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**JUMPING INTO THE ACTAVIS BRIAR PATCH—INSIGHT  
INTO HOW COURTS MAY STRUCTURE REVERSE  
PAYMENT ANTITRUST PROCEEDINGS AND THE  
QUESTIONS THAT ACTAVIS LEFT UNANSWERED**

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I. INTRODUCTION.....	1371
II. WHAT ARE REVERSE PAYMENT SETTLEMENT AGREEMENTS?.....	1372
A. <i>The Basic Framework of Hatch-Waxman Litigation</i> .....	1373
B. <i>The Federal Trade Commission’s View of Reverse Payment         Settlements and Its Future Goals</i> .....	1376
III. LESSONS LEARNED FROM ACTAVIS.....	1378
A. <i>Synopsis of the Facts of the Actavis Decision</i> .....	1379
B. <i>A Detailed Review of the Supreme Court’s Five Sets of         Considerations to Bring a Claim</i> .....	1380
1. <i>Potential Genuine Adverse Effect on Competition</i> .....	1381
2. <i>Was the Payment “Justified”</i> .....	1383
3. <i>The Patentee’s Ability to Bring About the             Anticompetitive Harm</i> .....	1384
4. <i>The Size of the Unexplained Payment Is a Workable             Surrogate for Litigating the Patent Issues and Makes             the Antitrust Litigation Feasible</i> .....	1385
5. <i>Antitrust Liability for Large Unjustified Reverse             Payments Does Not Prevent Parties from Settling</i> .....	1385
C. <i>What Is Left Unanswered by Actavis</i> .....	1386
1. <i>What Is “Payment”?</i> .....	1386
a. <i>District Court Construes Reverse Payment                 Settlements as Requiring a Monetary Payment</i> .....	1387
b. <i>District Courts Construe Reverse Payments as                 Including Nonmonetary Payments</i> .....	1389
2. <i>What Constitutes a “Large” Payment?</i> .....	1393

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3. *What Impact, If Any, Does Giving up the 180-Day Market Exclusivity Have?*..... 1395

IV. STRUCTURING OF THE RULE-OF-REASON ANTITRUST LITIGATION ..... 1395

A. *Guidance from the Supreme Court’s Actavis Opinion*..... 1395

B. *Application of the Actavis Rule-of-Reason Analysis*..... 1396

1. *Market Power in the Relevant Market* ..... 1397

2. *Anticompetitive Consequences*..... 1398

3. *Weighing Economic Detriments Against the Economic Benefits* ..... 1400

4. *Exception to Antitrust Liability—Noerr-Pennington Immunity*..... 1401

V. INSIGHT INTO HOW COURTS MAY STRUCTURE ANTITRUST PROCEEDINGS AND APPLY THE *ACTAVIS* RULE-OF-REASON... 1402

VI. CONCLUSION ..... 1405

## I. INTRODUCTION

While the Supreme Court’s recent opinion in *Federal Trade Commission v. Actavis, Inc.*<sup>1</sup> resolved the circuit split regarding reverse payment settlements,<sup>2</sup> the full scope of its decision is yet to be seen. The Court declined to hold that reverse payments were presumptively unlawful or that they were immune from antitrust attack. Rather, the Court held that a rule-of-reason approach should apply when evaluating the antitrust implications of a reverse payment settlement. The Court left it to lower courts to “jump in the briar patch”<sup>3</sup> and structure the rule-of-reason antitrust litigation. Yet, the *Actavis* decision, statements by the Federal Trade Commission (FTC), and some subsequent rulings provide insight into what may constitute an acceptable reverse payment settlement

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

2. *Id.* at 2227. These settlements have been referred to by a variety of names. While some may find this term misleading or pejorative, the Court chose to use this term to describe a specific type of settlement and I will do the same for consistency.

3. *See In re AndroGel Antitrust Litig.* (No. II), No. 1:09-MD-2084, 2013 U.S. Dist. LEXIS 174273, at \*10 (N.D. Ga. Oct. 23, 2013) (“As much as I would love some guidance from the Eleventh Circuit on how in the heck a trial judge (and a jury) is supposed to apply the *Actavis* decision to an actual case, I doubt that the Eleventh Circuit is going to jump into that briar patch until it has to.”).

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agreement. Lower courts will have to decide some seminal questions in light of the decision:

- (1) What is a “reverse payment”? Can it include nonmonetary compensation?
- (2) What makes a payment “large”?
- (3) If the first-filed Abbreviated New Drug Application (ANDA) applicant gave up its statutorily granted 180-day market exclusivity, does that impact the analysis?
- (4) When is a reverse payment justified?
- (5) Should courts apply the rule-of-reason analysis to all patent settlements or only after it has determined that there was a reverse payment?

The *Actavis* decision does *not* directly answer these questions. However, a detailed review of the facts of *Actavis*, the decision itself, statements by the FTC regarding its view of reverse payment agreements, and some subsequent rulings provide insight into how these questions may be answered and what may constitute an acceptable reverse payment settlement agreement.

## II. WHAT ARE REVERSE PAYMENT SETTLEMENT AGREEMENTS?

The Court characterized a “reverse payment” settlement agreement as a settlement that “requires the patentee to pay the alleged infringer, rather than the other way around.”<sup>4</sup> The Court described these settlements as typically taking the form of Company A suing Company B for patent infringement. Company A and Company B settle under terms that require (1) the claimed infringer, Company B, to stay off the market until the patent’s term expires, and (2) the patentee, Company A, paying Company B. The Court noted that

[a]pparently most if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation, and specifically in the context of suits brought under statutory provisions allowing a generic drug manufacturer (seeking speedy marketing approval) to challenge the validity of a patent owned by an already approved brand name drug owner.<sup>5</sup>

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

5. *Id.* at 2227. In his dissent, Chief Justice Roberts disagrees with this assertion. He points out that a patentee may pay an alleged infringer to drop counterclaims of invalidity. *Id.* at 2245 (Roberts, C.J., dissenting).

In its brief, Respondent Solvay posited as to why this might be the case. According to Solvay, these settlements have “a different appearance” due to the Hatch-Waxman statutory framework.<sup>6</sup> This framework typically provides for patent litigation before any allegedly infringing product enters the market and before any monetary damages can accrue. The FTC views reverse payments as subverting the balance of competing policies struck by this framework.<sup>7</sup> According to the FTC, the framework reflects “a balance of benefits for generic manufacturers and protections from competition for brand-name manufacturers.” Reverse payments upset this balance by giving the brand name manufacturer the added opportunity to “purchase still more protections by sharing monopoly profits.”<sup>8</sup>

A. *The Basic Framework of Hatch-Waxman Litigation*

Under the framework of the Hatch-Waxman Act, patent litigation is typically required. A drug manufacturer seeking to market a new prescription drug must submit a New Drug Application with the Food and Drug Administration (FDA).<sup>9</sup> According to the Pharmaceutical Research and Manufacturers of America, on average, an innovator pharmaceutical company invests more than one billion dollars for each FDA-approved medicine.<sup>10</sup> To protect these investments, brand name manufacturers seek patent protection. Once the FDA has approved the brand name drug for marketing, a manufacturer of a generic drug can enter the market by filing an ANDA.<sup>11</sup> An ANDA requires that the generic manufacturer specify that its product will have the same active ingredient and is biologically equivalent to the approved brand name drug.<sup>12</sup> This allows the generic manufacturer to avoid the “costly and time-consuming” studies needed to obtain approval”

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6. Brief for Respondent Solvay Pharmaceuticals, Inc. at 18, *Actavis*, 133 S. Ct. 2223 (No. 12-416), 2012 WL 5507198.

7. Brief for the Petitioner at 16–17, *Actavis*, 133 S. Ct. 2223 (No. 12-416), 2013 WL 267027.

8. *Id.*

9. See 21 U.S.C. § 355(b)(1) (2012).

10. Brief for Pharmaceutical Research & Manufacturers of America (PhRMA) as Amici Curiae in Support of Respondents at 6, *Actavis*, 133 S. Ct. 2223 (No. 12-416), 2013 WL 769196.

11. See 21 U.S.C. § 355(j)(2).

12. *Id.* § 355(j)(2)(A).

for the brand name drug.<sup>13</sup> As such, the average generic drug costs only about one-third as much as the average brand name drug.<sup>14</sup> Yet, the consumers cannot enjoy these cost savings immediately.

The timing of an ANDA's approval depends on the patent covering the brand name drug, since the FDA cannot authorize a generic drug that would infringe a patent.<sup>15</sup> To facilitate approval, the Hatch-Waxman framework directs brand name manufacturers to list the patents covering the drug in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book").<sup>16</sup> In turn, the generic manufacturer, when filing its ANDA, must provide assurances that its proposed product will not infringe any patent. This can take the form of certifying that the relevant patents have expired, requesting approval to market once the patents still in force expire, or by certifying that any listed relevant patent "is invalid or will not be infringed by the manufacture, use or sale" of the proposed drug (typically called a "paragraph IV" certification).<sup>17</sup> The filing of a paragraph IV certification is a technical act of infringement and often provokes the litigation.<sup>18</sup> If the patentee brings suit within forty-five days of the paragraph IV certification, the FDA must withhold approval of the ANDA until a court resolves the issues of patent validity and infringement, or thirty months have expired.<sup>19</sup> The framework also provides an incentive to the first ANDA filer by granting the first filer 180 days of exclusivity.<sup>20</sup> During this period of exclusivity, no other generic can compete with the brand name drug. As stated by the Supreme Court, the "vast majority of potential profits for a generic manufacturing materialize during this 180-day exclusivity period."<sup>21</sup>

This structure is not conducive to "typical settlements." In a "typical" patent case, the monetary value of potential damage from

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13. *Actavis*, 133 S. Ct. at 2228 (citing *Eli Lilly & Co. v. Medtronic Inc.*, 496 U.S. 661, 676 (1990)).

14. Brief for Generic Pharmaceutical Association as Amici Curiae Supporting Respondents at 8–9, *Actavis*, 133 S. Ct. 2223 (No. 12-416), 2013 WL 769341.

15. *Caraco Pharm., Inc. v. Novo Nordisk*, 132 S. Ct. 1670, 1676 (2012).

16. *Id.*; see also 21 U.S.C. § 355(b)(1).

17. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

18. *Actavis*, 133 S. Ct. at 2228.

19. 21 U.S.C. § 355(j)(5)(B)(iii).

20. *Id.* at § 355(j)(5)(B)(iv).

21. *Actavis*, 133 S. Ct. at 2229 (internal quotation marks omitted) (quoting Brief for the Petitioner, *supra* note 7, at 6).

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the infringement helps guide the form of the settlement. The accused infringer can evaluate the risk by calculating the amount of money that a jury will award. This is tied to the amount of sales/profit made from the alleged infringing product. The patentee can evaluate its risk by looking at the historical impact the alleged infringing product had on its product. The patentee can, at least in some respects, make an educated assessment of the value of the risk of trial. These risk/reward calculations are more speculative in the Hatch-Waxman context. The generic manufacturer's calculus is based upon the likelihood that it will succeed in litigation, the timing of the result, and the forecasted profits for the potential drug. The brand name manufacturer's calculus is based upon the likelihood of success at litigation, the timing of the result, and the forecasted impact of the generic on the market.

Because of the automatic stay of FDA approval, the timing of the result is of great importance. Unlike a typical patentee that wants to reach the result as soon as possible to realize its monetary loss, or at a minimum prevent the alleged infringer from taking some of its future profits, the brand name manufacturer is incentivized to keep the litigation going. The brand name manufacturer does not face any threat of competition until the FDA approves the generic drug. The FDA will not approve the drug without a court order or until the thirty-month stay has expired. Thus, the brand name manufacturer has no incentive to accept payment from the generic manufacturer. The brand name manufacturer is not currently suffering a monetary loss and does not need to "stop the bleeding." Without a competitor in the marketplace, there is generally no incentive for the brand name manufacturer to accept any payment from the generic manufacturer that is not close to the amount of profits it will receive during the term of the patent. Unlike the typical alleged infringer who is accruing profits during the litigation, the generic manufacturer has no product during the litigation. The generic manufacturer seeks quick resolution so it can enter the marketplace. Thus, the generic manufacturer has no incentive to pay the brand name manufacturer anything more than future litigation costs to enter the market. These incentives create settlements with a "different appearance." Settlements generally do

not take the form of the alleged infringer paying the patentee to drop its claim and end the litigation.<sup>22</sup>

*B. The Federal Trade Commission's View of Reverse Payment Settlements and Its Future Goals*

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the FTC and the Department of Justice are charged with reviewing patent litigation settlements between the brand name manufacturer and the generic manufacturer.<sup>23</sup> Each year, the FTC reports the number of settlements it deems potentially anticompetitive. For fiscal year 2012 (October 1, 2011–September 30, 2012) the FTC reviewed 140 patent settlements and deemed forty settlements as potentially involving “pay-for-delay”<sup>24</sup> payments.<sup>25</sup> The FTC designated them as potentially involving pay-for-delay “because they contain both compensation to the generic manufacturer and a restriction on the generic manufacturer’s ability to market its product.”<sup>26</sup> Of these forty settlements, nineteen contained what the FTC classified as compensation in “the form of a brand manufacturer’s promise not to make an authorized generic (‘AG’) in competition with the generic manufacturer’s product for some period of time (a ‘no-AG agreement’).”<sup>27</sup> Of the remaining 140 settlements, the FTC deemed eighty-one as “restrict[ing] the generic manufacturer’s ability to market its product, but contain[ing] no explicit compensation,” and nineteen as having no restrictions on generic entry.<sup>28</sup> According to the FTC, there were a record number of settlements containing potential pay-for-delay

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22. The preceding considerations are based on the author’s experience.

23. See *Actavis Inc.*, 133 S. Ct. at 2242 (Roberts, C.J., dissenting). For an explanation of the Act’s filing requirements, see the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1111–1118, 117 Stat. 2066, 2461–64.

24. The FTC’s definition of “pay-for-delay” appears on its face to be broader than the Court’s definition of reverse payments. The details in each of these settlement agreements are not publicly available.

25. BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003, at 1 (2012), available at <http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf>.

26. *Id.*

27. *Id.*

28. *Id.*

agreements in fiscal year 2012.<sup>29</sup> As shown in the table below, the FTC has increasingly classified settlements as pay-for-delay.

Fiscal Year	2004	2005	2006	2007	2008	2009	2010	2011	2012
Final Settlements	14	11	28	33	66	68	113	156	140
Potential Pay-for-Delay	0	3	14	14	16	19	31	28	40
Potential Pay-for-Delay Involving First Filers	0	2	9	11	13	15	26	18	23

Figure 1: Settlements Classified as Pay-for-Delay<sup>30</sup>

Yet, as pointed out by Respondents Par/Paddock in their joint response brief, and as shown below, percentage of final settlements that are classified as pay-for-delay agreements is generally declining.<sup>31</sup>

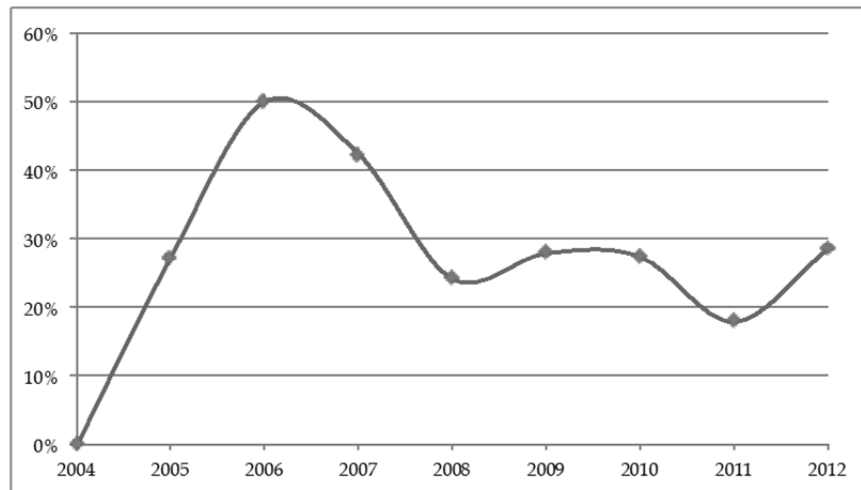


Figure 2: Percentage of Final Settlements FTC Classified as Pay-for-Delay<sup>32</sup>

29. *Id.* at 2.

30. *See Id.*

31. The rise in “potential pay-for-delay” agreements in FY 2012 appears to reflect an increase in settlement agreements in which the brand manufacturer agreed not to market an “authorized generic.”

32. Chart created by author based on data in Brief for Respondents Par/Paddock at 21–22, Fed. Trade Comm’n v. Actavis, Inc. 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 682804.



The FTC believes that the *Actavis* decision puts it in a much stronger position.<sup>33</sup> The FTC has stated its commitment to take the following actions in light of the decision:<sup>34</sup>

- pursue pay-for-delay matters currently in litigation and seek appropriate relief for consumers;
- monitor private litigations alleging pay-for-delay agreements and leverage Commission experience and expertise by filing *amicus* briefs where appropriate;
- investigate pending pay-for-delay matters;
- examine new settlements that companies file with the Commission pursuant to the Medicare Modernization Act of 2003 (“MMA”) and investigate those that raise anticompetitive concerns; and
- issue regular reports on pharmaceutical settlements filed with the Commission pursuant to the MMA.<sup>35</sup>

The FTC has also committed to re-examine previously filed settlements in light of the *Actavis* decision.<sup>36</sup> The FTC intends to use all of the tools at its disposal, “including prospective restrictions to prevent future violations, rescinding the illegal agreement, and taking other actions to help expedite generic entry,”<sup>37</sup> such as seeking determination that a first filer has forfeited its 180-day exclusivity.<sup>38</sup>

### III. LESSONS LEARNED FROM *ACTAVIS*

While the Supreme Court left it for lower courts to structure the rule-of-reason for this kind of antitrust litigation, the Court’s opinion provides some insight into how lower courts should view a

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33. *Pay-for-Delay Deals: Limiting Competition and Costing Consumers: Hearing Before the Subcomm. on Antitrust, Competition Policy & Consumer Rights of the S. Comm. on the Judiciary*, 113th Cong. 2 (2013) [hereinafter *Pay-for-Delay Hearing*] (statement of Edith Ramirez, Chairwoman, Federal Trade Commission).

34. *Id.* at 10. The FTC has also committed to pursue its two pending pay-for-delay litigations: *Actavis* and *Federal Trade Commission v. Cephalon, Inc.*, No. 08-cv-2141 (E.D. Pa. filed Feb. 13, 2008).

35. *Pay-for-Delay Hearing*, *supra* note 33, at 3 (footnote omitted).

36. *Id.* at 12.

37. *Id.* at 3.

38. *Id.* at 3 n.11 (“[A] generic company automatically forfeits its entitlement to the 180-day exclusivity period that is otherwise available to first filing generics if it is found to have violated the antitrust laws or the Federal Trade Commission Act. Amended 21 U.S.C. § 355(j) (5) (D) (i) (V) (2003).”).

reverse payment. To gain a full understanding of the Court's opinion it is important to view the case against the backdrop of the facts.

A. *Synopsis of the Facts of the Actavis Decision*

Solvay received FDA approval for the brand name pharmaceutical drug AndroGel in 2000.<sup>39</sup> In January 2003, Solvay obtained the relevant patent and listed it in the Orange Book.<sup>40</sup> Later that year, in May 2003, Actavis, Inc. (previously known as Watson Pharmaceuticals) filed its ANDA seeking to make a generic version of AndroGel. Actavis was the first filer, and by statute, was eligible for the 180 days of market exclusivity once it launched its generic version.<sup>41</sup> Shortly thereafter, Paddock filed an ANDA for its own product.<sup>42</sup> Both Actavis and Paddock certified under paragraph IV that the proposed products did not infringe the patent and/or that the patent was invalid.<sup>43</sup> Par did not file its own ANDA. Rather, it joined Paddock's ANDA and agreed to share in the patent litigation costs as well as share in any profits Paddock might receive from selling its generic product.<sup>44</sup> In August 2003, Solvay sued Actavis and Paddock separately.<sup>45</sup> From late 2003 to late 2005, the cases progressed with discovery, the parties filed claim construction briefs, and Actavis and Par/Paddock filed motions for nondispositive partial summary judgment.<sup>46</sup> In January 2006, the thirty-month stay expired and Actavis received final FDA approval.<sup>47</sup> At this point, Actavis could have launched "at risk" (i.e. Actavis could have launched its generic drug despite the pending litigation).<sup>48</sup> Had it launched, Actavis would have been liable for significant damages if it had lost the pending litigation.<sup>49</sup>

39. Fed. Trade. Comm'n v. Actavis, Inc., 133 S. Ct. 2223, 2229 (2013).

40. See *id.*; Brief for Respondent Actavis, Inc. at 5–6, *Actavis*, 133 S. Ct. 2223 (No. 12-416), 2013 WL 662705 (discussing the process by which Unimed and Besins's NDA was approved and listed in the Orange Book and Solvay's later acquisition of Unimed).

41. Brief for Respondent Actavis, Inc., *supra* note 40, at 6.

42. *Id.*

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

44. *Id.*

45. Brief for Respondent Actavis, Inc., *supra* note 40, at 6.

46. *Id.*

47. *Id.*

48. *Id.*

49. *Id.*

In September 2006, the parties settled both litigations.<sup>50</sup> The district court had not issued a decision on claim construction or on the pending partial summary judgment motions.<sup>51</sup> The settlement agreements dismissed the pending cases. The agreements granted patent licenses to Actavis and Par/Paddock. The patent licenses allowed Actavis and Par/Paddock to launch their respective generic drugs starting in August 2015. This was five years before the patent was set to expire. As part of the settlement, Actavis relinquished its claim to the 180-day market exclusivity.<sup>52</sup>

The parties also agreed to compensation for other services. Solvay agreed to pay Actavis, over nine years, an estimated \$19–30 million annually for Actavis to promote AndroGel to urologists.<sup>53</sup> Solvay agreed to pay Paddock \$12 million to provide backup manufacturing capacity for AndroGel from 2006 until 2012. Finally, Solvay agreed to pay Par \$10 million annually for Par to have its sales force promote AndroGel to primary care physicians.<sup>54</sup> Solvay's payments represented less than ten percent of AndroGel revenues.<sup>55</sup> For example, in 2007, AndroGel had sales of more than \$400 million.<sup>56</sup>

*B. A Detailed Review of the Supreme Court's Five Sets of Considerations to Bring a Claim.*

Faced with these facts, the Supreme Court concluded that “the FTC should have been given the opportunity to prove its antitrust claim.”<sup>57</sup> The Court based its conclusion on the following five sets of considerations:

- (1) The restraint has the “potential for genuine adverse effects on competition.”<sup>58</sup>
- (2) The anticompetitive consequences of the reverse payment “will at least sometimes prove unjustified.”<sup>59</sup>

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50. *Id.*

51. *Id.* at 7.

52. *Id.* at 8.

53. Fed. Trade Comm'n v. Actavis, Inc., 133 S. Ct. 2223, 2229 (2013).

54. Brief for Respondent Actavis, Inc., *supra* note 40, at 8; Brief for the Petitioner, *supra* note 21, at 11–12.

55. Brief for Respondent Solvay Pharmaceuticals, Inc. at 6, *Actavis*, 133 S. Ct. 2223 (No. 12-416) 2013 WL 648743.

56. Brief for the Petitioner, *supra* note 21, at 11–12.

57. *Actavis*, 133 S. Ct. at 2234.

58. *Id.*

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- (3) “Where a reverse payment threatens to work unjustified . . . harm, the patentee likely possesses the power to bring that harm.”<sup>60</sup>
- (4) The antitrust action is feasible and it is normally not necessary to litigate the patent’s validity.<sup>61</sup>
- (5) “The fact that a large, unjustified reverse payment risks antitrust liability does not prevent [potential settlement of the patent claims].”<sup>62</sup>

Reviewing each of these considerations, and, in turn, considering the facts of *Actavis*, it appears that almost any payment from the brand name manufacturer to the generic manufacturer can serve as a basis for an antitrust action.

*1. Potential Genuine Adverse Effect on Competition*

Based on the Court’s opinion, a payment from the brand name manufacturer to the generic manufacturer, regardless of the parties’ stated purpose for the payment, is sufficient to meet this first consideration. In the Court’s view, “[t]he payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product.”<sup>63</sup> The fact that Solvay, Actavis, and Par/Paddock classified the payments as part of a separate business deal did not factor into the Court’s opinion. Rather, presumably because this was a motion to dismiss, the Court viewed the settlement on terms set by the FTC—a payment in return for staying out of the market and keeping prices at patentee-set levels.<sup>64</sup> The Court conceded that settlements, like the one at issue, which permit the generic manufacturer to enter the market prior to the patent expiring, would bring about competition that benefits the consumer.<sup>65</sup> But the Court did not view the early entry as enough to overcome the adverse effect of the payment. Rather, the Court stated that the payment may “provide strong evidence that the

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59. *Id.* at 2235–36.

60. *Id.* at 2236.

61. *See id.*

62. *Id.* at 2237.

63. *Id.* at 2234.

64. *Id.*

65. *Id.*

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patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.”<sup>66</sup>

In addition, the Court did not take into account that the settlement at issue allowed the second filer, Par/Paddock, early market entry. Actavis gave up its 180-day exclusivity,<sup>67</sup> so Par, Paddock, and Actavis would all enter the market on the same day. Arguably, consumers received a large benefit by Actavis giving up its right as competition would increase. According to the FTC, the price typically drops twenty percent when a first generic enters the market and up to eighty-five percent when there are multiple generics in the marketplace.<sup>68</sup> While, as the Court recognized, the 180-day market exclusivity granted to the first filer provided a valuable right which “can be worth several hundred million dollars,” the Court focused its analysis on the payment itself.<sup>69</sup> The Court noted that according to scholars, “where only one party owns a patent, it is virtually unheard of outside of pharmaceuticals for that party to pay the accused infringer to settle the lawsuit.”<sup>70</sup>

The Court was not persuaded that the Hatch-Waxman Act’s unique regulatory framework required a different result.<sup>71</sup> The Court viewed the Hatch-Waxman Act’s grant of 180-day market exclusivity as a barrier to competition.<sup>72</sup> According to the Court, subsequent ANDA filers would be deterred from bringing suit once the first filer settles.<sup>73</sup> Because of the 180-day exclusivity, a litigation victory by a subsequent ANDA filer will free not only that ANDA filer, but all other potential competitors. Thus, according to the Court, the potential reward to the subsequent challenger is significantly less than the patentee’s payment to the first filer.<sup>74</sup> In addition, the subsequent ANDA filer, after learning that the first filer has settled, if sued, will have to wait roughly thirty months before receiving FDA approval.<sup>75</sup> Because of these features, the Court concluded that a reverse payment settlement with the first

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66. *Id.* at 2235.

67. Brief for Respondent Actavis, Inc., *supra* note 40, at 8.

68. *Pay-for-Delay Hearing*, *supra* note 33, at 6.

69. *Actavis*, 133 S. Ct. at 2235.

70. *Id.*

71. *Id.*

72. *Id.*

73. *Id.*

74. *Id.*

75. *Id.* (citing 21 U.S.C. § 355(j)(5)(B)(iii) (2012)).

filer “removes from consideration the most motivated challenger, and the one closest to introducing competition.”<sup>76</sup> Thus, from the Court’s perspective, the payment from the patentee to the alleged infringer, alone, is enough to meet the consideration that there is potential for genuine adverse effects on competition.<sup>77</sup>

## 2. Was the Payment “Justified”

The Court also determined that anticompetitive consequences from reverse payments will sometimes be unjustified. The Court noted that there may be legitimate justifications for payment.<sup>78</sup> But the time to raise justifications is at the antitrust proceedings.<sup>79</sup>

The Court did provide some insight into potential justifications. First, the reverse payment may be no more than a rough approximation of the litigation expenses saved through settlement.<sup>80</sup> However, this amount may not be enough to incentivize the parties to settle. The typical cost of Hatch-Waxman litigation is approximately \$6 million through trial.<sup>81</sup> Of this \$6 million, it costs approximately \$3.25 million to reach the end of discovery.<sup>82</sup> For example, in *Actavis*, the parties had completed discovery.<sup>83</sup> Based on the typical litigation costs, a rough approximation of the litigation expenses saved through settlement would be \$2.75 million in total. In contrast, Actavis settled for an estimate of \$20–30 million per year, Paddock settled for \$2 million per year, and Par settled for \$10 million per year.<sup>84</sup> Based on these numbers, it is questionable whether litigation expenses saved through settlement alone provides enough incentive to settle Hatch-Waxman litigation.

The Court also noted that payment from the brand name manufacturer to the generic manufacturer may represent

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76. *Id.* (citing C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1586 (2006)).

77. *See id.* at 2235.

78. *Id.* at 2236.

79. *Id.*

80. *Id.*

81. *See* AM. INTELLECTUAL PROP. LAW ASS’N, REPORT OF THE ECONOMIC SURVEY 37 (2013) (referring to more than \$25 million at risk).

82. *See id.*

83. *See* Brief for Respondent Actavis, Inc., *supra* note 40, at 8.

84. *See Actavis*, 133 S. Ct. at 2229; Brief for Respondent Actavis, Inc., *supra* note 40, at 8; Brief for the Petitioner, *supra* note 21, at 11–12.

compensation for other services, such as distributing the brand name drug or developing a market for the drug.<sup>85</sup> In *Actavis*, the settlement stated that the payments were for other services.<sup>86</sup> Actavis was paid to promote the brand name drug to urologists, Paddock was paid to provide backup manufacturing capacity for the brand name drug, and Par was paid to have its sales team promote the brand name drug to primary care physicians.<sup>87</sup> Yet, at this stage of the proceedings, these factors did not sway the Court. Rather, the Court left this issue for the antitrust proceedings.<sup>88</sup>

The Court did not limit the justification to these examples. The Court clearly stated that “[t]here may be other justifications” that would not raise the concern that the patentee was using its monopoly profits to avoid the risk of losing the litigation.<sup>89</sup>

### 3. *The Patentee’s Ability to Bring About the Anticompetitive Harm*

The Court determined that the size of the reverse payment is indicative of market power and thus the patentee’s power to bring the harm into practice.<sup>90</sup> The Court did not provide any analysis as to whether the size of Solvay’s payments were “large sums” in the context of the case and thus indicative of its power. Rather, relying on studies referred to by the FTC in its briefing, the Court stated that “reverse payment agreements are associated with the presence of higher-than-competitive profits—a strong indication of market power.”<sup>91</sup>

The strength of Solvay’s patent also did not factor into this consideration. While the Court stated that “[a]n important patent itself helps to ensure such power,” the Court did not analyze the strengths and weaknesses of Solvay’s patent.<sup>92</sup> It appears that, in the context of Hatch-Waxman settlements, a payment from patentee to the alleged infringer was sufficient to meet this consideration. The logical conclusion is that the “importance” of the patent, and thus, patentee’s market power, is dictated by the patentee listing the patent in the Orange Book as covering the brand name drug.

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85. *Actavis*, 133 S. Ct. at 2236.

86. *Id.* at 2229.

87. See Brief for Respondent Actavis, Inc., *supra* note 40, at 6–7.

88. *Actavis*, 133 S. Ct. at 2238.

89. *Id.* at 2236.

90. *Id.*

91. *Id.*

92. See *id.*

4. *The Size of the Unexplained Payment Is a Workable Surrogate for Litigating the Patent Issues and Makes the Antitrust Litigation Feasible.*

It is the Court's view that it is not necessary to litigate the patent to answer the antitrust questions arising from a reverse payment.<sup>93</sup> Rather, the Court relies on the size and justification of the payment. According to the Court "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival."<sup>94</sup> The Eleventh Circuit disagreed with this assessment. In its opinion, "[w]hen hundreds of millions of dollars of lost profits are at stake, 'even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.'"<sup>95</sup> Thus, the payment size was reflective of the "reality of patent litigation and the risks it presents to the patent holder."<sup>96</sup> While the Court recognized that a patentee may be willing to make a large payment to avoid the risk of invalidity, that justification alone is insufficient to avoid antitrust liability.<sup>97</sup> The payment, without any additional explanation, "likely seeks to prevent the risk of competition."<sup>98</sup> Simply put, in the Court's view, the size of an unexplained payment could be used as a "workable surrogate" instead of litigating the patent issues.<sup>99</sup>

5. *Antitrust Liability for Large Unjustified Reverse Payments Does Not Prevent Parties from Settling*

The final consideration in the Court's analysis is the parties' ability to settle. According to the Court, parties are still able to settle patent claims.<sup>100</sup> The primary example the Court provides is a settlement which allows the generic manufacturer to enter the market prior to expiration and without payment from the brand name drug.<sup>101</sup> Yet, this is only an example. The Court refused to

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93. *See id.* at 2237.

94. *Id.*

95. *Fed. Trade Comm'n v. Watson Pharm. Inc.*, 677 F.3d 1298, 1313 (11th Cir. 2012) (quoting *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003)).

96. *Id.*

97. *See Actavis*, 133 S. Ct. at 2236.

98. *Id.*

99. *See id.* at 2236–37.

100. *Id.* at 2237.

101. *Id.*



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hold that all reverse payment settlements are presumptively unlawful. Rather, the question is simply what the reasons for the reverse payment are. As the Court notes, “[i]f the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.”<sup>102</sup>

C. *What Is Left Unanswered by Actavis*

Dismissing antitrust claims based on reverse payment settlements has become more challenging given the Court’s analysis and its decision to allow the FTC the opportunity to prove its case. A broad reading of the opinion would lead to the conclusion that to survive a motion to dismiss, the FTC must plead that there was a large payment from the innovator company to the generic filer. While throughout its analysis the Court classified the payment as unexplained or unjustified, it explicitly stated that an antitrust defendant may have legitimate justifications for the payment.<sup>103</sup> If this is the case, the Court leaves open three seminal questions: (1) what constitutes a payment?; (2) what makes a payment “large”?; and (3) what impact, if any, does giving up 180-day exclusivity have in the analysis?

1. *What Is “Payment”?*

In *Actavis*, the payment was clear. Payment was in the form of money from Solvay to the generic challengers. The question remains whether nonmonetary benefits should also be viewed as a payment. Many settlements include terms that provide non-monetary benefits to the generic manufacturer. For example, brand name manufacturers enter into no-authorized-generic (AG) agreements with generic manufacturers. These no-AG agreements, according to the FTC, typically take the “form of a brand manufacturer’s promise not to market an [AG] in competition with the generic manufacturer’s product for some period of time.”<sup>104</sup>

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102. *Id.*

103. *Id.* at 2236.

104. FED. TRADE COMM’N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2012, at 1 (2013), available at <http://www.ftc.gov/sites/default/files/documents/reports>

The FTC classifies these types of agreements as pay-for-delay, but district courts have reached various conclusions.

*a. District Court Construes Reverse Payment Settlements as Requiring a Monetary Payment*

For example, in *In re Lamictal Direct Purchaser Antitrust Litigation*, Judge Walls found that a no-AG agreement was not payment.<sup>105</sup> In that case, GlaxoSmithKline (GSK) sold Lamictal Tablets and Lamictal Chewables to treat epilepsy and bipolar disorder.<sup>106</sup> The drug was profitable; for example, domestic sales of Lamictal Tablets from March 2007 to March 2008 exceeded \$2 billion.<sup>107</sup> Teva filed two ANDAs, which contained paragraph IV certifications, with the FDA in 2002.<sup>108</sup> GSK brought suit.<sup>109</sup> The case went to trial and the judge ruled from the bench that one claim of the asserted patent was invalid.<sup>110</sup> The judge was still deliberating the validity of the remaining claims when the parties reached a settlement.<sup>111</sup> The settlement did not include a monetary payment. The key settlement terms were: (1) Teva was permitted to sell generic chewables by June 1, 2005, supplied by GSK, approximately thirty-seven months before the expiration of the patent, and before FDA approval of Teva's tablet ANDA; (2) Teva was permitted to sell generic tablets on the expiration date of the patent on July 21, 2008 and, if GSK did not receive pediatric exclusivity, Teva could enter the market approximately six months earlier; (3) GSK granted Teva a waiver of any pediatric exclusivity GSK was granted; and (4) GSK agreed not launch its own AG until January 2009.<sup>112</sup>

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/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf.

105. *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-995, 2014 U.S. Dist. LEXIS 9257 (D.N.J. Jan. 24, 2014). In light of the *Actavis* decision, Judge Walls reconsidered his previous finding that a settlement including a non-AG agreement was not a sufficient basis for an antitrust claim. The earlier opinion can be found at *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-995, 2012 U.S. Dist. LEXIS 183627 (D.N.J. Dec. 6, 2012) (unpublished).

106. *In re Lamictal*, 2014 U.S. Dist. LEXIS 9257, at \*2.

107. *Id.* at \*2.

108. *Id.* at \*3.

109. *Id.*

110. *Id.* at \*3-4.

111. *Id.*

112. *Id.* at \*4-6.

Direct purchasers brought suit alleging that the settlement violated antitrust law.<sup>113</sup> Defendants GSK and Teva moved to dismiss for failing to allege a cause of action on the grounds that the settlement did not involve a cash-only reverse payment.<sup>114</sup>

The court, in an unpublished decision, initially granted the defendants' motion to dismiss.<sup>115</sup> In its earlier decision, the court found that "the term 'reverse payment' was not sufficiently broad to encompass any benefit that may fall to Teva in a negotiated settlement."<sup>116</sup> Moreover, the court recognized that Teva received consideration in the settlement and "consideration is an essential element of any enforceable contract."<sup>117</sup> The court also noted that "there is 'payment' in every settlement" and classified this settlement as based on negotiated entry dates.<sup>118</sup> Accordingly, the court found that the settlements met a strong policy objective by introducing "generic products onto the market sooner than what would have occurred had GSK's patent not been challenged."<sup>119</sup> The court also considered the real-world impact of settlement. When monetary payments are not part of the settlement equation, "companies with abundant cash have less leverage to delay entry of generic drugs."<sup>120</sup> GSK needed to find a different bargaining chip and "GSK's promise not to enter the market with its own generic products is such an example."<sup>121</sup>

The *Actavis* decision did not alter the court's view of the settlement. According to the court, *Actavis* only applies to monetary reverse payments.<sup>122</sup> The court was unwilling to extend the *Actavis* holding beyond its facts.<sup>123</sup> The court found that "nothing in *Actavis* says that a settlement contains a reverse payment when it confers substantial financial benefits or that a [no-AG] agreement is a

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113. *Id.* at \*6.

114. *Id.*

115. *Id.*

116. *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-995, 2012 U.S. Dist. LEXIS 183627, at \*15 (D.N.J. Dec. 6, 2012).

117. *Id.* at \*16.

118. *Id.*

119. *Id.* at \*19.

120. *Id.* at \*20.

121. *Id.*

122. *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-995, 2014 U.S. Dist. LEXIS 9257, at \*18–26 (D.N.J. Jan. 24, 2014).

123. *Id.* at \*25–26.

‘payment.’”<sup>124</sup> The court read the majority and dissenting opinions as “reek[ing] with discussion of payment of money.”<sup>125</sup> While the court recognized that Black’s Law Dictionary defined “payment” as “[p]erformance of an obligation by the delivery of money *or some other valuable thing* accepted in partial or full discharge of an obligation,” the court did not find that *Actavis* supported such a broad reading.<sup>126</sup>

*b. District Courts Construe Reverse Payments As Including Nonmonetary Payments*

While Judge Walls found that the term “reverse payments” and the decision in *Actavis* constituted only cash payments, two courts have recently reached a different conclusion.<sup>127</sup> Judge Sheridan viewed the term differently in *In re Lipitor Antitrust Litigation*.<sup>128</sup> Pending before the court was the direct purchaser class plaintiffs’ motion for leave to amend the consolidated complaint and the defendants’<sup>129</sup> motion to dismiss various complaints on multiple grounds.<sup>130</sup> The motions were originally briefed before the *Actavis* decision. The court requested supplemental briefing in light of the decision.<sup>131</sup> The case involves Pfizer’s drug Lipitor.<sup>132</sup> Pfizer obtained seven patents covering different aspects of the Lipitor product.<sup>133</sup> “Ranbaxy filed the first . . . ANDA to market generic Lipitor.”<sup>134</sup> Ranbaxy certified, under paragraph IV, that the selling of its product would not infringe any valid claim.<sup>135</sup> Pfizer brought suit. “From 2003 to 2006, the patent litigation progressed through discovery, trial,” a district court decision, and a federal circuit decision.<sup>136</sup> In late 2006, the district court enjoined the FDA from

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124. *Id.* at \*21.

125. *Id.*

126. *Id.* at \*22 (alteration in original).

127. Judge Walls found these decisions’ interpretation of *Actavis* as “unsupported by the words of *Actavis* or are inapposite.” *Id.* at \*27.

128. No. 3:12-cv-2389, 2013 U.S. Dist. LEXIS 126468 (D.N.J. Sept. 5, 2013).

129. Defendants include Pfizer, Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Co., and Warner-Lambert Co., LLC. *Id.* at \*15.

130. *Id.* at \*14–15, \*54–85.

131. *Id.* at \*92–93.

132. *Id.* at \*18.

133. *Id.* at \*19.

134. *Id.* at \*32.

135. *Id.* at \*32–33.

136. *Id.* at \*33.

approving Ranbaxy's ANDA until March 2010.<sup>137</sup> While the U.S. litigation was pending, Pfizer filed numerous international lawsuits against generic manufacturers.<sup>138</sup> In 2007, Pfizer also initiated re-issue proceedings for one of the patents.<sup>139</sup> Ranbaxy filed numerous protests during the re-issue proceedings.<sup>140</sup> In addition, on March 24, 2008, Pfizer sued Ranbaxy alleging infringement of two non-Orange Book process patents, even though Ranbaxy was enjoined from selling its generic Lipitor.<sup>141</sup>

In April 2008, Pfizer and Ranbaxy settled the reissue proceedings,<sup>142</sup> and in June 2008, the parties entered into an agreement that "settled global patent proceedings regarding Lipitor including the U.S. patent litigations."<sup>143</sup> Ranbaxy agreed not to enter the market until November 30, 2011. Ranbaxy did not waive its 180-day exclusivity but dropped any challenges to the reissued patent.<sup>144</sup> Pfizer also agreed to forgive the outstanding money judgments against Ranbaxy that were unrelated to Lipitor and settled Pfizer's suit against Ranbaxy regarding a generic version of Caduet.<sup>145</sup> Pfizer also agreed to dismiss an action against Ranbaxy regarding Ranbaxy's "at risk" launch of a generic version of Accupril.<sup>146</sup>

The court dismissed most of the antitrust claims. However, the plaintiffs sought to amend their complaint to clarify and augment their reverse payment allegations.<sup>147</sup> The plaintiffs argued that the Pfizer/Ranbaxy settlement of the Accupril litigation was a payment by Pfizer to Ranbaxy to delay the launch of generic Lipitor, despite the fact that Ranbaxy made a \$1 million payment to Pfizer.<sup>148</sup> The defendants argued that the proposed amendments were futile since *Actavis* applies only to settlements involving large monetary payments. Judge Sheridan disagreed. While declining to decide

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137. *Id.* at \*36.

138. *Id.* at \*37-40.

139. *Id.* at \*40.

140. *Id.* at \*40-41.

141. *See id.* at \*45-47.

142. *Id.* at \*42.

143. *Id.* at \*47-48.

144. *Id.*

145. Caduet is a combination drug which contains the active ingredient in Lipitor. *See id.* at \*48.

146. *Id.*

147. *Id.* at \*94.

148. *Id.*

whether the amendments would survive a motion to dismiss, the court noted that “nothing in *Actavis* strictly requires that the payment be in the form of money, and . . . decline[d] to hold that the amendments would be futile on that basis.”<sup>149</sup>

In *In re Nexium (Esomeprazole) Antitrust Litigation*,<sup>150</sup> Judge Young shared Judge Sheridan’s broad reading of *Actavis*.<sup>151</sup> In this case, a group of wholesale drug distributors filed antitrust claims against AstraZeneca and each of three generic defendants—Ranbaxy, Teva, and Dr. Reddy’s. The plaintiffs alleged that AstraZeneca and each of the three generic defendants entered into reverse payment agreements to keep a generic version of Nexium off the market. The defendants filed motions to dismiss the complaint. AstraZeneca listed fourteen patents in the Orange Book as covering Nexium.<sup>152</sup> Ranbaxy was the first ANDA filer. Ranbaxy filed its ANDA, which included a paragraph IV certification stating that it would not infringe any valid claim for the patents that expired after October 2007.<sup>153</sup> AstraZeneca filed an infringement suit against Ranbaxy.<sup>154</sup> Several months after AstraZeneca filed suit, Teva provided notice of its paragraph IV certification and was subsequently sued by AstraZeneca.<sup>155</sup> Later that same year, Dr. Reddy’s provided notice of its paragraph IV certification and was also sued by AstraZeneca.<sup>156</sup>

After the parties completed discovery in the Ranbaxy case, AstraZeneca and Ranbaxy settled.<sup>157</sup> Ranbaxy agreed to the following:

- (1) Admit that the patents-in-suit were valid and enforceable;
- (2) Admit that Ranbaxy’s generic product would infringe some of the patents; and
- (3) Delay launch of its generic product until May 27, 2014.<sup>158</sup>

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149. *Id.* at \*95.

150. No. 12-md-02409-WGY, 2013 U.S. Dist. LEXIS 129696, at \*10 (D. Mass. Sept. 11, 2013).

151. *See id.* at \*62 (“This Court does not see fit to read into the opinion a strict limitation of its principles to monetary-based arrangements alone.”).

152. *Id.* at \*25.

153. *Id.* at \*25–26.

154. *Id.* at \*26.

155. *Id.* at \*28.

156. *Id.* at \*29.

157. *Id.* at \*30. Allegedly, under the terms of the settlement, AstraZeneca agreed to pay Ranbaxy over \$1 billion. *Id.*

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Ranbaxy retained its 180 days of market exclusivity. Before the court could enter final judgment in the Teva matter, AstraZeneca and Teva settled.<sup>159</sup> The terms of this settlement were similar to the Ranbaxy settlement. Teva agreed to:

- (1) Admit that the patents listed in the Orange Book were valid and enforceable;
- (2) Admit that its proposed product would infringe some of the patents; and
- (3) Delay launch of its generic product until May 27, 2014.<sup>160</sup>

Teva did not receive a monetary payment from AstraZeneca. Rather, Teva had additional liability to AstraZeneca related to its “at risk” launch of a generic version of Prilosec.<sup>161</sup> The Federal Circuit upheld a decision that the Prilosec patents were valid and infringed.<sup>162</sup> Allegedly, as part of the Nexium settlement, AstraZeneca forgave a significant portion of the monetary damages for the Prilosec infringement.

Similarly, before the court could enter judgment in the Dr. Reddy’s matter, AstraZeneca settled with Dr. Reddy’s.<sup>163</sup> Dr. Reddy’s agreed to refrain from challenging the Nexium patents and to defer launch of its product until May 27, 2014.<sup>164</sup> Dr. Reddy’s also did not receive a monetary payment from AstraZeneca. Rather, Dr. Reddy’s had additional liability to AstraZeneca related to its “at risk” launch of a generic version of Accolate. AstraZeneca agreed to forgive this liability.<sup>165</sup>

In their motion to dismiss, the generic defendants argued that they did not receive a monetary payment from AstraZeneca.<sup>166</sup> Rather, the defendants argued that AstraZeneca and Ranbaxy entered into a no-AG agreement granting Ranbaxy the exclusive

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158. *Id.* at \*30–32.

159. *Id.* at \*34–35.

160. *Id.* at \*35.

161. *Id.* at \*35–36.

162. *Id.* at \*36 (citing *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1375 (Fed. Cir. 2008)).

163. *Id.* at \*37.

164. *Id.*

165. *Id.*

166. *Id.* at \*59. The alleged billion dollar payment from AstraZeneca to Ranbaxy was in dispute. Judge Young stated that it did not factor in his analysis. *See id.* at \*59 n.20.

license to market during its 180-day period of market exclusivity.<sup>167</sup> AstraZeneca also forgave Teva and Dr. Reddy's of contingent liabilities for past patent infringement. Judge Young applied a broad reading of the term "payment" and found that these agreements constituted a reverse payment. Judge Young noted that "[n]owhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction to take place for an agreement between a brand and generic manufacturer to constitute a reverse payment."<sup>168</sup> Yet, the court admitted that "the Supreme Court spoke only to the merits of cash payouts as a quid pro quo for promises of delayed generic market entry."<sup>169</sup> Judge Young adopted a broader interpretation of payment. Relying on the FTC's view that no-AG agreements are pay-for-delay, Judge Young determined the AstraZeneca/Ranbaxy no-AG agreement was equivalent to a reverse payment.<sup>170</sup> Judge Young also viewed the Teva and Dr. Reddy's agreements as reverse payments since courts have recognized that contingent liabilities have value.<sup>171</sup>

## 2. What Constitutes a "Large" Payment?

In addition to the lack of clarity regarding what constitutes a "payment," it is unclear what exactly constitutes a "large" payment. Throughout the *Actavis* opinion, the Court repeatedly states that the payment must be "large."<sup>172</sup> The opinion, however, provides little insight into what makes a payment "large."

In its briefing, Solvay pointed out that its payments to the generic manufacturers represented less than ten percent of the AndroGel revenues.<sup>173</sup> The *Actavis* Court was not swayed by this argument and did not mention it in the opinion. Rather, the Court indicated that a payment would be "large" if the patentee pays a generic challenger a sum even larger than what the generic would gain in profits if it won the litigation and entered the market.<sup>174</sup> According to an amicus brief, the payments from Solvay to the generic manufacturers (\$29–42 million per year) were estimated to

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167. *Id.* at \*60.

168. *Id.* at \*61.

169. *Id.*

170. *See id.* at \*62 n.22.

171. *See id.*

172. Fed. Trade Comm'n v. *Actavis, Inc.*, 133 S. Ct. 2223, 2235–37 (2013).

173. Brief for Respondent Solvay Pharmaceuticals, Inc., *supra* note 55, at 6.

174. *Actavis*, 133 S. Ct. at 2235.



be greater than what the generics could have made by entering the market (\$31.25 million per year).<sup>175</sup> This begs the question: If Solvay settled with all of the generic manufacturers for only \$29 million per year, would the payment be “large”? In addition, conducting such an analysis requires some detail in the record.<sup>176</sup> Would the plaintiff need to make such an assertion in its complaint to withstand a motion to dismiss?

Moreover, the Court did not view the individual payments to each generic. Actavis gave up its 180-day exclusivity.<sup>177</sup> Therefore, Paddock and Par could enter the market the same time as Actavis, yet still received significantly smaller payments from Solvay (\$2 million and \$10 million per year respectively) than Actavis.<sup>178</sup> It is unclear whether Paddock and Par received a sum larger than what it would have gained in profits if they had won the litigation and entered the marketplace, given that Actavis gave up its 180-day exclusivity. From the discussion in the opinion, it appears that the Court viewed the payments in total, rather than by the individual settlements. The Court viewed all of the parties as initial filers.<sup>179</sup> Solvay settled with Actavis, Par, and Paddock at around the same point in time.<sup>180</sup> Would the Court have viewed the size of the Par and Paddock payments differently had Actavis given up its 180-day exclusivity and Par and Paddock settled significantly after Actavis?

The Court also seemed to indicate that payments that reflect “traditional settlement considerations,” such as an amount no more than a rough approximation of the litigation expenses saved through settlement or the fair value for services, would be a legitimate justification for a reverse payment.<sup>181</sup> However, the Court stated that the defendant would have an opportunity to present these justifications during the antitrust proceedings.<sup>182</sup> Moreover, the Court explicitly distinguished size from scale, and independence from other services when explaining the rule-of-reason

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175. Brief Amici Curiae of 118 Law, Economics, and Business Professors and the American Antitrust Institute in Support of Petitioners at 25, *Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 391001.

176. *Id.* at 25 n.7 (noting that they could not “determine the exact number because the district court did not allow development of the record”).

177. Brief for Respondent Actavis, Inc., *supra* note 40, at 7.

178. *See supra* text accompanying notes 52–54.

179. *Actavis*, 133 S. Ct. at 2235.

180. *See supra* text accompanying notes 49–51.

181. *Actavis*, 133 S. Ct. at 2236.

182. *Id.*

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approach.<sup>183</sup> The Court stated that the “anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”<sup>184</sup> Therefore, it is unclear what constitutes a “large” payment, and it is left by the Supreme Court for district courts to determine.

3. *What Impact, If Any, Does Giving up the 180-Day Market Exclusivity Have?*

The Court did not address the impact of Actavis’s choice to give up its 180-day exclusivity. While the Court recognized that this is a valuable right that can be “worth several hundred million dollars,”<sup>185</sup> it does not appear to have impacted the Court’s analysis. By giving up this right, Actavis provided significant benefits to the consumer by allowing more generics to enter the market. Would this justify the payment? Giving up such a right does not on its face reflect traditional settlement considerations, since Solvay did not receive a direct benefit. In fact, this increased competition and pushed prices down. But this may be one of the “other justifications” referenced by the Court for the reverse payments, since it is an “offsetting or redeeming virtue” of the agreement.<sup>186</sup>

#### IV. STRUCTURING OF THE RULE-OF-REASON ANTITRUST LITIGATION

While the Court chose to leave it to the lower courts to structure the new rule-of-reason antitrust proceedings, it did provide some guidance.

A. *Guidance from the Supreme Court’s Actavis Opinion*

First, the Court pointed out that there is always a sliding scale when applying a reasonableness standard and noted that “the quality of proof required should vary with the circumstances.”<sup>187</sup> Thus, lower courts need not insist that a plaintiff “litigate the patent’s validity, empirically demonstrate the virtues or vices of the

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183. *Id.* at 2237.

184. *Id.*

185. *Id.* at 2235.

186. *See id.* at 2236.

187. *Id.* at 2237–38 (citation omitted).

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patent system, present every possible supporting fact or refute every possible pro-defense theory.”<sup>188</sup> Second, the Court added additional insight into the rule-of-reason analysis. The likelihood that a reverse payment brings about anticompetitive effects depends upon the following four factors:

- (1) The size of the payment;
- (2) The scale of the payment in relation to the payor’s future litigation costs;
- (3) The payment’s independence from other services for which it may represent payment;
- (4) The lack of any other convincing justification.<sup>189</sup>

The antitrust defendant may show that factors (2)–(4) provide a justification for the payment.<sup>190</sup>

*B. Application of the Actavis Rule-of-Reason Analysis*

So far, no court has reached the merits of an antitrust reverse payment case and applied a rule-of-reason analysis. But Judge Walls in *In re Lamictal* and Judge Young in *In re Nexium* provide some insight into what this analysis may look like. Judge Walls viewed *Actavis* as requiring a three part test—two steps to determine when to apply the rule-of-reason and then a third step applying the rule-of-reason analysis.<sup>191</sup> According to Judge Walls, in determining whether to apply the rule-of-reason analysis, the district court should ask:

- (1) “Is there a reverse payment?”

The answer to this question is based upon what the parties exchanged in settlement and must include monetary payment.<sup>192</sup>

- (2) “Is the reverse payment large and unjustified?”

The court noted that only *certain* reverse payments will actually warrant scrutiny.<sup>193</sup>

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188. *Id.* at 2237.

189. *Id.* (“The existence and degree of any anticompetitive consequence may also vary among industries.”).

190. *See id.* at 2236.

191. *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-995, 2012 U.S. Dist. LEXIS 183627, at \*13 (D.N.J. Dec. 6, 2012).

192. *Id.*

193. *Id.*

If these two questions are answered in the affirmative, only then does the court apply the reason-of-rule analysis.<sup>194</sup>

In contrast, in evaluating a motion to dismiss, Judge Young applied a detailed rule-of-reason analysis to evaluate the direct purchasers' claims. Judge Young did not ask Judge Walls's preliminary questions. Rather, instead of applying a three-part test, Judge Young evaluated whether there was a reverse payment and whether the payment was large and unjustified. As described in detail above,<sup>195</sup> the direct purchasers challenged agreements between AstraZeneca and three generic defendants (Ranbaxy, Teva, and Dr. Reddy's). In applying the rule-of-reason analysis, Judge Young considered three primary factors: "(1) whether 'the alleged agreement involved the exercise of power in a relevant economic market,' (2) whether 'this exercise had anti-competitive consequences,' and (3) whether 'those detriments outweighed efficiencies or other economic benefits.'"<sup>196</sup>

#### 1. *Market Power in the Relevant Market*

In Judge Young's case, the defendants challenged the direct purchasers' proposed market—the brand name drug, Nexium, and its generic equivalents.<sup>197</sup> The defendants argued that the proposed market was too narrow because it excluded other products that either have similar chemical structure or were used to treat comparable medical conditions.<sup>198</sup> Judge Young found that this argument "r[a]ng hollow."<sup>199</sup> The relevant market for antitrust purposes is made up of "commodities reasonably interchangeable by consumers for the same purposes."<sup>200</sup> According to Judge Young, reasonable interchangeability does not depend on similarity of forms and functions, but instead on the cross-elasticity of demand—"the extent to which purchasers will accept substitute

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194. *Id.* at \*13–14.

195. *See supra* Part II.C.1.b.

196. *In re* Nexium (Esomeprazole) Antitrust Litig., Civ. A. No. 12-MD-02409-WGY, 2013 U.S. Dist. LEXIS 129696, at \*44 (D. Mass. Sept. 11, 2013) (internal citations omitted).

197. *Id.* at \*46.

198. *Id.* at \*46–47.

199. *Id.* at \*47.

200. *Id.* at \*48 (citing *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956)).

products in instances of price fluctuation and other changes.”<sup>201</sup> The direct purchasers expressly alleged that Nexium only exhibits positive cross-elasticity with AB-rated generic versions.<sup>202</sup> Noting that other courts have ruled that both a brand name drug and the related generics fall within the bounds of the relevant market, Judge Young decided that such an intense factual determination is best left to a jury.<sup>203</sup>

For the purposes of deciding the motion to dismiss, Judge Young presumed that the relevant market was simply the brand name drug and the generic, and found that the Plaintiffs alleged more than enough facts for a reasonable jury to conclude that the defendants exercised market power.<sup>204</sup> Judge Young found that direct evidence of market power,<sup>205</sup> and that AstraZeneca, as a monopolist, charged supracompetitive prices for brand name Nexium.<sup>206</sup>

## 2. *Anticompetitive Consequences*

Defendants also argued that the direct purchasers failed to allege a cognizable injury to competition.<sup>207</sup> The direct purchasers alleged that the generic defendants would have entered the market prior to the expiration of the patents *but for* the settlement agreements.<sup>208</sup> The defendants assert this was too speculative.<sup>209</sup> The generic defendants argued that there was no indication that they would have prevailed in litigation or launched “at risk.”<sup>210</sup> Dr. Reddy’s further argued that Ranbaxy’s right of 180-day exclusivity precluded it from entering the market.<sup>211</sup> Judge Young recognized that the case law was divided as to whether allegations based on speculations about generic entry into the market resting upon *but-for* theories of causation raised a triable antitrust issue.<sup>212</sup> However,

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201. *Id.* at \*48 (citing *George R. Whitten, Jr., Inc. v. Paddock Pool Builders, Inc.*, 508 F.2d 547, 552 (1st Cir. 1974)).

202. *Id.* at \*48–49.

203. *Id.* at \*49–50.

204. *Id.* at \*50–52.

205. *Id.* at \*52–53.

206. *Id.* at \*53.

207. *Id.* at \*53–54.

208. *Id.* at \*54.

209. *Id.*

210. *Id.*

211. *See id.*

212. *See id.* at \*55–56.

Judge Young found that the direct purchasers' allegations were sufficient. Judge Young noted that the generic defendants had launched "at risk" in the past and rejected Dr. Reddy's argument, because courts have been skeptical of agreements that allow a first filer who does not intend to market its drug to use its 180-day exclusivity period to prohibit other generic competition.<sup>213</sup>

In addition, Judge Young applied an "additional gloss to the standard antitrust-injury analysis" outlined in *Actavis*.<sup>214</sup> As described above, the Supreme Court identified four factors that impact the likelihood that a reverse payment has anticompetitive effects—(1) the size of the payment, (2) the scale in relation to future litigation costs; (3) the independence from other services; and (4) the lack of any other convincing justification.<sup>215</sup> Judge Young, at this stage in the proceedings, did not explicitly apply each factor. Rather, he viewed the test as stating that "only those reverse payment agreements whose anticompetitive consequences are sufficiently great and sufficiently unrelated to the settlement of a particular patent dispute will be censured by the courts."<sup>216</sup>

As described in detail above, Judge Young found that AstraZeneca's no-AG agreement with Ranbaxy and AstraZeneca's forgiveness of Teva's and Dr. Reddy's contingent liabilities for past patent infringement regarding different drugs should be classified as a payment.<sup>217</sup> Judge Young determined that there was no "persuasive procompetitive justification" for the agreements.<sup>218</sup> Viewing the allegations in the light most favorable to the direct purchasers, Judge Young found that the agreements sufficiently implicate anticompetitive consequences to allow the case to proceed.<sup>219</sup>

In his case, *In re Lamictal*, Judge Walls viewed the no-AG agreement differently. Judge Walls found the agreement would have minimal effects on competition because the generic was allowed six months of early entry, there was no payment of money, and the duration of the no-AG agreement was a relatively brief six

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213. *Id.* at \*56–57.

214. *Id.* at \*57.

215. *See* Fed. Trade Comm'n v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013).

216. *See In re Nexium*, 2013 U.S. Dist. LEXIS 129696, at \*58.

217. *See supra* text accompanying notes 165–71.

218. *See In re Nexium*, 2013 U.S. Dist. LEXIS 129696, at \*58.

219. *Id.* at \*58–59.

months.<sup>220</sup> Judge Walls also found that the no-AG agreement was justified. While the “value to [the generic] of the [no-AG agreement] likely exceeds what the parties would have spent litigating the patent dispute, the consideration which the parties exchanged in the settlement is reasonably related to the removal of uncertainty created by the dispute.”<sup>221</sup>

### 3. *Weighing Economic Detriments Against the Economic Benefits*

In *In re Nexium*, Judge Young further determined that the defendants did not put forth “a shred of affirmative evidence” that tended to show that the agreements had any “procompetitive” benefits.<sup>222</sup> According to Judge Young, the only conceivable benefit of reverse payment agreements is the settlement of patent disputes, and this benefit does not overcome the anticompetitive consequences caused by the agreements.<sup>223</sup> Judge Young noted that *Actavis* recognized that reverse payments that reflect “traditional settlement considerations, such as avoided litigation costs or fair value for services” do not raise the same concerns.<sup>224</sup> Judge Young did not find that these “traditional settlement considerations” were present.<sup>225</sup>

Judge Young appeared to doubt the economic benefit of the agreements. Judge Young noted that the presumption of validity for patents is in doubt and that while patent holders have broad exclusionary rights, those rights are limited. He cited an FTC study claiming that “[g]eneric applicants prevail[] [seventy-three] percent of the time.”<sup>226</sup> Therefore, Judge Young concluded that the direct purchasers’ complaint was sufficient.<sup>227</sup>

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220. *In re Lamictal Direct Purchaser Antitrust Litig.*, 2014 U.S. Dist. LEXIS 9257, at \*28 (D.N.J. Jan. 24, 2014).

221. *Id.* at \*29. Judge Walls distinguished *In re Nexium* by stating that there was “one crucial distinction: the plaintiffs alleged that the brand name manufacturer not only entered into a [no-AG] agreement but also paid the first filing generic millions of dollars. *Id.* at \*26. *But see In re Nexium*, 2013 U.S. Dist. LEXIS 129696, at \*60 n.20 (“[T]he inclusion of a monetary payment [from the brand name manufacturer to the first filed generic] ultimately does not affect this Court’s analysis . . .”).

222. *In re Nexium*, 2013 U.S. Dist. LEXIS 129696, at \*64.

223. *Id.*

224. *Id.* at \*64–65.

225. *Id.* at \*65.

226. *Id.*

227. *Id.* at \*66.

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4. *Exception to Antitrust Liability—Noerr-Pennington Immunity*

The Noerr-Pennington doctrine provides immunity “to persons and organizations who, with the intent to restrain trade and diminish competition, act in concert to petition the government to adopt laws and implement policies that are anticompetitive in nature.”<sup>228</sup> AstraZeneca argued, on behalf of all defendants, that because the New Jersey District Court entered consent judgments sanctioning the settlement agreements, any anticompetitive harm is attributable to government action.<sup>229</sup> Each of the agreements required court approval to go into effect. Moreover, the New Jersey District Court formally enjoined the generic defendants from placing the generic on the market.<sup>230</sup>

Generally, private settlement agreements that are not approved by a judge are not provided this immunity.<sup>231</sup> However, there is a question as to whether consent judgments are provided immunity. Relying on the framework outlined in a thirteen-year-old law review article, Judge Young determined that the consent judgments in this case would grant such immunity.<sup>232</sup>

Judge Young’s analysis boiled down to answering a single question: “Is the private conduct a valid effort to influence government?”<sup>233</sup> Judge Young determined that a consent judgment could not be considered as direct “petitioning” of the government.<sup>234</sup> His rationale was that in settlement negotiations, the parties privately negotiate the terms and present them to the court.<sup>235</sup> In contrast, a judicial opinion is aided by the adversarial process and the judge can review the merits of the claims.<sup>236</sup> In addition, Judge Young found that the consent judgment was not “incidental” to the litigation.<sup>237</sup> While such things as pre-suit demand letters, discovery communications, decisions regarding

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228. *Id.* at \*67–68.

229. *Id.* at \*69.

230. *Id.* at \*70.

231. *Id.* at \*71 (citing Raymond Ku, *Antitrust Immunity, the First Amendment and Settlements: Defining the Boundaries of the Right to Petition*, 33 IND. L. REV. 385, 404 (2000)).

232. *Id.*

233. *Id.* at \*72.

234. *Id.* at \*74.

235. *Id.*

236. *Id.* at \*73–74.

237. *Id.* at \*75–76.



settlement offers, and litigation threats have been granted immunity, Judge Young found these distinct from consent judgments, since they have the common purpose of persuading a judicial officer to redress a grievance.<sup>238</sup> Such is not the case with a consent judgment. Most settlements are made without a final stamp from the judge and consent judgments are made at the behest of the private parties.<sup>239</sup> Judge Young determined that the consent judgments in this action served only to “memorialize a bargained-for agreement” and that nothing prevented the parties from simply stipulating to dismiss the patent actions.<sup>240</sup>

Judge Young viewed the role of the New Jersey District Court as merely perfunctory.<sup>241</sup> While AstraZeneca argued that the New Jersey District Court exercised its discretion in enjoining the generic defendants, it was unclear to Judge Young how much content in the agreements could be found in the consent judgment, since the agreements were heavily redacted and entering a consent decree did not reflect a court’s assent to the substance of the settlement agreements.<sup>242</sup> Thus, Judge Young determined that the consent judgments were not afforded immunity.<sup>243</sup>

#### V. INSIGHT INTO HOW COURTS MAY STRUCTURE ANTITRUST PROCEEDINGS AND APPLY THE *ACTAVIS* RULE-OF-REASON

The differences in Judge Walls’s approach and Judge Young’s approach of applying *Actavis* demonstrate the uncertainty that the decision has created. Yet, the decisions provide at least some insight into how courts may view antitrust proceedings. First, reaching early resolution through a motion to dismiss or a motion for summary judgment may be challenging depending upon which approach a district court adopts and the specific terms of the settlement. For example, if a district court adopts Judge Young’s approach of subjecting all settlements to a rule-of-reason analysis, disagreement on the appropriate market can cause a factual dispute. While Judge Young appeared to be willing to entertain the notion that the market was larger than simply the brand name drug

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238. *Id.* at \*76.

239. *Id.* at \*77.

240. *Id.*

241. *Id.* at \*79.

242. *Id.* at \*81.

243. *Id.* at \*82.

and its AB-rated generic versions,<sup>244</sup> he deemed it a factual inquiry for the jury. In *In re Nexium*, the defendants proposed a market that included Prilosec (the active ingredient is omeprazole) and Nexium (the active ingredient is esomeprazole).<sup>245</sup> Omeprazole is a mixture of two optical isomers<sup>246</sup>—esomeprazole (S-omeprazole) and R-omeprazole.<sup>247</sup> Both are used to treat acid-related diseases.<sup>248</sup> Despite these similarities,<sup>249</sup> Judge Young was unwilling to expand the market without a more detailed factual record.<sup>250</sup>

Second, providing a detailed justification for the reverse payment will be extremely important. Judge Young took a very broad view of what constituted “payment” from the brand name manufacturer to the generic manufacturer by including the no-AG agreements and forgiveness of contingent liabilities.<sup>251</sup> Since there is divergent case law on whether nonmonetary compensation constitutes a “payment,” it is important to be able to justify any compensation that flows from the brand name manufacturer to the generic manufacturer. Reading *Actavis* as holding that reverse payments are only justified if they reflect the payor’s future litigation costs is incorrect. The Supreme Court clearly stated that the payment may represent compensation for other services, or

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244. The FDA evaluates whether certain drugs are therapeutically equivalent. As part of this evaluation, the FDA assigns certain codes or ratings. A drug product that has been demonstrated as bioequivalent has the identical active ingredient, dosage form, route of administration, and the same strength as another drug product that will be given an AB-rating to that drug product. For a detailed discussion of FDA codes, see U.S. DEP’T OF HEALTH & HUMAN SERVS., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, at xiii–xx (34th ed. 2013), available at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>.

245. *In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-02409-WGY, 2013 U.S. Dist. LEXIS 129696, at \*26 (D. Mass. Sept. 11, 2013).

246. This describes two chemical structures that are mirror images of each other.

247. See T. Andersson et al., *Pharmacokinetics and Pharmacodynamics of Esomeprazole, the S-Isomer of Omeprazole*, 15 ALIMENTARY PHARMACOLOGY & THERAPEUTICS 1563, 1563 (2001).

248. *Id.*

249. In very simplistic terms, the active ingredient in Prilosec contains the active ingredient in Nexium plus a compound that is the mirror image of Nexium’s active ingredient.

250. See *In re Nexium*, 2013 U.S. Dist. LEXIS 129696, at \*50.

251. *Id.* at \*60–62 (“Adopting a broader interpretation of the word ‘payment,’ on the other hand, serves the purpose of aligning the law with modern-day realities.”).

there may be some other convincing justification.<sup>252</sup> The procedural posture of *Actavis* should not be forgotten. While the *Actavis* defendants described the payments as for other services, such as marketing to urologists and backup manufacturing, the FTC alleged that these payments were intended to keep the generics off the market.<sup>253</sup> The Court was simply determining whether or not the FTC should be allowed to proceed with its case. The Court did not determine whether the defendants' justifications were meritorious.

Third, in addition to providing a detailed justification for the reverse payment, it is important to show how the payment reflects "traditional settlement considerations." While not critical to Judge Walls's analysis, Judge Young determined that the agreements in *In re Nexium* did not reflect traditional settlement considerations.<sup>254</sup> Judge Young appeared to have a very narrow view of what constitutes traditional settlement considerations. Part of the Teva and Dr. Reddy's settlement agreements dealt with forgiving contingent liabilities from other cases.<sup>255</sup> It is common for parties to enter into broad settlements that settle a variety of issues between them. In addition, it is not readily apparent how relief of an unrelated liability is "using . . . monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement."<sup>256</sup> Rather, it could simply be that the parties wanted to call a truce. Whether such global settlements or "side deals" are part of "traditional settlement considerations" is up for debate.

Fourth, antitrust defendants should be prepared to present evidence regarding the strength of the underlying patent. Judge Young made a point to mention that the presumption of validity of patents is in doubt and cited the FTC statistic that generics prevail seventy-three percent of the time.<sup>257</sup> While other studies have found

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252. Fed. Trade Comm'n v. *Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013) ("[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.").

253. *Id.* at 2229.

254. *In re Nexium*, 2013 U.S. Dist. LEXIS 129696, at \*65.

255. *Id.* at \*58.

256. *Actavis*, 133 S. Ct. at 2236.

257. *In re Nexium*, 2013 U.S. Dist. LEXIS 129696, at \*65 (citing FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 16* (2002), available at <http://www.ftc.gov/sites/default/files/documents/reports>

that the generic success rate is typically less than fifty percent,<sup>258</sup> antitrust defendants may have to demonstrate why in their underlying patent case a generic victory would have been difficult. The evidence required will depend upon the specific allegations and facts of the underlying patent case.

Fifth, there is a very slight chance that settlements may be granted Noerr-Pennington immunity.<sup>259</sup> While Judge Young said that “the very fact that the Defendants can with a straight face advance this Noerr-Pennington argument based on consent judgments” should give judges pause, in his opinion he appears to slightly struggle with the fact that the New Jersey District Court enjoined the generic manufacturer’s from entering the market.<sup>260</sup> The settlement agreements were heavily redacted, and it was not clear how much of the settlement agreements had been endorsed by the court.<sup>261</sup> This may present an opening, however small, for Noerr-Pennington immunity. If the defendants in an antitrust action can show that the court in the underlying patent dispute considered the terms of the settlement agreement in issuing judgment, there is a slight chance that the judgment may be provided immunity.

## VI. CONCLUSION

In his dissent in *Actavis*, Justice Roberts predicted “that the majority’s decision may very well discourage generics from challenging pharmaceutical patents in the first place.”<sup>262</sup> Only time will tell if Justice Roberts is correct. One thing is for certain: there will be more litigation outlining the contours of the *Actavis* decision. The FTC has committed to pursue litigation of past, present, and future agreements it deems as pay-for-delay.

Courts will have to address the basic question of what is a “payment.” The FTC holds the view that no-AG agreements are

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/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy\_0.pdf).

258. See PRICEWATERHOUSECOOPERS LLP, 2012 PATENT LITIGATION STUDY 28 (2012).

259. See Melissa Lipman, *Drug Cos. Say Noerr Doctrine Bars FTC’s Pay-for-Delay Suit*, LAW360 (Jan. 17, 2014), <http://www.law360.com/articles/496522/drug-cos-say-noerr-doctrine-bars-ftc-s-pay-for-delay-suit>.

260. *In re Nexium*, 2013 U.S. Dist. LEXIS 129696, at \*82 n.29.

261. *Id.* at \*81–82.

262. Fed. Trade Comm’n v. *Actavis, Inc.*, 133 S. Ct. 2223, 2247 (2013) (Roberts, C.J., dissenting).

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reverse payments. Will courts read *Actavis* narrowly and follow the rationale in *In re Lamictal* that reverse payments are simply monetary payments? Or will courts interpret *Actavis* broadly and follow Judge Young's rationale that payments include monetary and nonmonetary compensation? And courts will have to establish criteria for what makes a payment "large." Is the size of the payment based solely on the expected profits of the generic had it won the patent litigation? Or is "large" simply in the eye of the beholder?

Courts will also have to address when to apply the rule-of-reason analysis. Is Judge Walls correct that the district court must first determine whether there was a reverse payment and whether that payment was large and unjustified before applying the rule-of-reason analysis? Or is Judge Young correct that such questions are part of the rule-of-reason analysis?

While courts are sifting through these basic questions, one thing is clear: antitrust defendants should be prepared to justify any payment. *Actavis* clearly contemplates that the payment can be something more than a rough estimate of future litigation costs to the brand name manufacturer. Payments can be for unrelated services, but antitrust defendants should be prepared to explain, in detail, the value of the services and how the parties reached that number. What is unclear is what other justifications may exist for a reverse payment. If a first filer gives up its 180-day market exclusivity, like *Actavis* did, does that impact the analysis? Are there other "traditional settlement considerations," like global litigation settlements, that would justify a reverse payment?

While the Court rejected the FTC's desire for a "quick look" approach, the rule-of-reason approach may encourage the parties, at least in part, to argue the merits of the underlying case. When a court weighs the economic detriments against the economic benefits, the likelihood of the generic prevailing may become an issue. What courts, and ultimately juries, decide is sufficient evidence to demonstrate that the patent is strong depends on the facts of the individual case and will be determined over time.