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## ANDA Reverse Payments and the Post-Actavis Landscape

Michele M. Kang

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# ANDA Reverse Payments and the Post-*Actavis* Landscape

by MICHELE M. KANG\*

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## I. Introduction

Imagine that you have come down with a cold. You immediately head to the nearest drug store in search of medicine to relieve your symptoms. You walk up and down the aisle and you notice that there are multiple variations of the drug that you need — Tylenol next to acetaminophen, Robitussin next to guaifenesin, etc. You compare the two equivalent drugs and you note that most, if not all, of the ingredients are the same. The only difference, aside from the name and packaging, seems to be the price at which these drugs are sold. Did you ever consider what the effects would be if competitive non-brand-name drugs did not enter the market at all?

A “generic drug” is defined as a term referring to any drug product that is marketed under its chemical name that is comparable to a brand-name drug product in dosage form, strength, quality and performance characteristics, and intended use.<sup>1</sup> Generic drugs are sold at a price substantially discounted from their respective brand-name drug, even though they are chemically identical.<sup>2</sup> Creating a new drug is expensive because extensive research and development are required along with clinical trials. Because generic drug makers do not need to develop a drug from scratch, the costs to bring drugs to the market are significantly less than drugs recently created through research and development.<sup>3</sup> Consequently, generic drugs are significantly cheaper than brand-name drugs. Thus, generic drugs save consumers an estimated eight to ten billion dollars a year at retail pharmacies, and even billions more when used by hospitals.<sup>4</sup>

Like most new products and inventions, new drugs are developed under patent protection. Generally speaking, a patent application filed on or after June 8, 1995 has a term that begins on the date the patent issues and ends twenty years from its filing date.<sup>5</sup> The patent serves to protect the investment made in the development of the new drugs by granting the company, who conducted the research, the exclusive right to sell the drug

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1. *Generic Drugs: Questions and Answers*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm> (last visited Jan. 7, 2015).

2. Generic Drugs, *supra* note 1.

3. *Id.*

4. *A CBO Study: How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, THE CONGRESS OF THE UNITED STATES CONGRESSIONAL BUDGET OFFICE, at 14, (July 1998), available at <http://www.cbo.gov/sites/default/files/pharm.pdf>.

5. U.S. Patent Act 35 U.S.C. §154(2).

while the patent is in effect.<sup>6</sup> Generic drugs, however, have been allowed an exception through the Drug Price Competition and Patent Term Restoration Act of 1984 — more commonly known as the Hatch-Waxman Act. Drug companies can submit an abbreviated new drug application (“ANDA”) for approval to market a generic product.<sup>7</sup> An ANDA must contain data, which when submitted to the Food and Drug Administration’s (“FDA”) Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and approval of a generic drug product.<sup>8</sup> Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, and low-cost alternative to the American public.<sup>9</sup> This ANDA process does not require the generic drug company to repeat costly clinical research related to ingredients or dosage forms that have already been approved for safety and effectiveness for the brand-name drugs.<sup>10</sup> The first company to file an ANDA for a particular drug gets exclusive rights to market the drug as the generic alternative to the brand named drug for 180-days.<sup>11</sup> After this six months period, other companies may sell generics and enter the marketplace.

In response to the Hatch-Waxman Act, brand-name companies and generic drug companies now settle lawsuits in order to maximize their own profits. Any two competitors can profit by agreeing not to compete with each other, as long as they can find a way to split the profits.<sup>12</sup> The longer the competition is delayed, the more profits will be accumulated. In 2013, the Supreme Court dealt with this issue in the case *FTC v. Actavis*, and deemed that these types of patent settlements could potentially face antitrust scrutiny.<sup>13</sup> The Supreme Court considered the legality of patent litigation settlements that affect competition between branded and generic competitors. These policies and precedents, alongside antitrust competition policy, underscore the importance of drug market competition in U.S.

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6. Generic Drugs, *supra* note 1.

7. *Id.*

8. *Abbreviated New Drug Application (ANDA): Generics*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics> (last visited July 14, 2015).

9. ANDA, *supra* note 8.

10. Generic Drugs, *supra* note 1.

11. 21 U.S.C. § 505(j)(2)(A)(vii)(IV) (2012).

12. Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Actavis and Error Costs: A Reply to Critics*, THE ANTITRUST SOURCE, at 1 (Oct. 2014).

13. See *FTC v. Actavis*, 133 S. Ct. 2223, 2232 (2013).

healthcare policy.<sup>14</sup> Accordingly, in my Note, I will discuss the effect of generic brands in the market, how the Hatch-Waxman Act affects anti-competition within the pharmaceutical sphere, how the Supreme Court approaches this issue, and how lower courts have responded to the Supreme Court's ruling regarding these settlements.

## II. The Effects of Generic Drugs in the Marketplace

The Hatch-Waxman Act, which brought about the abbreviated pathway for generic drug approval, spurred the growth of the current generic drug industry in the United States.<sup>15</sup> To gain FDA approval, a generic drug must contain the same active ingredients as the innovator drug; be identical in strength, dosage form, and route of administration; have the same use indications; be bioequivalent, meet the same batch requirements for identity, strength, purity, and quality; and be manufactured under the same strict standards of FDA's good manufacturing practice regulations required for innovator products.<sup>16</sup> The Generic Pharmaceutical Association noted that the generic drug industry has saved the American public \$1.2 trillion over the past thirty years since the launch of the Hatch-Waxman Act.<sup>17</sup> The increased trend in new drug approvals is a positive sign of the level of innovation demonstrated by the industry.<sup>18</sup>

The use of generics has increased substantially since the mid-1990s, in part because of increases in the mechanisms available to promote generic use, including incentives in commercial insurance plans and public coverage, such as tiered formularies with lower patient co-payments for

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14. Luke M. Olson & Brett W. Wendling, *The Effect of Generic Drug Competition on Generic Drug Prices During the Hatch-Waxman 180-Day Exclusivity Period*, BUREAU OF ECONOMICS FEDERAL TRADE COMMISSION 1 (Apr. 2013), <https://www.ftc.gov/sites/default/files/documents/reports/estimating-effect-entry-generic-drug-prices-using-hatch-waxman-exclusivity/wp317.pdf>.

15. Mike Chace-Ortiz, *Trends and Development in the U.S. Generics Drug Industry 2014*, LIFE SCIENCES CONNECT (June 26, 2014), <http://lsconnect.thomsonreuters.com/trends-developments-u-s-generics-drug-industry-2014/>.

16. Generic Drugs, *supra* note 1.

17. *Generic Drug Savings in the U.S.*, GENERIC PHARM. ASSOC. 2 (2013), available at [http://www.gphaonline.org/media/cms/2013\\_Savings\\_Study\\_12.19.2013\\_FINAL.pdf](http://www.gphaonline.org/media/cms/2013_Savings_Study_12.19.2013_FINAL.pdf).

18. Jody Fisher, *U.S. Drug Market Trends: Looking Beyond the LOE to the New Normal*, PM360ONLINE (June 1, 2013), <http://www.pm360online.com/u-s-drug-market-trends-looking-beyond-the-loe-to-the-new-normal/>.

generic than for brand-name drugs, and restricting formulary coverage to generics in certain therapeutic categories.<sup>19</sup>

Since 1993, sales of drugs have increased from about \$50 billion per year to around \$300 billion in 2012.<sup>20</sup> Many policymakers view generic drug competition as the principal method to contain the rapid growth in drug costs, which currently represents the fastest growing segment of healthcare expenditures in the United States.<sup>21</sup>

Total healthcare system spending on medicine reached \$320 billion in 2011.<sup>22</sup> Over 80% of a brand's prescription volume is replaced by generics within six months of a patent expiring.<sup>23</sup> As a result, generic products have increased its share of total dispersed prescriptions in the US from 36% in 1994 to 84% in 2012.<sup>24</sup> Generics also bring savings directly to patients. In 2010, the average copayment for a generic drug was \$6.06 per prescription, compared to \$34.77 for brand named drugs.<sup>25</sup> During that year, generic use generated more than \$157 billion in savings.<sup>26</sup> Savings from generic medications have continued to grow at an exponential rate, reaching more than \$360 billion from 2001 by the end of 2010.<sup>27</sup>

The number of generic companies manufacturing a specific drug further affects the market. New brand-name drugs generate nearly all of their sales during a market exclusivity period ("MEP"), which is the time period between market launch of a brand-name drug and the launch of its first generic.<sup>28</sup> On average, the first generic competitor prices its product only slightly lower than the price of the brand-name manufacturer.<sup>29</sup> The

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19. Henry Grabowski, Genia Long & Richard Mortimer, *Brief Report: Recent Trends in Brand-Name and Generic Drug Competition*, J. MED. ECON. 2, available at <http://fds.duke.edu/db/attachment/2575>.

20. Fisher, *supra* note 18, at 1.

21. Olson & Wendling, *supra* note 14, at 1.

22. *The Use of Medicines in the United States: Review of 2011*, IMS INST. FOR HEALTHCARE INFORMATICS 2 (2012), available at [https://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII\\_Medicines\\_in\\_US\\_Report\\_2011.pdf](https://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_US_Report_2011.pdf).

23. *The Use of Medicines in the United States: Review of 2010*, IMS INST. FOR HEALTHCARE INFORMATICS 3 (2011), available at [http://www.imshealth.com/deployedfiles/imshealth/Global/Content/IMS%20Institute/Static%20File/IHII\\_UseOfMed\\_report.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/IMS%20Institute/Static%20File/IHII_UseOfMed_report.pdf).

24. Grabowski et al., *supra* note 19, at 2.

25. IMS INST. FOR HEALTHCARE INFORMATICS, *supra* note 23, at 14.

26. *SAVINGS: An Economic Analysis of Generic Drug Usage in the U.S.*, GENERIC PHARM. ASSOC. 3 (2011), available at [https://www.tevagenerics.com/assets/base/pdf/Savings\\_AnEconomicAnalysis.pdf](https://www.tevagenerics.com/assets/base/pdf/Savings_AnEconomicAnalysis.pdf).

27. Savings, *supra* note 26.

28. Grabowski et al., *supra* note 19.

29. *Generic Competition and Drug Prices*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm> (last updated Mar. 1, 2010).

entrance of a second generic manufacturer reduces the average generic price to nearly half the brand name price.<sup>30</sup> Any additional generic companies manufacturing the brand-name drug affect the market less drastically.<sup>31</sup> For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price.<sup>32</sup>

### III. Patent Settlements

#### A. Reverse Payment Settlements

A trend that has been rising in response to the increasing number of generics entering the pharmaceutical market are patent settlements that allow brand-name drugs to hold onto their control of the market. These types of arrangement raise concerns associated with anticompetitive behavior by brand-name companies preventing other players in the market from entering.<sup>33</sup> Over the past ten years, patent settlements have enabled dozens of first-time generics to come to market many months before patents on the counterpart brand-name drugs expired.<sup>34</sup> In 2011, of the twenty-two new generic drug launches, settlements allowed sixteen of these generics to launch prior to patent expiry.<sup>35</sup>

One particular type of settlement is a reverse payment settlement agreement, also known as “pay-for-delay” deals, which involve a brand-name drug manufacturer compensating a generic brand entrant to abandon its patent challenge and not to enter the market for a number of years.<sup>36</sup> This settlement requires the patentee to pay the alleged infringer, rather than the other way around, which is what is usually expected.<sup>37</sup> The Federal Trade Commission (“FTC”) estimated that these deals cost American consumers \$3.5 billion a year.<sup>38</sup> These generic firms are now agreeing to delay their launches not just for cash, but for a promise from the patent-holder to delay or cancel the launch of its authorized generic.<sup>39</sup>

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30. Generic Competition, *supra* note 29.

31. *Id.*

32. *Id.*

33. Robin Feldman, *Ending Patent Exceptionalism and Structuring the Rule of Reason: The Supreme Court Opens the Door for Both*, 15 MINN. J.L. SCI. & TECH. 61, 66 (2014).

34. IMS INST. FOR HEALTHCARE INFORMATICS, *supra* note 25, at 6.

35. *Id.*

36. *Something Rotten*, ECONOMIST (Aug. 6, 2009), <http://www.economist.com/node/14172627>.

37. *FTC v. Actavis*, 133 S.Ct. 2223, 2227 (2013).

38. *Id.*

39. The Economist, *supra* note 36.

The four most common scenarios involving a brand-name company's consideration to a generic brand are: cash, poison pill clauses, no-authorized generic provisions, and forgiveness of damages.<sup>40</sup> Cash is a form of consideration in which a brand-name drug manufacturer pays cash to a generic to delay entering the market.<sup>41</sup> In this situation, the generic receives a type of consideration that would not have been available as a result of litigation — because under no circumstance would the brand-name company supplement the generic's entry into the market by paying it money.<sup>42</sup>

A second type of compensation is a poison pill clause which ensures that a generic drug company can expedite its entry when another generic enters the market.<sup>43</sup> These clauses ensure that no other generic manufacturer, no matter how much time and resources it spends in its litigation, can enter the market before the generic that has a poison pill agreement with the brand-named company.

Another specific type of pay-for-delay agreement is a no-authorized generic ("No-AG") arrangement. When a generic enters the market to compete with the brand, typically the brand-name drug producer can introduce its own authorized generic version of the drug, making three drugs available for consumers (one brand and two generics).<sup>44</sup> The entry of an authorized generic would make that 180-day window for the unauthorized generic brand much less profitable. In a No-AG pay-for-delay arrangement, the generic manufacturer is being compensated for agreeing to delay entry by the brand manufacturer's own commitment to delay entry with its authorized generic.<sup>45</sup> In effect, this allows the generic manufacturer to keep their generic prices higher than they would be otherwise.

The fourth scenario, brand forgiveness of damages, involves a situation in which a generic has already entered the market. Even though generics sell their products cheaper than brand-name drugs, a generic found to be infringing on a brand-name drug's patent could be liable for the higher level of damages in the amount of the brand-name drug's lost

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40. See Michael A. Carrier. *Payment After Actavis*. 100 IOWA L. REV. 7, 36-47.

41. Carrier, *supra* note 40, at 36.

42. *Id.* at 36-37.

43. *Id.* at 37.

44. Joshua D. Wright, Comm'r, Fed. Trade Comm'n, Remarks at the Antitrust Master Course VII (Oct. 10, 2014), available at [https://www.ftc.gov/system/files/documents/public\\_statements/591131/141010actavisspeech.pdf](https://www.ftc.gov/system/files/documents/public_statements/591131/141010actavisspeech.pdf).

45. *Id.*

profits.<sup>46</sup> In addition to lost profits, generics could also be liable for any reduction in brand prices resulting from the introduction of the generic drug.<sup>47</sup> With this type of settlement, the brand-name drug company could settle by agreeing to forgive some of these damages.<sup>48</sup>

When a party with no claim for damages walks away with money or other forms of compensation, simply so that it will stay away from the patentee's market, antitrust issues come into question for these unjustified settlements.<sup>49</sup>

### **B. Patent Exceptionalism Conflicts with Antitrust Goals**

The clash between patent law and antitrust law is a colossal one, with antitrust law abhorring monopoly and patent law advocating it.<sup>50</sup> Patent exceptionalism is a misconstrued idea of the patent system to exercise free reign to patent holders.<sup>51</sup> Patent exceptionalism follows the line of reasoning that when a patent is at play, antitrust should yield, and the government should keep its nose out.<sup>52</sup> This reasoning derives that given a patent holder's lawful right to exclude others from the market, a patent conveys the right to cripple competition.<sup>53</sup> Patent exceptionalism flows from a distorted view of a patent's actual function.<sup>54</sup> As long as an invention is useful, new, and obvious a patent can be obtained. A patent does not grant the right to do anything at all; except to exclude others from making, using, or selling the invention that is patented.<sup>55</sup> The mere fact that you have a patent is not an act of infringement. Multiple patents may have overlapping rights to exclude,<sup>56</sup> since a patent cannot infringe upon another patent. Antitrust law, on the other hand, characterizes exclusion as the prevention of an incursion of a rival in a competitive sphere.<sup>57</sup>

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46. Carrier, *supra* note 40, at 44.

47. *Id.*

48. *Id.* at 45.

49. Verizon Comm'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 408 (2004) (“[C]ollusion is ‘the supreme evil of antitrust.’”).

50. Feldman, *supra* note 33, at 66–67.

51. *See Id.* at 62.

52. *Id.* at 66.

53. *Id.*; FTC. v. Watson Pharm.s, Inc., 677 F.3d 1298, 1330 (11th Cir. 2012).

54. *Id.* at 68.

55. *Id.*

56. *Id.*

57. *Id.*

### C. Antitrust Scrutiny of Patent Settlements

Congress passed the Sherman Antitrust Act in 1890 to combat anticompetitive practices, to reduce market domination by individual corporations, and to preserve unfettered competition as the rule of trade.<sup>58</sup> Violations under the Sherman Act take one of two forms — a “per se violation” or a violation of the “rule of reason.”<sup>59</sup> A per se violation is delineated in Section 1 of the Sherman Act as certain business practices, and requires no further inquiry into the practice’s actual effect on the market or the intentions of those individuals who engaged in the practice.<sup>60</sup> A “rule of reason” analysis applies a totality of the circumstances test and inquires as to whether the challenged practice promotes or suppresses market competition.<sup>61</sup> Intent and motive are often relevant in predicting future consequences during a rule of reason analysis.<sup>62</sup>

The “rule of reason” doctrine is used to interpret the Sherman Antitrust Act. In a traditional rule of reason analysis:

[The] court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its conditions before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the Reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences.<sup>63</sup>

This inquiry seems three-pronged: (1) What harm to competition results or may result from the collaborators’ activities? (2) What is the object they are trying to achieve and is it a legitimate and significant one? And (3) are there less restrictive alternatives to the challenged restraint?<sup>64</sup>

When applied to patents, the Sherman Act “imposes strict limitations on the concerted activities in which a patent owner may lawfully engage

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58. Legal Information Institute, *Antitrust: An Overview*, CORNELL UNIVERSITY LAW SCHOOL, <https://www.law.cornell.edu/wex/antitrust>.

59. *Id.*

60. The Sherman Antitrust Act, 15 U.S.C.A. § 1 (West 2015).

61. Legal Information Institute, *supra* note 58.

62. *Id.*

63. *Bd. of Trade of City of Chicago v. U.S.*, 246 U.S. 231, 238 (1918).

64. Phillip Areeda, *The “Rule of Reason” in Antitrust Analysis: General Issues*, HARVARD UNIVERSITY, FEDERAL JUDICIAL CENTER, [http://www.fjc.gov/public/pdf.nsf/lookup/antitrust.pdf\\$file/antitrust.pdf](http://www.fjc.gov/public/pdf.nsf/lookup/antitrust.pdf$file/antitrust.pdf).

in.”<sup>65</sup> In *United States v. Singer Mfg.* the Supreme Court held that the agreements, although settling patent disputes, violated antitrust laws.<sup>66</sup> That was because “the public interest in granting patent monopolies” exists only to the extent that “the public is given a novel and useful invention” in “consideration for its grant.”<sup>67</sup>

#### IV. The Hatch-Waxman Act

Numerous laws, regulations and legal precedents play an important role in directly affecting drug competition by altering the structure and shaping the competitive environment of these markets.<sup>68</sup> One piece of legislation in particular, The Hatch-Waxman Act, has been instrumental in constructing the market for both generic and branded drugs.<sup>69</sup> The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, amended the Federal Food, Drug, and Cosmetic Act to create an abbreviated pathway for approval of new drugs that are therapeutically equivalent to a brand drug. This process prescribes pharmaceutical manufacturers to file an ANDA for approval of a generic drug by the FDA.<sup>70</sup> Congress’ objective when enacting the legislation was to increase generic competition while balancing the resulting cost savings with sufficient incentives to encourage continued medical innovation through the development of new drugs.<sup>71</sup>

In addition to the patents that protect new inventions, the Hatch-Waxman Act grants periods of exclusivity to manufacturers that have new drugs approved by FDA.<sup>72</sup> Generic manufacturers frequently challenge patents protecting these brand-name drugs.<sup>73</sup>

Apparently 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

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65. *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196 (1963).

66. *Id.* at 195–97.

67. *Id.* at 199 (White, J., concurring).

68. Olson & Wendling, *supra* note 14.

69. *Id.*

70. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) (2015).

71. Grabowski, *supra* note 19, at 1.

72. *ASPE Issue Brief: Expanding the Use of Generic Drugs*, OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION OFFICE OF SCIENCE AND DATA POLICE – U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, 3 (2010).

73. Grabowski, *supra* note 19, at 1.

allowing a generic drug manufacturer to challenge the validity of a patent owned by an already approved brand-name drug owner.<sup>74</sup>

There are four key features of the Hatch-Waxman Act. The first of these features is that a drug manufacturer must submit a New Drug Application to the FDA if they wish to market a new prescription drug.<sup>75</sup> The manufacturer must submit as part of the application: full reports of investigations on the safety of the drug, a list of the articles used as components of the drug, a full statement of the composition of the drug, and more.<sup>76</sup> Then, these new prescription drugs undergo a long, comprehensive, and costly testing process in order to receive marketing approval from the FDA.<sup>77</sup> If a company only develops one drug, the median spending is still around \$351 million.<sup>78</sup> The median cost per new drug is \$4.2 billion for companies that have launched more than three drugs; this value increases to \$5.3 billion for those that have launched more than four drugs.<sup>79</sup>

The second feature of the Hatch-Waxman Act as the previously mentioned is the abbreviated procedure for generic drugs, which grants permission of a generic drug manufacturer to obtain similar marketing approval.<sup>80</sup> The generic drug manufacturer can file an Abbreviated New Drug Application specifying that the generic has the same active ingredients and is a bioequivalent to the already-approved brand-name drug.<sup>81</sup> This allows the generic manufacturer to avoid the costs and time involved with the research of developing these drugs, which are required to obtain approval. This in turn speeds the introduction of low-cost generic drugs to market thereby furthering drug competition.

The third feature of the Hatch-Waxman Act addresses special procedures for identifying and resolving related patent disputes. It requires the brand-name manufacturer to list in its New Drug Application the number and the expiration date of any relevant patent.<sup>82</sup> The generic

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74. *FTC. v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013); Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 24 (2004).

75. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b) (1) (2015).

76. *Id.* at § 355(b)(1)(A)–(G).

77. *Id.* at § 355(b)(1).

78. Matthew Herper, *How Much Does Pharmaceutical Innovation Cost? A Look at 100 Companies*, FORBES, Aug. 11, 2013, <http://www.forbes.com/sites/matthewherper/2013/08/11/the-cost-of-inventing-a-new-drug-98-companies-ranked/>.

79. *Id.*

80. 21 U.S.C. § 355(j)(1)–(2).

81. 21 U.S.C. § 355(j)(2)(iv) (2013).

82. *See Id.* at § 355(b)(1)(G).

manufacturer must then assure the FDA that the generic will not infringe the brand-name's patents by: certifying that the brand-name manufacturer has not listed any relevant patents, certify that any relevant patents have expired, request approval to market beginning when any still-in-force patents expire, or certify that any listed relevant patent is invalid or will not be infringed by the manufacture, use, or sale of the drug described in the Abbreviated New Drug Application.<sup>83</sup> This last option is also known as the "Paragraph IV" route and automatically counts as patent infringement.

The fourth feature is a special incentive for a generic to be the first to file an Abbreviated New Drug Application taking the Paragraph IV route. That applicant gets a period of 180-day exclusivity, where no other generic can compete with the brand-name drug.<sup>84</sup> Of the provisions in the Hatch-Waxman Act aimed at facilitating generic drugs entrance into the market, I will further discuss the ANDA process and Paragraph IV litigation.

#### **A. Abbreviated New Drug Application**

The ANDA process greatly reduces the cost of completing an FDA application for approval of a generic drug.<sup>85</sup> To meet the FDA standards prior to the Hatch-Waxman amendments, generic manufacturers had to duplicate many of the brand-name manufacturer trials, and submit their own safety and efficacy data on their products.<sup>86</sup> However, under the ANDA process, generic manufacturers only need to demonstrate that their products have the same active ingredients and are "bioequivalents" to their brand-name counterparts.<sup>87</sup> Under the Hatch-Waxman Act, generics are also given an exemption to patent law rules, to begin research on the brand-name's drug prior to that brand-name drug company's patent expiration.<sup>88</sup>

#### **B. Paragraph IV Litigation**

Another exemption to patent law that Hatch-Waxman allows generics is Paragraph IV litigation. The Hatch-Waxman Act created incentives for generic manufacturers to challenge brand-name patents before they expire.<sup>89</sup> During this process, the generic manufacturer notifies the FDA that either its generic product does not infringe on a listed patent on the

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83. *See Id.* at § 355 (j)(2)(A)(vii)(IV).

84. *See Id.* at § 355 (j)(5)(B)(iv).

85. Grabowski, *supra* note 19, at 2.

86. *Id.*

87. *Id.*

88. *Id.*

89. *Id.*

brand-name drug, or that the brand-name drug's patent is not valid.<sup>90</sup> A Paragraph IV challenge can be made at the dosage form or strength level.<sup>91</sup> The challenged brand-name drug company then has 45 days of receiving notice of a Paragraph IV litigation to file a patent infringement action against the generic company.<sup>92</sup> The FDA cannot approve the generic company's ANDA until the company prevails either in court, settlement, or expiration of a 30-month stay.<sup>93</sup>

The incentive for a generic manufacturer to file a Paragraph IV challenge and to receive FDA final approval of its application is a 180-day period of exclusivity.<sup>94</sup> The victor is then the only ANDA-approved generic version allowed on the market.<sup>95</sup> The first-to-file status is determined by the day of filing.<sup>96</sup> Multiple generic manufacturers can share first-to-file status if they file on the same day.<sup>97</sup> As mentioned above in the previous section, the first generic manufacturer to enter the market generally drops their prices only slightly below the manufacturer's price. Therefore, this 180-day window is potentially very profitable to a first-to-file Paragraph IV challenger.

The likelihood of a Paragraph IV challenge being filed has increased substantially in recent years, and has been occurring earlier in the drug life-cycle. Only 9% of drugs experiencing first generic entry in 1995 had experienced a Paragraph IV challenge prior to their first generic launch.<sup>98</sup> That number has increased to 81% by drugs experiencing first generic entry in 2012.<sup>99</sup> Paragraph IV challenges also have been occurring in a shorter amount of time following the launch of a brand-name drug. In 1995, the average time between the launch of the brand-name drug and the first Paragraph IV challenge was 18.7 years.<sup>100</sup> In 2012, that span of time dropped to an average of 6.9 years.<sup>101</sup>

There are a variety of factors that affect the initiation of a Paragraph IV challenge. Paragraph IV challenge activity is even more aggressive for

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90. *Id.*

91. *Id.*; *See* 21 U.S.C. § 355(j)(2)(iii) (2013).

92. *Id.* at § 355(j)(5)(B)(iii).

93. Grabowski, *supra* note 19, at 2; *See* 21 U.S.C. § 355(j)(5)(D)(i)(I) (2013).

94. Grabowski, *supra* note 19, at 2.

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.* at 6 (Figure 3).

99. *Id.*

100. *Id.*

101. *Id.*

new drugs with sales greater than \$250 million.<sup>102</sup> Another factor that comes into play is the drug's sales prior to generic entry, the nature of the patents protecting the drug, and the ease with which generic manufacturers can imitate the drug to satisfy FDA regulations.<sup>103</sup> For example, for higher-revenue drugs, generic manufacturers may be less selective when filing challenges, as even a low likelihood of success in litigation can yield a large expected return on the investment necessary to challenge a patent.<sup>104</sup>

### V. The Supreme Court's Opinion on Reverse Payments

The most recent Supreme Court decision regarding reverse payments is *Federal Trade Commission v. Actavis*.<sup>105</sup> In this case, Respondent Solvay Pharmaceuticals obtained a patent for its brand-name drug AndroGel.<sup>106</sup> The FDA approved the application and Solvay obtained a patent in 2003.<sup>107</sup> The pharmaceutical companies Actavis, Inc. and Paddock Laboratories filed Abbreviated New Drug Applications for a generic drugs modeled after AndroGel for their own generic products.<sup>108</sup> Both companies certified under Paragraph IV that Solvay's patent was invalid and that their generic drugs did not infringe it.<sup>109</sup> Solvay initiated Paragraph IV litigation against Actavis and Paddock claiming patent infringement.<sup>110</sup> The FDA approved of Actavis' generic product, but instead of bringing its drug to market, Actavis and the other generic manufacturers entered into a "reverse payment" settlement agreement with Solvay.<sup>111</sup> The specific terms of this agreement included Actavis agreeing not to bring its generic to market for a specified number of years (specifically sixty five months) before Solvay's patent expired, and agreeing to promote AndroGel to doctors in exchange for millions of dollars".<sup>112</sup> The other generic companies made roughly similar promises.<sup>113</sup>

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102. *Id.* at 6.

103. *Id.*

104. *Id.*

105. Found by looking up "reverse payments" and filtering to Supreme Court cases in LexisNexis (last visited May 8, 2015).

106. *Actavis*, 133 S. Ct. at 2224.

107. *Id.* at 2229.

108. *Id.*

109. *Id.* at 2224–25.

110. *Id.* at 2225.

111. *Id.*

112. *Id.*

113. *Id.* at 2229.

Solvay agreed to pay millions of dollars to each generic.<sup>114</sup> The FTC stepped in and filed suit, alleging that the parties “violated §5 of the Federal Trade Commission Act by unlawfully agreeing to abandon their patent challenges, to refrain from launching their low-cost generic drugs, and to share in Solvay’s monopoly profits for nine years.”<sup>115</sup> The companies described these reverse payments as compensation for other services the generics promised to perform, but the FTC contended that those services had little value.<sup>116</sup> According to the FTC, the true point of the payments was to compensate the generics for agreeing not to compete against AndroGel until 2015.<sup>117</sup> The basic question addressed here is whether such an agreement can sometimes unreasonably diminish competition in violation of antitrust laws.<sup>118</sup>

The Eleventh Circuit concluded that as long as the anticompetitive effects of a settlement fall within the scope of the patent’s exclusionary potential, the settlement is immune from antitrust attack.<sup>119</sup> The Supreme Court rejected this “scope of the patent” test used by the Eleventh Circuit.

The Supreme Court ruled that reverse payment settlement agreements between branded and generic pharmaceutical companies are subject to antitrust scrutiny and should be analyzed under the traditional antitrust “rule of reason” analysis.<sup>120</sup> The Supreme Court recognized that these reverse payment settlements tend to have significant adverse effects on competition.<sup>121</sup> These agreements may lead to higher prices for pharmaceuticals by deterring generic entry, and contribute to increased health care costs that consumers, employers, and governments are struggling to contain.<sup>122</sup>

#### **A. *FTC v. Actavis*’ Antitrust Claim**

The Court in *Actavis* concluded that the FTC should have been given the opportunity to prove its antitrust claim for five reasons.<sup>123</sup> First, the Court reasoned that the specific restraint at issue has the potential for

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114. *Id.*

115. *Id.* at 2230; App. 29, Complaint ¶5 (encompassing practices that violate the Sherman Act and the other antitrust laws).

116. *Id.* at 2229.

117. *Id.*

118. *Id.* at 2227.

119. *FTC v. Watson Pharms., Inc.*, 667 F.3d 1298, 1312 (2012).

120. Wright, *supra* note 44, at 2.

121. *Id.* at 3.

122. *Id.*

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

genuine adverse effects on competition.<sup>124</sup> The 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.<sup>125</sup> Permitting the patent challenger to enter the market before the patent expires would also bring about competition for the consumer's benefit.<sup>126</sup>

Second, these anticompetitive consequences will at least sometimes prove unjustified.<sup>127</sup> When a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is no same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation.<sup>128</sup> Traditionally, a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim.<sup>129</sup> However, in the reverse payment settlement at issue, a party with no claim for damages (something that is usually true of a Paragraph IV litigation defendant) walks away with money simply to stay away from the patentee's market.<sup>130</sup>

Third, where a reverse payment threatens to encourage unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice.<sup>131</sup> This imbalance of power is reflected in the amount the pharmaceutical company is willing to pay off the generic brand. However, a strong and valid patent itself would help to assure such power in a way that would lessen the incentive of a company seeking to induce others to stay out of the market.<sup>132</sup>

Fourth, an antitrust action is likely to prove more administratively feasible. An unexplained large reverse payment suggests that the patentee has serious doubts about their patent's survival.<sup>133</sup> The objective of the payment would then be to maintain high levels of profits and share it with the patentee and the challenger, rather than face a potentially competitive market.<sup>134</sup>

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124. *Indiana Federation of Dentists*, 476 U.S. at 460-461.

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

126. *Id.*

127. *Id.* at 2235.

128. *Id.* at 2236.

129. *Id.* at 2233.

130. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (stating collusion is "the supreme evil of antitrust").

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

132. *Id.*

133. *Id.*

134. *Id.*

Lastly, the fact that a large unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit.<sup>135</sup> It is entirely possible to have settlements that do not include such unjustified reverse payments.

### **B. The *Actavis* Court's Conclusion**

The Court in *Actavis* concludes that a reverse payment, where “large and unjustified”, can bring the risk of significant anticompetitive effects.<sup>136</sup> A court should examine the size of the payment, and assess its likely anticompetitive effects along with its potential justifications.<sup>137</sup> The Court held that reverse payment settlements should be analyzed under the traditional “rule of reason” framework, and that the plaintiff’s *prima facie* demonstration of a settlement’s anticompetitive effects necessarily “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 other convincing justification.”<sup>138</sup> This conclusion lends itself to the next issue namely: what constitutes a reverse payment that is worth litigation over a patent’s validity?

The Court explained that when future courts analyze a payment that presents anticompetitive concerns, those courts should look to the payment’s “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>139</sup> The Court has a strong preference for determining patent strength by examining the payment rather than the patent itself.<sup>140</sup> An unexplained large reverse payment could suggest that the patent holder has serious doubts about the patent’s survival.<sup>141</sup> Therefore, forms of payment from the brand-name drug to the generic drug company could constitute anticompetitive harm, in which even strong patents would not be protected from scrutiny.

The *Actavis* Court however recognized two categories for which the settling parties could offer justifications.<sup>142</sup> The settling parties should be allowed to show that the payment is either (1) no larger than litigation

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135. *Id.* at 2237.

136. *Id.*

137. *Id.*

138. *Id.* at 2237–38.

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

140. Carrier, *supra* note 40, at 18.

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

142. Carrier, *supra* note 40, at 19.

costs, or (2) that the payment is for unrelated generic services rather than delayed entry.<sup>143</sup> Regarding litigation costs, if a defendant can justify payments that amount to no more than rough approximation of the litigation expenses saved through a settlement with redeeming virtues, then there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.<sup>144</sup>

The second justification involves brand payments for unrelated generic services. These can include the brand-named drug paying for a generic company to market its product, to provide inventory or backup manufacturing services, to supply them with raw material or finished drug products, and/or for development agreements for unrelated products.<sup>145</sup> If the brand really is paying for generic services in a transaction that does not involve the dividing of monopoly profits to pay for the delayed entry, it could offer a legitimate justification for its payment to the generic.<sup>146</sup>

Aside from those two situations, *Actavis* leaves open for question of the type of compensation that constitutes an exclusion payment violating antitrust laws. The *Actavis* Court directs lower courts to focus on the presence of significant unjustified anticompetitive consequences, and emphasized four elements to consider.<sup>147</sup> These include: payments' size, scale in relation to the payer's anticipated future litigation costs, independence from other services for which it might represent payment, and lack of any other convincing justification.<sup>148</sup> How the lower courts have interpreted *Actavis* will come up later in discussion.

### C. The Commissioner's Response to the *Actavis* Holding

Joshua Wright was sworn in as a Commissioner of the Federal Trade Commission on January 11, 2013, to a term that expires in September 2019.<sup>149</sup> Wright said there was no question the ruling covers all kinds of considerations.<sup>150</sup> He states that, "Actavis clearly applies to reverse payment settlements involving noncash compensation."<sup>151</sup> To not involve

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143. *Id.*

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

145. *Carrier*, *supra* note 40, at 22.

146. *Carrier*, *supra* note 40, at 21–22.

147. *Carrier*, *supra* note 40, at 30.

148. *Id.*

149. *Joshua D. Wright: Commissioner*, FEDERAL TRADE COMMISSION, <https://www.ftc.gov/about-ftc/biographies/joshua-d-wright>.

150. Melissa Lipman, *No Question Actavis Goes Beyond Cash, FTC's Wright Says*, LAW 360 (Oct. 10, 2014, 9:54 PM), <http://www.law360.com/articles/586388>.

151. *Id.*

such payments would create artificial limitations that simply do not make economic sense and would impose a rule that elevates form over substance.”<sup>152</sup>

One standard the Supreme Court set for deals that might pose antitrust problems is comparing a payment to the costs the drug maker saves by avoiding further litigation as an appropriate benchmark.<sup>153</sup> Wright however suggests that those litigation savings are not a good benchmark because even “very large payments,” much bigger than avoided litigation costs, can produce settlements that ultimately benefit consumers.<sup>154</sup>

A litigation cost benchmark does not reliably identify anti-competitive settlements and generates considerable risk of chilling consumer welfare-increasing settlements. As lower courts continue to struggle with how to identify reverse payment settlements that likely reduce consumer welfare, it is important to accurately identify the relationship between payment size and harm before concluding payment size is indeed a ‘workable surrogate for a patent’s weakness,’ as the court suggested it may be.<sup>155</sup>

Beyond advocating a “rule of reason” analysis, the Court did not set forth a clear structure for reviewing settlement agreements and left this job to the district courts.<sup>156</sup>

The Commissioner notes that the post-*Actavis* landscape remains unsettled with respect to a number of critical questions concerning how lower courts will and should evaluate reverse payment settlements.<sup>157</sup> Particularly, he notes three questions: (1) does *Actavis* apply to noncash payments, (2) are reverse payments that are larger than avoided litigation costs considered to be “large and unjustified” within the Court’s framework, and (3) should courts balance competitive harms associated with delayed generic entry of a particular drug against any consumer welfare benefits to consumers of other drugs that would not occur but for the settlement.<sup>158</sup>

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152. *Id.*

153. *Id.*

154. *Id.*

155. *Supra* note 44, at 14.

156. Jason Oliver, *Supreme Court Holds Reverse Payment Settlement Agreements to be Analyzed Under “Rule of Reason” Approach*, BAKER & HOSTETLER LLP (June 21, 2013), <http://www.lexology.com/library/detail.aspx?g=1bf5b27a-6c24-4e24-9750-48d7ae135587>.

157. *Supra* note 44, at 2

158. *Id.*

Regarding the first question of whether or not reverse payments must take the form of cash to be subject to antitrust scrutiny, Wright believes that *Actavis* clearly applies to reverse payment settlements involving noncash compensation.<sup>159</sup> Even before *Actavis*, brand-name and generic pharmaceutical manufacturers had entered into increasingly complex and creative settlement agreements that frequently included noncash consideration.<sup>160</sup> Today's settlement agreements include any number of nonmonetary elements in which a brand-name company agrees to not introduce an authorized generic that might compete with the generic firm's product, such as complex supply agreements, marketing, and other advertising arrangements.<sup>161</sup>

Regarding the second question, Wright contemplated the economic conditions under which inferences about competitive harm can reliably be drawn from a large payment and how exactly one interested in enforcing the antitrust laws or counseling clients would proceed to identify such payments.<sup>162</sup> He finds that litigation costs are not an appropriate benchmark for evaluating reverse payments under the "rule of reason".<sup>163</sup> He suggests that lower courts should be reluctant to rely on a truncated litigation cost benchmark substitute for a more full-blown "rule of reason" inquiry.<sup>164</sup>

The next question is how to analyze large noncash payments under the rule of reason. This is an inquiry that is difficult to define. In the most common form of noncash payment from a brand manufacturer to a generic manufacturer to delay entry, a no-authorized generic agreement, the consumer welfare impact of such an arrangement is simple to analyze because the No-AG commitment offers no consumer benefits. But this is not always the case, as pharmaceutical companies are settling their patent disputes in evermore complex fashions, often attempting to disguise the reverse payment.<sup>165</sup> The rule of reason would require lower courts to analyze all the costs and benefits associated with the challenged conduct.

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159. *Id.* at 5.

160. *Id.*

161. Lipman, *supra* note 150.

162. *Id.* at 9.

163. *Id.* at 12.

164. *Id.* at 15.

165. *FTC Files Amicus Brief explaining That "No-AG" Agreements Are Used by Drug Companies to Delay Generic Competition*, FTC (Aug. 13, 2012), <https://www.ftc.gov/news-events/press-releases/2012/08/ftc-files-amicus-brief-explaining-no-ag-agreements-are-used-drug>.

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## VI. Post-*Actavis* Landscape

### A. Circuit Courts

The Third Circuit is the first Court of Appeals to take on a pay-for-delay case since the U.S. Supreme Court ruled on this matter.<sup>166</sup> Experts say that the case will be significant as the first appellate ruling applying *Actavis* since the justices ruled in 2013.<sup>167</sup> The Third Circuit will weigh in on the question of whether generic drug makers must receive cash for a deal to count as a reverse payment.

The Appellate Court heard arguments over whether a New Jersey district court correctly concluded that the justices were only talking about cash settlements when they opened the door to antitrust challenges to Hatch-Waxman Act settlements.<sup>168</sup> In *King Drug Co. of Florence, Inc.*,<sup>169</sup> the plaintiffs argued that the Third Circuit incorrectly dismissed their suit. They accused GlaxoSmithKline PLC of paying off Teva Pharmaceutical Industries Ltd. to delay launching a generic version of the drug Lamictal until the day before GSK's patents were set to expire. In exchange, plaintiffs argued that GSK promised not to launch its own authorized generic during Teva's 180-day exclusivity window.<sup>170</sup> The defendants say that a no-authorized-generic promise was simply a term of an exclusive early-entry license, which has always been allowed under patent law.<sup>171</sup> The defendants also make a case that a no-authorized generic provision is basically an exclusive license, and exclusive licenses are something that are expressly allowed under patent law.<sup>172</sup> This issue comes down to what kind of payment the Supreme Court was referring to in *Actavis*.

### B. District Courts

Of the seven courts to have considered this reverse settlement issue in light of *Actavis*, only two have ruled that *Actavis* requires cash payments.<sup>173</sup> The bulk of other district courts that looked at the issue of these types of

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166. Melissa Lipman, *3rd Circ. To Decide If Reverse Payments Must Be Cash*, LAW 360 (Nov. 17, 2014, 4:19 PM), <http://www.law360.com/articles/591582/3rd-circ-to-decide-if-reverse-payments-must-be-cash>.

167. *Id.*

168. *Id.*

169. *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015).

170. Lipman, *supra* note 166.

171. *Id.*

172. *Id.*

173. Lipman, *supra* note 150.

payments seem to agree that *Actavis* goes beyond straightforward cash payments.<sup>174</sup> A broader issue that has come up is whether or not, for pleading purposes, the plaintiffs would have to specify a number for the payment value.<sup>175</sup> *Actavis* merely says the payment must be “large and unjustified.”<sup>176</sup> How should noncash payments have to be estimated in monetary terms in order to figure out if the payment counts as “large and unjustified”?<sup>177</sup> Drug manufacturers will be arguing over whether settlements have to include cash payments to receive antitrust scrutiny under *Actavis*.<sup>178</sup>

*In re Loestrin 24 Fe Antitrust Litigation* held that the *Actavis* decision required cash consideration in order to trigger the “rule of reason” scrutiny in determining whether a reverse settlement payment violates federal antitrust law.<sup>179</sup> The court held that plaintiffs had not adequately alleged payment in the form of cash in exchange for agreement to stay out of the market for that drug, and the plaintiffs failed to state a plausible claim upon which relief could be granted.<sup>180</sup> The motion to dismiss was therefore granted.<sup>181</sup> The court stated the five factors in determining whether reverse settlement payments satisfy the rule of reason and how it could be measured when the reverse payment is made in cash. However, noncash settlements were almost impossible to measure against these factors.<sup>182</sup>

In a second case, the New Jersey District Court held that the buyers’ class action complaint challenging the patent settlement failed to state an antitrust claim, since there was no transfer of money in the settlement.<sup>183</sup>

A majority of courts seem to take the opposite position that a reverse payment is not limited to cash payments. The District Court of New Jersey, acknowledged that *Actavis* addressed cash payments, but concluded

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174. Lipman, *supra* note 166.

175. *Id.*

176. *Id.*

177. Lipman, *supra* note 150.

178. *Id.*

179. See *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 195 (D.R.I. 2014).

180. *Id.*

181. *Id.*

182. *Id.* at 191.

183. *In re Lamictal Direct Purchaser Antitrust Litig.*, No. CIV. 12-995 WHW, 2012 WL 6725580, at \*7 (D.N.J. Dec. 6, 2012) *adhered to on reconsideration*, 18 F. Supp. 3d 560, 566 (D.N.J. 2014).

that the Supreme Court focused on the antitrust intent of the settling parties rather than the manner of payment.<sup>184</sup>

The United States District Court in the Northern District of California stated that to constitute a “payment” under the “rule of reason” test, used in conjunction with evaluating terms of reverse payment in settlements involving patent infringement suits, the court must be able to calculate a value.<sup>185</sup> The court found no need to restrict the definition of payment only to cash, since there are many plausible methods by which a court may calculate the value of nonmonetary terms.<sup>186</sup>

The Eastern District of Pennsylvania also held that a reverse “payment” was not limited to cash.<sup>187</sup> That court also concluded that a non-authorized generic provision did not have the same economic effect as a grant of exclusive license to enter market prior to expiration of a patent.<sup>188</sup>

The District Court in Massachusetts also did not see it fit to read into the opinion a strict limitation of its principles to monetary-based arrangements alone.<sup>189</sup> Adoption of a broader interpretation of the word “payment” would serve the purpose of aligning the law with modern-day realities. Nowhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction to take place for an agreement between a brand and a generic manufacturer to constitute a reverse payment.<sup>190</sup>

The District Court of Connecticut also follows the same line of reasoning and does not think these payments should be limited to cash payments.<sup>191</sup> Since large and unjustified reverse payments can bring with them the risk of significant anticompetitive effects regardless of the particular form of transfer, they should not be limited to cash payments.<sup>192</sup>

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184. *In re Effexor XR Antitrust Litig.*, No. 11-5479, 2014 WL 4988410, at \*20 (D.N.J. Oct. 6, 2014).

185. *United Food and Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069 (N.D. Cal. 2014).

186. *Id.* at 1069–70.

187. *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa 2014).

188. *Id.* at 750.

189. *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

190. *Id.* at 392.

191. *In re Aggrenox Antitrust Litig.*, No. 3:14-md-2516, 2015 WL 1311352 at \*11-12 (D. Conn. 2015).

192. *Id.* at 12.

## VII. Conclusion

Pharmaceutical companies spend much of their time and resources in conducting research and clinical trials to develop new drugs. Under the Hatch-Waxman Act, generic drugs can refer to the same tests that the brand-name drugs have conducted, as long as the generic brands can prove similarities in the biological makeup of both drugs. As a result, pharmaceutical companies have been paying off generic companies to not enter the market until their patents are nearly expired — a transaction known as a reverse payment. These companies have been settling lawsuits in order to maximize their own profit, at the expense of the benefit to society. This trend of reverse payment patent settlements that has developed in response to the Hatch-Waxman Act has promoted anti-competition in the marketplace, and even rises to the level of antitrust scrutiny. While proving to be beneficial to the pharmaceutical industry, reverse payments create an antitrust issue by allowing the pharmaceutical companies to monopolize the market space, as well as creating a public interest problem by taking away public access to cheaper drugs.

Congress' objective when enacting the Hatch-Waxman legislation was to increase generic competition while balancing the resulting cost savings with sufficient incentives to encourage continued medical innovation through the development of new drugs. Like most of the district courts that have taken on this post-*Actavis* issue, I agree that reverse payments should not be confined to cash payments in order to rise to the level of antitrust scrutiny. Given the complexity of modern day payment formulations, it would be detrimental for future reverse payment cases to pigeon-hole the parameters of payments to cash. In determining the antitrust scrutiny level, it is important to consider whether the brand-name drug has conveyed to the generic a type of consideration that is not a direct consequence of winning the lawsuit.

Generic drugs play an important role in the pharmaceutical consumer landscape. Many policymakers view generic drug competition as the principal method to contain the rapid growth in drug costs. Therefore, restricting options for American consumers would go against the original intent of the Hatch-Waxman Act.