good Idea, but Can It Work?*, SCOTUSBLOG (July 25, 2012, 10:23 AM), <http://www.scotusblog.com/2013/07/commentary-subjecting-reverse-payments-in-patent-cases-to-antitrust-scrutiny-sounds-like-a-good-idea-but-can-it-work/>.

A. *Alternative Forms of Pay-for-Delay Settlement May Result in Equally Anticompetitive Outcomes as Overt Reverse Payment Settlements—  
The Lamictal Case*

The *Actavis* decision makes it clear that a large, unexplained reverse payment is unlikely to stand up to antitrust scrutiny. This addresses one form of anticompetitive settlement agreement, but leaves the door open for brand-name manufacturers to settle patent litigation in other ways that seem ostensibly anticompetitive. The post-*Actavis* case, *Lamictal*, addressed a settlement between a brand-name manufacturer, GlaxoSmithKline (“GSK”), and a generic manufacturer, Teva Pharmaceuticals.<sup>106</sup> The settlement involved no ostensible monetary payment from brand-name to generic manufacturer, but as will be discussed in greater detail below, effectively amounted to a pay-for-delay settlement. Nonetheless, the District Court in *Lamictal* found *Actavis* applicable to only those cases involving a monetary reverse payment, and dismissed the plaintiffs’ antitrust complaint.<sup>107</sup>

1. Facts

GSK held a patent (“the ‘017 patent”) on lamotrigine, the active ingredient in Lamictal, a medication for bipolar disorder and epilepsy.<sup>108</sup> The ‘017 patent was set to expire in July, 2008. However, in 2002, Teva filed an ANDA containing a Paragraph IV certification, and in response, GSK sued for infringement.<sup>109</sup> On January 27, 2005, the judge in the patent litigation ruled from the bench that claim I of the ‘017 patent was invalid.<sup>110</sup> Six days later, in response to the judge’s ruling on invalidity, the parties to the patent litigation informed the judge that they were involved in settlement negotiations and requested that the judge refrain from issuing any further rulings.<sup>111</sup>

The parties subsequently reached an agreement which provided, among other things, that Teva would be permitted to sell chewable versions of lamotrigine beginning on June 1, 2005, thirty-seven months before the ‘017 patent was set to expire.<sup>112</sup> Under the agreement, the chewable tablets would be provided to Teva by GSK.<sup>113</sup> In exchange, Teva agreed that it would not

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106. *Lamictal Direct Purchaser Antitrust Litig. v. All Direct Purchaser Action (In re Lamictal Direct Purchaser Antitrust Litig.)*, No. 12-cv-995 (WHW), 2014 U.S. Dist. LEXIS 9257 (D.N.J. Jan. 24, 2014).

107. *Id.* at \*30.

108. *Id.* at \*2-3.

109. *Id.* at \*3.

110. *Id.*

111. *Id.*

112. *Lamictal Direct Purchaser Antitrust Litig. v. All Direct Purchaser Action (In re Lamictal Direct Purchaser Antitrust Litig.)*, No. 12-995 (WHW), 2012 U.S. Dist. LEXIS 183627, at \*7-8 (D.N.J. Dec. 6, 2012). The actual settlement was slightly more complex, involving issues of FDA regulatory law beyond those discussed above. However, for the purposes of this note, this is the pertinent element of the settlement agreement.

113. *Id.* at \*8.

sell generic non-chewable lamotrigine tablets until the expiration date of the '017 patent.<sup>114</sup> Crucially, the patent litigation court entered an order withdrawing its ruling invalidating claim I of the '017 patent—a patent claim that had been invalidated was effectively reinstated by the court pursuant to the settlement agreement.<sup>115</sup>

Following the settlement, a class action lawsuit was initiated by a group of direct purchasers of drugs containing lamotrigine alleging that the terms of the settlement violated federal antitrust laws by including an impermissible reverse payment.<sup>116</sup> On December 6, 2012, (before *Actavis*) the District Court granted defendants' motion to dismiss on the grounds that the term "reverse payment" only applied to monetary payments. Since *Actavis* had not been decided at this point, the District Court was relying on the Third Circuit's holding in the *K-Dur Antitrust Litigation*.<sup>117</sup>

## 2. The Post-*Actavis Lamictal* Ruling

*Actavis* was decided while the District Court's dismissal of the antitrust action was on appeal before the Third Circuit.<sup>118</sup> After *Actavis* was decided, the Third Circuit remanded the antitrust action to allow the District Court to reconsider its dismissal in light of *Actavis*.<sup>119</sup> On January 24, 2014, the District Court ruled that *Actavis* did not extend antitrust scrutiny to settlement arrangements not involving monetary reverse payments.<sup>120</sup> The District Court noted that the majority opinion (as well as the dissent) "reek[ed] with discussion of payment of money."<sup>121</sup> The Court specifically noted that the Court in *Actavis* approved of parties "sett[ing] in other ways . . . by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration."<sup>122</sup> Based on this conclusion, the District Court affirmed its 2012 decision dismissing the antitrust action.

## 3. The Anticompetitive Effects of the *Lamictal* Settlement

The District Court was technically correct in finding that the *Lamictal* settlement did not provide for any monetary reverse payment. Additionally, the court was correct in finding that the language of *Actavis* is largely addressed to monetary payments. Nonetheless, the terms of the settlement resulted in a *de facto* reverse payment being made to Teva in exchange for

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114. *Id.*

115. *See id.* at \*8-9.

116. *See id.* at \*2.

117. *See id.* at \*20.

118. *Lamictal Direct Purchaser Antitrust Litig. v. All Direct Purchaser Action (In re Lamictal Direct Purchaser Antitrust Litig.)*, No. 12-cv-995 (WHW), 2014 U.S. Dist. LEXIS 9257, at \*2 (D.N.J. Jan. 24, 2014).

119. *Id.*

120. *Id.* at \*20-21.

121. *Id.* at \*21.

122. *Id.* at \*29-30.

keeping non-chewable, generic lamotrigine off the market until the expiration of the '017 patent. This arrangement resulted in anticompetitive harm identical to that caused by overt monetary pay-for-delay arrangements.

Specifically, the settlement agreement substantially delayed widespread generic proliferation. Recall that Teva had effectively won its patent challenge; the judge in the patent litigation had issued a ruling invalidating Claim I of the '017 patent.<sup>123</sup> In the absence of the settlement agreement, Teva's ANDA for a generic version of lamotrigine would have been approved pursuant to its Paragraph IV certification.<sup>124</sup> Teva would have received the benefit of the 180-day exclusivity period, after which other generic manufacturers would have been able to enter the market. Instead, Teva dropped its (successful) patent challenge after being offered the opportunity to participate in a lucrative distribution scheme for chewable lamotrigine. Although no money changed hands, Teva was given a product that it could easily sell for money in exchange for withholding another product (non-chewable lamotrigine) from the market.

It is true that another generic manufacturer could have upset this agreement by attempting to invalidate the '017 patent after Teva dropped its challenge. However, as noted in Part II, *supra*, only the first ANDA filer is entitled to the 180-day exclusivity period. If the first-filer settles, the current regulatory regime does not allow a subsequent-filer to claim the benefit of the 180-day window. As a result, even though the odds of success were high (given the initial ruling in the patent litigation), subsequent would-be ANDA filers may not have been adequately incentivized to incur the monetary and time cost of patent litigation.

Thus, although the settlement agreement allowed one generic manufacturer to enter the market prior to the expiration of the '017 patent, its overall effect was to significantly curb competition. A brand-name manufacturer that had already lost its patent challenge made a *de facto* reverse payment to a generic manufacturer. A patent litigation defendant with no claim for damages was rewarded by the plaintiff (albeit without an overt reverse payment) simply for walking away from its patent challenge. The agreement gave GSK and Teva a duopoly in the market for chewable lamotrigine, and maintained GSK's exclusivity in the market for non-chewable lamotrigine. In spite of its clear anticompetitive thrust, under one District Court's conception of *Actavis*, this agreement was held immune from antitrust scrutiny because the reverse payment at issue was not monetary.

#### B. Selection of a Favorable Forum

It is possible that the *Lamictal* court's holding will be reversed on appeal. The Third Circuit may clarify that it believes *Actavis* to encompass

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123. *Id.* at \*3.

124. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (2012).

more than monetary reverse payments.<sup>125</sup> But, in those circuits that previously applied the “scope of the patent test” (e.g., the Eleventh Circuit), courts may find the logic of the *Lamictal* court appealing. Courts in these circuits, which previously espoused a broad view of patent rights, may be inclined to similarly restrict the *Actavis* holding to monetary reverse payments, as a means of limiting antitrust scrutiny. This section suggests that it may be relatively easy for the parties to a pay-for-delay settlement to steer antitrust litigation to these more favorable fora.

*Actavis* itself is instructive on how patent litigants may be able to select a favorable forum for antitrust litigation. Solvay initiated its 2003 patent infringement suit in the Northern District of Georgia (part of the Eleventh Circuit).<sup>126</sup> In 2009, when the FTC initiated its antitrust suit, it was joined by a group of direct and indirect AndroGel purchasers who filed complaints in a number of different federal district courts.<sup>127</sup> Ultimately, however, the case was consolidated and transferred to the Northern District of Georgia, where the underlying patent litigation had taken place. The district court in the antitrust case noted that all of the cases had been transferred either by change of venue or by order of the United States Judicial Panel on Multi-District Litigation (JPML).<sup>128</sup>

In determining a transferee court and judge, the JPML considers a number of factors.<sup>129</sup> Two of these factors are salient here: 1) The location of related court proceedings, and 2) the familiarity of the transferee judge with factual or legal issues in the litigation.<sup>130</sup> Thus, the *Actavis* patent litigants had a strong argument that the antitrust litigation should be transferred to the same venue as the underlying patent litigation. This argument clearly prevailed as the antitrust litigation was transferred not only to the district in which the underlying patent litigation was initiated, but also to the judge to whom the patent litigation was originally assigned.<sup>131</sup>

The course of the *Actavis* litigation demonstrates how patent litigants may steer an antitrust inquiry to a court likely to respond favorably to arguments limiting the scope of *Actavis*. The critical step is to initiate the underlying patent litigation in a district court in the desired circuit. If patent litigants plan ahead in selecting a forum for patent litigation, subsequent

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125. Recall that the Third Circuit was one of the circuits relatively hostile to pay-for-delay arrangements before the *Actavis* decision, subjecting such arrangements to a quick-look rule of reason analysis. See *supra* Part II.B.

126. *In re AndroGel Antitrust Litig.* (NO. II), 687 F. Supp. 2d 1371 (N.D. Ga. 2010).

127. *Id.* at 1375-76.

128. *Id.* at 1376.

129. Daniel A. Richards, Note, *An Analysis of the Judicial Panel on Multidistrict Litigation's Selection of Transferee District and Judge*, 78 *FORDHAM L. REV.* 311, 321-22 (2009).

130. *Id.* at 321-22.

131. See *AndroGel Antitrust Litig.*, 687 F. Supp. 2d at 1371, 1376; *In re AndroGel Antitrust Litig.* (No. II), 655 F.Supp.2d 1351, 1351-52 (J.P.M.L. 2009).

multi-district antitrust litigation may well be transferred back to that same court.

When the FTC acts unilaterally by ordering the cessation of an anticompetitive practice, patent litigants have an even easier path to antitrust review by the circuit of their choice. Under the FTC Act, a party challenging an FTC order may seek review with the court of appeals for any circuit in which the party resides or carries on business.<sup>132</sup> In that situation, the parties to a pay-for-delay settlement being challenged by the FTC need only request that their appeal be directed to their forum of choice.

The issue of forum selection is important because it suggests that antitrust litigation may be steered to those circuits which, prior to *Actavis*, were the most receptive to pay-for-delay settlements—those circuits applying the “scope of the patent” test. It is possible that these circuits will change course following the ruling in *Actavis*. However, the more likely result is that courts in these circuits will try to limit the *Actavis* holding to better fit their broad conception of patent rights.

#### IV

The previous section suggests that *Actavis* may not be sufficient in itself to curb more insidious forms of reverse payment settlements, specifically, those not involving an overt monetary payment. This problem may be especially pronounced in jurisdictions that were previously inclined to treat pay-for-delay arrangements favorably. This Note now turns to potential solutions to these issues. After concluding that judicial and antitrust-based legislative solutions are unlikely to be forthcoming or effective, this Note proposes a modification to the FDA regulatory regime designed to make anticompetitive settlement arrangements less appealing to both brand-name and generic manufacturers. This section concludes by demonstrating how the proposed modification would apply under the facts of *Actavis* and *Lamictal*.

A possible, though unlikely, solution to the issues raised in Part III would be Supreme Court action to clarify and expand the holding of *Actavis* to encompass pernicious non-monetary settlement arrangements. Although the Supreme Court might eventually clarify its position on this issue, such a decision seems unlikely to occur in the immediate future. A second solution would be for Congress to pass antitrust-based legislation codifying and expanding the *Actavis* holding. This solution also seems unlikely. There have been several attempts made in Congress to legislate broadly against pay-for-delay settlements under antitrust law, but thus far these attempts have been unsuccessful.<sup>133</sup>

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132. 15 U.S.C. § 45(c) (2012).

133. See, e.g., THOMAS, *supra* note 5, at 12.

A more effective, and possibly more feasible, approach would be to alter the regulatory framework of the pharmaceutical industry to reduce the economic incentives for pay-for-delay arrangements involving both overt monetary reverse payments and non-monetary *de facto* reverse payments. This Note now proposes a solution in this vein: the FDA should make the 180-day Hatch-Waxman generic exclusivity period available to a subsequent ANDA filer if the first-filer settles its patent challenge.

This proposal modifies two elements of the existing regime. First, if the first ANDA-filer settles its patent challenge by agreeing to delay entry into the market, then that manufacturer should forfeit the 180-day period of generic exclusivity provided by the Hatch-Waxman Act. As noted in Part I.A, the forfeiture provision is difficult to trigger in the event of settlement— forfeiture requires a final appellate judgment that the proposed settlement violates antitrust law.<sup>134</sup> Hemphill and Lemley have argued, and this Note agrees, that the forfeiture provision of the Hatch-Waxman Act should be augmented to reach those instances where the first-to-file generic manufacturer settles without obtaining a judgment of non-infringement or patent invalidity.<sup>135</sup>

Second, in the event that the first-filer forfeits the 180-day period of exclusivity, the exclusivity window should be made available to the next-in-line ANDA-filer. This is the crux of the current proposal. Recall that under the current regulatory regime, the period of generic exclusivity attaches only to the first-filer.<sup>136</sup> In the event that the first ANDA-filer forfeits the 180-day window, the period of exclusivity does not cede to any subsequent filer.<sup>137</sup> Allowing subsequent ANDA-filers the benefit of this period of exclusivity in the event that the first-filer settles would make anticompetitive arrangements like those in *Actavis* and *Lamictal* less feasible for the both the brand-name manufacturer and the generic manufacturer.

The proposed modification to the regulatory regime addresses the issue of pay-for-delay settlements at a different level than a judicial decision or new antitrust law. Rather than simply declaring a particular genus of settlement illegal or subject to heightened antitrust scrutiny, this modification works to reduce the incentives for anticompetitive pay-for-delay settlements. Additionally, as discussed below, the proposed modification to the regulatory regime is more adaptable in dealing with different forms of anticompetitive arrangements between brand-name and generic manufacturers. The following subsections describe how this proposed rule would operate under the facts of *Actavis* and *Lamictal* to reduce incentives for anticompetitive settlement.

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134. Hemphill & Lemley, *supra* note 30, at 971.

135. *Id.* at 971-72.

136. Hemphill, *supra* note 26, at 1560-61.

137. *Id.* at 1583-84.

### A. Applying the Proposed Rule to the Facts of Actavis

In *Actavis*, this rule would have dramatically increased the costs to Solvay of settling the Androgel patent litigation via reverse payment. The reverse payment to the first-filer, Actavis, was substantial: \$19-30 million annually for nine years. The potential 180-day exclusivity window available to Actavis as the first ANDA-filer made Actavis a highly motivated challenger. As a result, it was expensive for Solvay to pay Actavis to drop its patent challenge. By contrast, the two subsequent ANDA-filers received a far more meager combined \$72 million. Without the benefit of the generic exclusivity afforded to the first-filer, these subsequent challengers were willing to drop their cases for significantly less money than Actavis was.

The proposed rule would likely have prevented Solvay from settling the patent litigation with this type of declining payment scheme by creating a line of highly motivated generic challengers. Under the proposed regime, settlement by the first-filer would result in forfeiture, giving the next-in-line challenger the right to the 180-day period of generic exclusivity. This subsequent filer would now have the same incentive as the first-filer to see its patent challenge through, and would require a comparably high reverse payment to drop its challenge. The effect of creating multiple, subsequent, highly motivated challengers would be to make reverse payments cost-prohibitive for the brand-name manufacturer. Furthermore, such exorbitant reverse payment amounts would likely not pass muster under the *Actavis* antitrust inquiry, given the *Actavis* Court's emphasis on the reverse payment amount.

### B. Applying the Proposed Rule to the Facts of Lamictal

As applied to the facts of *Actavis*, the proposed rule generally operates on the brand-name manufacturer's incentives. The rule increases the cost to the brand-name manufacturer of settling with a reverse payment. Under the facts of *Lamictal*, the rule operates more effectively on the generic manufacturer's incentives. Teva would not have settled its case in the way it did if it knew that another generic manufacturer was pursuing a challenge to the '017 patent covering lamotrigine. If a subsequent challenger pursued its case to a judgment of invalidity or noninfringement, Teva would be left with a worthless exclusive license. Teva would forfeit the period of exclusivity upon settlement, and the exclusivity would cede to the next-in-line challenger. Given that Teva had already won its patent challenge, it would clearly be better off taking the 180-day statutory period of exclusivity than settling its case and allowing the exclusivity window to go to a competitor.

The Teva settlement worked for Teva (and GSK) because there were no next-in-line challengers. As the first-filer, only Teva was motivated to challenge GSK's lamotrigine patent. This made the *Lamictal* licensing agreement feasible. As suggested above, in Part III, this state of affairs stems



from a lack of incentives for subsequent generic challengers to initiate patent challenges. If a subsequent generic challenger could claim the benefit of the 180-day period of exclusivity, it would have far greater incentives to initiate a challenge to a brand-name patent (especially when, as in *Lamictal*, the brand-name patent stood on such tenuous footing).

Note that the proposed rule would have made the agreed-upon settlement unappealing to Teva in another respect. If a subsequent generic challenger prevailed in its patent challenge, Teva would be forced to remove its generic version of chewable lamotrigine from the market during the subsequent challenger's 180-day term of generic exclusivity. Teva would thus incur any costs associated with removing its product from the market.

As the above analysis demonstrates, the proposed rule's economic effects would curb anticompetitive settlements by making them less feasible for the parties to patent litigation. In the case of a typical reverse payment, the proposed rule increases the cost to the brand-name manufacturer of this type of settlement. Where the anticompetitive effect is predicated on a *de facto*, but non-monetary reverse payment (as in *Lamictal*), the rule operates by making it singularly unappealing for the generic manufacturer to settle its challenge in the face of a weak patent.

### CONCLUSION

In the wake of *Actavis* it appears that non-judicial mechanisms may be necessary to curb the problems posed by anticompetitive settlements between brand-name and generic manufacturers. The rule of reason analysis prescribed by the Court leaves room for anticompetitive pay-for-delay settlements, particularly those involving non-monetary provisions that function as reverse payments. As noted in Part III's discussion of the *Lamictal* case, these forms of settlement work a substantial anticompetitive harm. The *Lamictal* settlement effectively deprived consumers of nearly three years of widespread generic availability. This Note has suggested a change to the regulatory framework of the pharmaceutical industry that makes anticompetitive settlements less economically feasible. The rule appears to adapt well to both traditional, overt reverse payments as well as alternative forms of pay-for-delay arrangements.

The goal of this modification is not to undermine patent protection for brand-name drugs. But as in all other industries, patent-holders should be subject to challenges to their patents' validity. The modification to the law surrounding generic exclusivity suggested by this Note will incentivize generic firms to more aggressively pursue invalidation of brand-name patents. This is particularly important in the pharmaceutical context, where patent challenges may result in decreased costs to consumers for life-saving medication.



