

**CASHING OUT: HOW BIG PHARMA CONTINUES TO CAPITALIZE  
ON THE ANTITRUST LOOPHOLE CREATED IN *FTC v. ACTAVIS***

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*The drug industry is one of the most lucrative in the United States. Drug manufacturers routinely find themselves thrust into patent infringement litigation against generic manufacturers who are motivated by high potential returns from the marketplace. In lieu of expensive and time-consuming litigation, brand and generic manufacturers will often enter into settlement agreements; however, these agreements are frequently wrought with anticompetitive effects—commonly known in the industry as “reverse payment settlements.” In 2013, the Supreme Court was asked to determine if reverse payment settlements were violations of antitrust law, but it only addressed one type of settlement, opening the door for continued antitrust violations and lower court confusion. This Recent Development will examine the different forms of reverse-payment settlements, the Supreme Court’s silence, and why this issue continues to plague circuit courts around the nation.*

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#### PRE-INTRODUCTION

The increasing cost of prescription drugs in the United States has become a source of growing concern for patients, prescribers, payers, and policy makers.<sup>1</sup> Because pricing is left to market competition, the United States has significantly higher drug prices than in “countries where governments directly or indirectly control medicine costs.”<sup>2</sup> Although prices can vary widely around the world, U.S. drug prices per capita still substantially outpace those of nearly every other advanced country.<sup>3</sup> In 2013, the United

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<sup>1</sup> Aaron Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States*, 316 JAMA 858, 859 (2016) [hereinafter *The High Cost of Prescription Drugs*].

<sup>2</sup> Ben Hirschler, *Exclusive—Transatlantic Divide: How U.S. Pays Three Times More for Drugs*, REUTERS (Oct. 12, 2015, 12:28 PM), <http://www.reuters.com/article/us-pharmaceuticals-usa-comparison-idUSKCN0S61KU20151012>.

<sup>3</sup> B.S. Quon, R. Firszt & M.J. Eisenberg, *A Comparison of Brand-name Drug Prices Between Canadian-based Internet Pharmacies and Major US Drug Chain Pharmacies*, 143(6) ANNALS OF INTERNAL MED. 397 (2005); see also

States’ “per capita spending on prescription drugs was \$858 compared with an average of \$400 for nineteen [other] advanced industrialized nations.”<sup>4</sup> “Between 2013 and 2015, net spending on prescription drugs increased approximately [twenty percent] in the United States, outpacing a forecast [eleven percent] increase in . . . health care expenditures.”<sup>5</sup> Further, prices in the United States for top brand-name drugs increased 127 percent between 2008 and 2014 alone.<sup>6</sup> Not only have the prices of top drugs increased, they continue to be higher than prices in other industrialized nations, despite discount rates received by payers from drug manufacturers—which themselves are hard to quantify.<sup>7</sup> For example, in the United States the estimated monthly discount price of the drug insulin glargine<sup>8</sup> is \$183.86 USD, compared to \$67.00 USD in Canada, \$46.60 USD in France, and \$60.90 USD in Germany.<sup>9</sup> This obvious and alarming discrepancy in price differences has subjected the United States’ health care system to intense scrutiny from both industry professionals and outsiders.<sup>10</sup>

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Robert Langreth, Blacki Migliozi & Ketaki Gokhale, *The U.S. Pays a Lot More for Top Drugs Than Other Countries*, BLOOMBERG (Dec. 18, 2015), <http://www.bloomberg.com/graphics/2015-drug-prices/> (discussing how even after the discounts that drug manufacturers give to various payers, list prices of drugs in the U.S. are still higher than those in other industrialized nations).

<sup>4</sup> *The High Cost of Prescription Drugs*, *supra* note 1, at 859; *see also* Organisation for Economic Co-operation and Development. *Health at a Glance 2015: OECD Indicators*. Paris, France: OECD Publishing; 2015.

<sup>5</sup> *The High Cost of Prescription Drugs*, *supra* note 1, at 859.

<sup>6</sup> Hirschler, *supra* note 2, at 2.

<sup>7</sup> Langreth, Migliozi & Gokhale, *supra* note 3 (“A Merck spokeswoman said [Merck] doesn’t disclose the discounts [they give to insurers and pharmacy benefit managers] for competitive reasons . . . AbbVie said U.S . . . drug sales go through many channels with different levels of prices and rebates.”).

<sup>8</sup> “Insulin glargine is used to treat type 1 diabetes” and is a “man-made version of human insulin” that “works by replacing the insulin that is normally produced by the body and by helping move sugar from the blood into other body tissues where it is used for energy . . .”. *See Insulin Glargine (rDNA origin) Injection*, U.S. NAT’L LIBRARY OF MED., 2016, <https://medlineplus.gov/druginfo/meds/a600027.html>.

<sup>9</sup> *See* Langreth, Migliozi & Gokhale, *supra* note 3.

<sup>10</sup> *E.g.* Langreth, Migliozi & Gokhale, *supra* note 3; *The High Cost of Prescription Drugs*, *supra* note 1, at 859; Panos Kanavos, Alessandra Ferrario

One of the primary market forces allowing drug companies to maintain high prices in the United States is laws protecting competition.<sup>11</sup> This protective environment is comprised mainly of two legal structures: first, initial market exclusivity, granted through Food and Drug Administration (“FDA”) approval of a new (or “pioneer”) drug,<sup>12</sup> and second, patent exclusivity, afforded to drug manufacturers through the U.S. Patent and Trademark Office.<sup>13</sup> The Drug Price Competition and Patent Term Restoration Act,<sup>14</sup> commonly known as the Hatch-Waxman Act, codifies the significant exclusivity period afforded to new drugs entering the marketplace.<sup>15</sup> While the Hatch-Waxman Act was intended to encourage innovation and drug price competition, it inadvertently created a loophole for drug manufacturers to stifle their generic competition.<sup>16</sup>

Brand-name pharmaceutical companies can delay generic competition that lowers prices by agreeing to pay a generic competitor to withhold its competing product from the market for a

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Sotiros Vadoros & Gerard F. Anderson, *Higher US Branded Drug Prices and Spending Compared to Other Countries May Stem Partly from Quick Uptake of New Drugs*, 32 HEALTH AFF. 4, 753-61 (2013).

<sup>11</sup> See Food and Drug Administration, 21 C.F.R. § 314.108 (1992).

<sup>12</sup> *Id.*

<sup>13</sup> See 35 U.S.C. § 154(a)(2) (contents and term of patent: provisional rights); see also 35 U.S.C. §§ 102, 103 (conditions for patentability: novelty and non-obvious subject matter); Am. Jur. 2d, Patents §§ 69, 78, 79; C.J.S., Patents §§ 16, 28, 100.

<sup>14</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271), as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (collectively, the “Hatch Waxman Act”).

<sup>15</sup> 21 U.S.C. § 355(j)(5)(B)(iv). The first company to submit an ANDA containing a Paragraph IV certification is commonly referred to as the “first filer”; later companies that submit an ANDA for the same drug are called “subsequent filers.” See also Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 603 (2003).

<sup>16</sup> See David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321 (2000).

certain agreed-upon period of time.<sup>17</sup> This agreement is known in the industry as either a reverse or a pay-for-delay settlement.<sup>18</sup> Agreements that guarantee compensation from the brand manufacturer to the generic manufacturer prohibit generic entry to the market, on average, by nearly seventeen months longer than agreements without these payments.<sup>19</sup> Many of these agreements are still in effect, and they currently protect at least \$20 billion in sales of brand-name pharmaceuticals from generic competition.<sup>20</sup> In fact, a 2009 Federal Trade Commission (“FTC”) study determined that pay-for-delay agreements are estimated to cost American consumers \$3.5 billion per year—equating to \$35 billion over the next ten years.<sup>21</sup>

When called upon to review the legality of reverse-payment settlements, the Supreme Court ruled in *Federal Trade Commission v. Actavis, Inc.* that cash-based “pay-for-delay” settlements constituted anti-trust law violations, but the Court was ominously silent on the issue of non-cash settlements.<sup>22</sup> Further, the *Actavis* Court created a test in which the factors were largely

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<sup>17</sup> , *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, An FTC Staff Study (2010), F.T.C., <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf> [hereinafter *Pay for Delay*].

<sup>18</sup> *Id.*

<sup>19</sup> This 17-month delay attributed to payments was calculated by comparing the sales-weighted average time between the date of the agreement’s execution and the date of generic entry for agreements with and without compensation to the generic. *See id.*

<sup>20</sup> *See id.* at 11 n.7 (“[This] dollar amount represents the prior-year total sales of the brand-name pharmaceuticals that are currently covered by agreements with delay and compensation and thus indicates the order of magnitude of brand-name pharmaceutical sales for which generic competition [with lower prices] has likely been delayed.”).

<sup>21</sup> *See* Jon Leibowitz, “Pay-for-Delay” Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers’ Wallets, and Help Pay for Health Care Reform (*The \$35 Billion Solution*) at 8 (June 23, 2009), F.T.C., <http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf>.

<sup>22</sup> *FTC v. Actavis, Inc.*, 133 S.Ct. 2223, 2225-26 (2013).

based on monetary quantifications, leaving lower courts little to no guidance on how to decide the legality non-cash settlements in future cases.<sup>23</sup> The *Actavis* Court's troubling silence effectively allows drug manufacturers to continue eliminating generic competition, which in turn keeps drug prices high and burdens consumers.<sup>24</sup>

This Recent Development will address the high costs of prescription drugs, antitrust violations of non-cash reverse settlements, and the problems created by the Supreme Court's silence on non-cash settlements. Part I will briefly discuss the history of the regulation of the pharmaceutical industry in the U.S., and will introduce the Hatch-Waxman Act and its structure, scope, and subsequent criticism throughout the pharmaceutical industry. Part II will address relevant antitrust laws, including the rule of reason that was employed by the Supreme Court in its *Actavis* opinion, and will illustrate the concept of a reverse-payment settlement. Part III will examine the Supreme Court's ruling in *Federal Trade Commission v. Actavis, Inc.* by discussing what the Supreme Court correctly decided, and more pertinently, its controversial silence on non-cash settlements. Part IV will discuss subsequent district court cases that highlight the gaps in the *Actavis* ruling, how different circuit courts have interpreted *Actavis* and dealt with non-cash reverse settlements, and will also address the questions that still remain.

## **I: INTRODUCTION TO THE U.S. PHARMACEUTICAL INDUSTRY AND THE HATCH-WAXMAN ACT**

This section will brief the reader on the history and current state of the U.S. pharmaceutical industry. Part A will outline the history of the pharmaceutical industry in the United States, including the creation of the Food and Drug Administration and

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<sup>23</sup> The Court set forth a sliding scale approach to determine if a reverse-payment settlement has anticompetitive effects and employed the terms "large" and "unjustified" as elements to consider when analyzing the anticompetitive effect of a payment- terms that are commonly associated with a quantitative monetary amount. *Id.*

<sup>24</sup> *The High Cost of Prescription Drugs*, *supra* note 1, at 865.

subsequent Amendments. Part B will explain the most recent overhaul of the U.S pharmaceutical industry, the Hatch-Waxman Act of 1984, and its scope, relevant provisions, and criticisms.

*A. A Brief History of the U.S. Pharmaceutical Industry Prior to 1984*

The structure of the prescription drug industry in the United States has dramatically evolved over the course of the nation's history. Before 1938, various federal statutes loosely regulated pharmaceutical products on the market.<sup>25</sup> The first significant step towards consolidating a set of federal regulations for the drug industry occurred in 1938, when Congress enacted the Federal Food, Drug, and Cosmetics Act of 1938 ("FDCA").<sup>26</sup> The FDCA established a premarket notification process<sup>27</sup> by which manufacturers were required to submit data regarding the safety of a new drug before its entry to the consumer marketplace.<sup>28</sup> Manufacturers had to submit a New Drug Application ("NDA") to demonstrate, through evidence of research and development, that the drug was safe for human consumption before the FDA would approve the drug for sale on the marketplace.<sup>29</sup> The data submitted

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<sup>25</sup> See Biologics Act of 1902, Pub. L. No. 57-244, 32 Stat. 728 (1903); see also Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906).

<sup>26</sup> Federal Food, Drug, and Cosmetics Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301-399f (2015)).

<sup>27</sup> See Biologics Act of 1902, 728 (1903).

<sup>28</sup> See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1762-63 ("The 1938 Act's premarket notification system . . . did not apply to drugs that were not 'new drugs.' Moreover, a manufacturer could decide for itself whether the ingredient(s) it was preparing to market enjoyed a sufficient reputation for safety that could withstand a claim by FDA that the drug was not 'generally recognized as safe' and therefore was 'new.' Consequently, a manufacturer could introduce a drug whose safety FDA had no opportunity to review. Furthermore, FDA's authority over a product that was concededly a 'new drug' was formally limited to assessing whether the product was safe.").

<sup>29</sup> The NDA requirement for a new drug was one of the most significant changes by the FDCA to the process by which drugs were put on the market. It was a response to the infamous 'Elixir Sulfanilamide' disaster, in which over one hundred Tennessee residents were poisoned by the solvent diethylene glycol

in an NDA was kept confidential and could not be disclosed to or used by another drug manufacturer.<sup>30</sup> Under the FDCA, the Food and Drug Administration (“FDA”) had a gatekeeping role in determining whether a drug was safe to be marketed, but there were several ways in which a manufacturer could circumvent these regulatory requirements.<sup>31</sup>

In 1962, Congress passed the Drug Amendments of 1962,<sup>32</sup> which significantly strengthened the FDA’s regulatory authority.<sup>33</sup> These amendments created a more complex premarketing approval system, in which a drug manufacturer was required to submit its own preclinical and clinical data demonstrating the drug’s safety—and effectiveness—regardless of whether it was a new drug, and also had to wait for the FDA’s affirmative approval of the data.<sup>34</sup> These amendments gave the FDA an effective veto over the

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that a reckless producer incorporated in a new therapeutic potion without testing. Realizing that simply strengthening FDA’s ability to act against adulterated drugs would still leave the agency responding to evidence of harm rather than attempting to prevent it, Congress invented a new legal category— ‘new drugs’ which a manufacturer could not market without first notifying FDA and allowing it time to assess their safety. *See* David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 20 (1939); *see also* Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1761-62 (1996).

<sup>30</sup> *See* Ellen Flannery & Peter Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 275-76 (1985) (“The most significant difference in the 1938 Act from [the Hatch-Waxman Act] was that the data submitted in the DNA was confidential and could not be disclosed to or used by another manufacturer. This restriction prevented generic manufacturers from employing the information to bring similar or identical drugs to the market without incurring expensive initial start-up costs.”).

<sup>31</sup> *See* Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753 (1996).

<sup>32</sup> Pub. L. No. 87-781, 76 Stat. 780 (1962).

<sup>33</sup> Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 420 (2011).

<sup>34</sup> *See* Richard A. Merrill, *supra* note 31.



marketing of any drug it had reservations about.<sup>35</sup> They also raised the standard that a new drug had to satisfy by explicitly directing the FDA to confirm not only the drug's safety, but also its effectiveness.<sup>36</sup> The effectiveness requirement dramatically expanded the scope of the new drug approval process.<sup>37</sup> The lengthy FDA premarket approval process was substantially decreasing the effective life of a drug patent,<sup>38</sup> thus discouraging pioneer companies' incentives to innovate.<sup>39</sup> Further, under the regulatory system created by the 1962 Amendments, an innovator would be required to undergo years of testing in order to demonstrate that its drug was safe and effective, thereby delaying commercialization of the drug and substantially reducing the period in which the innovator could benefit in the marketplace from its patent exclusivity.<sup>40</sup> In an attempt to restore patent protection and encourage innovation, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984,<sup>41</sup> the landmark legislation commonly known as the Hatch-Waxman Act.

*B. The Drug Price Competition and Patent Term Restoration Act of 1984 (The Hatch-Waxman Act)*

The Drug Price Competition and Patent Term Restoration Act of 1984<sup>42</sup> (“the Hatch-Waxman Act” or “the H-W Act”) was

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<sup>35</sup> *Id.* at 1765.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 301 (1985).

<sup>39</sup> *Id.*

<sup>40</sup> See Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 588 (2003) (“Although not intended to do so, the 1962 Amendments resulted in a significant erosion of the term of exclusivity provided to pharmaceutical manufacturers under the patent laws.”).

<sup>41</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271), as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (collectively, the “Hatch Waxman Act”).

<sup>42</sup> *Id.*

enacted by Congress as an attempt to balance two competing issues in the pharmaceutical industry: the interests of research-based pharmaceutical companies (“innovators” or “brand manufacturers”) and the interests of generic drug manufacturers (“generics”).<sup>43</sup> The H-W Act was meticulously designed to simultaneously encourage innovators to continue investing in research and development of new drugs while also increasing generic drug competition in the pharmaceutical marketplace, thereby lowering prices of drugs and consumer costs.<sup>44</sup>

To achieve the H-W Act’s first goal of increasing the availability of generic drugs on the marketplace to reduce prices and consumer costs, the H-W Act created a process by which drugs previously found to be safe and effective could avoid the lengthy NDA process.<sup>45</sup> This shortcut is referred to as an Abbreviated New Drug Application (“ANDA”).<sup>46</sup> The ANDA process was crucial to the H-W Act’s goal of establishing a viable method for generic drugs to enter the marketplace, because it substantially relaxed the testing requirements for generic manufacturers, allowing them to more affordably enter the market in less time.<sup>47</sup> The H-W Act established the ANDA, a formalized and expedited system for approval of generic drug products, to ensure a competitive market and lower prices after a brand drug’s exclusivity period ended.<sup>48</sup> The statute implemented this system by permitting applicants to “file with the Secretary an abbreviated application for the approval of a new drug”<sup>49</sup> and specified that such an abbreviated application need only make a few certifications with respect to the drug

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<sup>43</sup> Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 417 (2011).

<sup>44</sup> *Id.*

<sup>45</sup> Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 274, 277 (1985).

<sup>46</sup> 21 C.F.R. § 314.2 (1992); *see also* Flannery & Hutt, *supra* note 45, at 274, 277.

<sup>47</sup> Kelly, *supra* note 43, at 417.

<sup>48</sup> 21 U.S.C. § 355(j) (2012).

<sup>49</sup> 21 U.S.C. § 355(j)(1) (2012).

product.<sup>50</sup> In this application, the applicant must demonstrate that the conditions of use recommended in the labeling for the new drug are the same as those for a drug already approved by the FDA as safe and effective.<sup>51</sup>

The second of the H-W Act's dual purposes was to encourage innovators to invest in research and development of new drugs.<sup>52</sup> Under the old regulatory system, the lengthy FDA premarket approval system substantially decreased the effective life of a drug patent, which also decreased its value.<sup>53</sup> This decrease discouraged any incentive to innovate.<sup>54</sup> The H-W Act attempted to remedy this devaluation of drug patents by providing that the FDA may not approve an ANDA until all patent protection and market exclusivity periods have expired.<sup>55</sup> The H-W Act also provided for a brand manufacturer to extend its patent term for a brand-name drug if the FDA premarket approval process decreased the effective life of the patent.<sup>56</sup> Under the Act, the term of an eligible patent is restored for a time equal to the "regulatory review period for the approved product."<sup>57</sup>

Despite the H-W Act's attempts to alleviate competing issues between generic and brand manufacturers, the Act has been largely criticized across the pharmaceutical industry.<sup>58</sup> On multiple

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<sup>50</sup> See 21 U.S.C. § 355(j)(2)(A)(i - viii) (2012); see also Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?* 15 YALE J. HEALTH POL'Y, L. & ETHICS 293, 303 (2015).

<sup>51</sup> 21 U.S.C. § 355 (j)(2)(A)(i) (2012).

<sup>52</sup> Kelly, *supra* note 43, at 418.

<sup>53</sup> *Id.*; see also Flannery & Hutt, *supra* note 45, at 301.

<sup>54</sup> Kelly, *supra* note 43, at 418; see also Flannery & Hutt, *supra* note 45, at 301.

<sup>55</sup> Kelly, *supra* note 43, at 418.

<sup>56</sup> Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 590-91 (2003).

<sup>57</sup> 35 U.S.C. § 156(c) (2012).

<sup>58</sup> See generally Kristin E. Behrendt, *The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?* 57 FOOD & DRUG L.J. 247 (2002); Elizabeth Powell-Bullock, *Gaming the Hatch-Waxman System: How Pioneer Drug Makers Exploit the Law to Maintain Monopoly Power in the Prescription Drug Market*, 29 J. LEGIS. 21 (2002).

occasions, surrogates for both generic and branded pharmaceutical manufacturers have been critical of the effects and effectiveness of the Act, each arguing that the other had exploited specific provisions for its benefit and that timely introduction of lower cost drugs, or truly innovative research and development of new drug products, suffered as a result.<sup>59</sup>

Perhaps the portion of the Hatch-Waxman Act that is most relevant—and controversial—to this discussion concerning the tensions between generic and brand manufacturers is the system that enabled the resolution of patent infringement disputes prior to the entry of generic competition.<sup>60</sup> The FTC has asserted that the H-W Act's terms have been abused by both branded and generic manufacturers, which have entered into settlements in lieu of litigation that the FTC regards as anticompetitive.<sup>61</sup> Further, many generic manufacturers complain both that timely introduction of lower cost drugs and truly innovative research and development of new drug products have suffered as a result,<sup>62</sup> particularly because

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<sup>59</sup> D. Christopher Ohly & Sailesh K. Patel, *The Hatch-Waxman Act: Prescriptions for Innovative and Inexpensive Medicines*, 19 U. BALT. INTELL. PROP. L.J. 107, 108 (2011).

<sup>60</sup> Weiswasser & Danzis, *supra* note 56, at 595.

<sup>61</sup> *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, An FTC Staff Study (2010), F.T.C., <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf> [hereinafter FED. TRADE COMM'N].

<sup>62</sup> See, e.g., Gerald Mossinghoff, *Overview of the Hatch Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD AND DRUG L. J. 187, 187 (1999) (“For those who ask whether Hatch Waxman was a good deal or a bad deal for the research based pharmaceutical industry, the most learned response is: It was not a good deal, unless one believed that FDA was going to go forward with its plans to implement abbreviated new drug applications (ANDAs) through regulation. If one thought that was going to happen—and FDA was working on it—then Hatch Waxman probably was a good balance. If one did not think that would ever happen, Hatch Waxman probably was not a good balance, at least at the time.”); see also M. Avery, *Continuing Abuse of the Hatch Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171 (2009); FED. TRADE COMM'N, *supra* note 61; T. Chen, *Authorized Generics: A Prescription for Hatch Waxman Reform*, 93 VA. L. REV. 459 (2007); D. Reiffin and M. Ward, “Branded Generics” As a

of companies' utilization of reverse-payment settlements as a mechanism for obtaining market monopolies.<sup>63</sup>

## **II: REVERSE-PAYMENT SETTLEMENTS AND ANTITRUST-LAW: APPLICATIONS TO THE PHARMACEUTICAL INDUSTRY**

This section will outline the relevant basic principles of antitrust law that come into play with regards to reverse-payment settlements in the pharmaceutical industry. Part A will explain the rule of reason and its use as a test for the anticompetitive nature of an agreement, and Part B will describe the mechanisms involved in a reverse-payment, or pay-for-delay, settlement.

### *A. Antitrust Law and the Rule of Reason*

In the pharmaceutical world, antitrust laws are used to prohibit agreements among competitors in the drug industry that unreasonably restrain trade, a category made unlawful by Section 1 of the Sherman Antitrust Act<sup>64</sup> and subsequently by Section 5 of the Federal Trade Commission Act.<sup>65</sup> Antitrust laws specifically address “agreements” because:

“[C]oncerted activity inherently is fraught with anticompetitive risk. It deprives the marketplace of the independent centers of decision-making that competition assumes and demands. In any conspiracy, two or more entities that previously pursued their own interests separately are combining to act as one for their common benefit. This not only reduces the diverse directions in

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*Strategy to Limit Cannibalization of Pharmaceutical Markets*, [www.uta.edu/faculty/mikeward/brandedgenerics.pdf](http://www.uta.edu/faculty/mikeward/brandedgenerics.pdf) (May 2005); Christopher Ponder, *The Dubious Value of Hatch Waxman Exclusivity*, 45 HOUSTON L. REV. 555 (2008).

<sup>63</sup> See *Pay for Delay*, *supra* note 17.

<sup>64</sup> In pertinent part, section 1 forbids “[e]very contract, combination . . . or conspiracy, in restraint of trade.” 15 U.S.C. § 1 (2004). This language has been understood to be less inclusive than its literal terms: to be limited to the prohibition of agreements in “undue” or unreasonable restraints of trade. See *Standard Oil Co. v. United States*, 221 U.S. 1, 59-60 (1911).

<sup>65</sup> Section 5 prohibits “unfair methods of competition.” 15 U.S.C. § 45 (2006).

which economic power is aimed but suddenly increases the economic power moving in one particular direction. Of course, such mergings of resources may well lead to efficiencies that benefit consumers, but their anticompetitive potential is sufficient to warrant scrutiny even in the absence of incipient monopoly.<sup>66</sup>

In antitrust law, there are two general types of unreasonable agreements. The first type involves an agreement between parties that the parties will refrain from either competing in some important aspect of competition, such as price, quality, or innovation; competing in a particular product field; or competing at all.<sup>67</sup> These agreements between potential competitors are referred to as horizontal agreements (or horizontal restraints) and are typically the most basic anticompetitive agreement<sup>68</sup> in terms of consumer welfare.<sup>69</sup> The second type of unreasonable agreement is a vertical agreement (or vertical restraint), which occurs between parties at different levels in the chain, production, or distribution. Examples of this type of relationship include agreements between a manufacturer and its supplier, a manufacturer and its wholesaler,

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<sup>66</sup> *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 767-69 (1984).

<sup>67</sup> *See Balto*, *supra* note 16, at 327.

<sup>68</sup> *See id.*; *see also* JOHN J. MILES, HEALTH CARE AND ANTITRUST LAW §2A-4: Elements of a Section 1 Violation—Agreement—Nature of the Agreement (2016) (“[H]orizontal agreements are among competitors and thus have substantial potential to restrict output and raise prices directly [and] they present greater antitrust concerns than other types of agreements . . .”).

<sup>69</sup> The term “consumer welfare” is used frequently in antitrust law and was first promulgated through the writings of Professor Robert Bork in the mid-1960s. It was later quoted by the Supreme Court and thus earned a spot in the commonplace vernacular of antitrust law. Bork drew on the legislative debates at the time of the Sherman Act’s enactment to argue at length that the intent of Congress was mainly to protect consumers from harm done by cartels while not undermining efficiency. He argued that Congress valued only “consumer welfare.” In *The Antitrust Paradox*, he summed up his historical research: “The Sherman Act was clearly presented and debated as a consumer welfare prescription.” For a detailed explanation of consumer welfare, *see* Gregory J. Werden, *Antitrust’s Rule of Reason: Only Competition Matters*, 79 ANTITRUST L. J. 713, 718-724 (2014).

a wholesaler and its retailer, or a retailer and its customer.<sup>70</sup> In antitrust law, horizontal agreements are sometimes characterized as “illegal *per se*,” while vertical agreements must be analyzed using the “rule of reason.”<sup>71</sup>

The “rule of reason” is a method of analysis applied to agreements whose competitive effects can only be evaluated by using specific facts of the nature of the business, the history of the agreement, and the reasons why it was imposed.<sup>72</sup> This method is the antithesis of the *per se* approach, which is limited to certain categories of agreements that are so plainly anticompetitive, and lacking in redeeming virtue, that they are conclusively presumed to be illegal without any further inquiry into the precise harm that they have caused or their otherwise permissible justifications.<sup>73</sup>

The rule of reason is regarded as the cornerstone of testing whether a practice restrains trade in violation of Section 1 of the Sherman Antitrust Act. The Supreme Court first utilized the rule of reason in its 1911 *Standard Oil* decision.<sup>74</sup> Chief Justice White’s opinion for the Court contemplated a “standard [to resort] to for

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<sup>70</sup> See JOHN J. MILES, HEALTH CARE AND ANTITRUST LAW § 4:1: VERTICAL AGREEMENTS (2016); see also, e.g., *Bus. Electronics Corp. v. Sharp Electronics Corp.*, 485 U.S. 717, 730 (1988) (explaining that restraints imposed by agreement between firms at different levels of distribution are vertical restraints); *Continental T. V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 97 S. Ct. 2549, 53 L. Ed. 2d 568 (1977); *In re Insurance Brokerage Antitrust Litigation*, 618 F.3d 300 (3d Cir. 2010); *Miles Distrib., Inc. v. Specialty Const. Brands, Inc.*, 476 F.3d 442, 448 (7th Cir. 2007) (“Trade restraining agreements between firms at different levels of distribution, e.g., a wholesale supplier and a retail distributor, are deemed vertical restraints.”).

<sup>71</sup> MILES, *supra* note 68.

<sup>72</sup> See *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 692 (holding that there are two complementary categories of antitrust analysis; in the first category are agreements whose nature and necessary effect are so plainly anticompetitive that no elaborate study of industry is needed to establish their illegality, and thus such agreements are “illegal *per se*”; in the second category are agreements whose competitive effect can only be evaluated by analyzing facts peculiar to business, history of restraint, and reasons why it was imposed).

<sup>73</sup> See, e.g., *N. Pac. Ry. Co. v. United States*, 356 U.S. 1 (1958); *Stifel, Nicolaus & Co. v. Dain, Kalman & Quail, Inc.*, 578 F.2d 1256 (8th Cir. 1978).

<sup>74</sup> *Standard Oil Co. v. United States*, 221 U.S. 1, 1 (1911).

the purpose of determining whether the prohibitions contained in [the Sherman Act] had or had not in any given case been violated.”<sup>75</sup> He drew from English common law treatment of contracts that were “unreasonably restrictive of competitive conditions” by their “nature or character” as illegal, concluded that Congress had intended “the standard of reason which had been applied at the common law,” and stated that “in every case where it is claimed that an act or acts are in violation of the Sherman Act the rule of reason, in the light of principles of law and public policy which the act embodies, must be applied.”<sup>76</sup> Chief Justice White later provided a more comprehensive statement of the rule of reason;<sup>77</sup> it has been expanded upon, and critiqued, by different justices over the subsequent years.<sup>78</sup> The rule of reason test is particularly relevant to the pharmaceutical world, primarily because of its application to reverse-payment settlements in order to determine if the settlements are violations of antitrust laws.

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<sup>75</sup> *Id.* at 60.

<sup>76</sup> *Id.* at 60, 66.

<sup>77</sup> See *United States v. Am. Tobacco Co.*, 221 U.S. 106, 179 (1911) (holding that Section 1 prohibits only restraints “operated to the prejudice of the public interests by unduly restricting competition, or unduly restricting the due course of trade, or which, either because of their inherent nature or effect, or because of the evident purpose of the acts, etc., injuriously injured trade . . .”).

<sup>78</sup> See, e.g., *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 691 (1978) (focusing the scope of the rule of reason on the “challenged restraint’s impact on competitive conditions”); *N Pac. Ry. Co. v. United States*, 356 U.S. 1, 4 (1958) (distinguishing the basic aim of the Sherman Act to prohibit actions that unreasonably restrain competition from certain agreements that are, because of their very nature, inherently unreasonable *per se*); *Bd. of Trade of Chicago v. United States*, 246 U.S. 231, 239 (1918) (“The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition 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.”).



*B. Reverse-Payment Settlements: Paying for Delays*

Reverse payment settlements, also referred to in the pharmaceutical industry as “pay-for-delay” agreements, are frequently invoked in the drug industry between competing drug manufacturers.<sup>79</sup> “Pay-for-delay” agreements can appear in a settlement of patent litigation between a brand-name manufacturer and a generic manufacturer.<sup>80</sup> This type of litigation usually takes place within the framework for generic entry to the market, as established by the Hatch-Waxman Act.<sup>81</sup>

Under the Hatch-Waxman framework,<sup>82</sup> a generic manufacturer can try to put its generic drug on the market prior to the expiration of the brand drug’s patent,<sup>83</sup> provided that the generic manufacturer follows the prescribed steps for early entry.<sup>84</sup> This is a strategic move for a generic manufacturer, not only because it has the potential to save consumers billions of dollars and thus promote general consumer welfare, but more specifically, because of the incentives that the Hatch-Waxman Act created for the first generic manufacturer to enter the market after a brand-name drug is already on the market.<sup>85</sup> Further, the FTC issued a study showing that generic drugs prevailed in 73% of the patent litigation

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<sup>79</sup> See *Pay for Delay*, *supra* note 17, at 1 (“[B]rand-name pharmaceutical companies can delay generic competition that lowers prices by agreeing to pay a generic competitor to hold its competing product off the market for a certain period of time.”).

<sup>80</sup> *Id.* at 3.

<sup>81</sup> *Id.* at 3.

<sup>82</sup> See *supra* Part I.

<sup>83</sup> See FED. TRADE COMM’N, *supra* note 61 (explaining the profit motives behind this strategy, the FTC estimated that about one year after market entry an average generic pharmaceutical product takes over ninety percent of the patent holder’s unit sales and sells for fifteen percent of the price of the name brand product).

<sup>84</sup> 21 U.S.C. § 355 (j)(5)(B)(iv) (2012); see also Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417 (2011).

<sup>85</sup> Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 424-25 (2011).

ultimately resolved by a court decision between 1992 and 2002,<sup>86</sup> thus, generic manufacturers have a substantial chance of winning against a brand manufacturer, providing even more incentives for generic market entry.

Section 355(j)(1)<sup>87</sup> of the Hatch-Waxman Act provides that any person may file an ANDA for the approval of a generic version of a pioneer drug.<sup>88</sup> This generic version can either be the “same” as the pioneer drug (with respect to active ingredient(s), route of administration, dosage form, strength, and conditions of use as recommended in the labeling) or “different” in one of the aforementioned aspects.<sup>89</sup> In submitting an ANDA for a generic drug that is the “same” as a pioneer drug, a generic company is thus required to submit bioequivalence data<sup>90</sup> that sufficiently demonstrates that its generic drug is as safe and effective as the original brand-name drug.<sup>91</sup>

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<sup>86</sup> See F.T.C., *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, Exec. Summary at viii (July 2002) (This study covered the period through June 2002; FTC began receiving patent settlement agreements in January 2004 pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003), <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>; see also *Pay for Delay*, *supra* note 17.

<sup>87</sup> 21 U.S.C. § 355(j)(1) (2012) (“Any person may file with the Secretary an abbreviated application for the approval of a new drug.”).

<sup>88</sup> See Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 277 (1985).

<sup>89</sup> See Flannery & Hutt, *supra* note 88, at 277 (“The statute does not provide definitions for the terms ‘same’ and ‘different,’ so the FDA uses its administrative discretion to give context to these two terms. A new dosage form or new use, or a combination drug which has never before been marketed, will clearly be “different.” Other circumstances which will be sufficient to make a generic version different from the pioneer drug will depend upon a variety of scientific factors.”).

<sup>90</sup> 21 U.S.C. § 355(j)(2)(A)(iv) (2012). Under 21 U.S.C. §355(j)(8)(B)(i) (2012), a drug is considered to be “bioequivalent” to a listed drug if “the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses.”

<sup>91</sup> Flannery & Hutt, *supra* note 88, at 279-80.

Specifically, the ANDA must demonstrate (1) that the conditions of use proposed for the generic drug have been previously approved for the pioneer drug; (2) that all active ingredients of the generic drug are the same as those of the pioneer drug; (3) that the strength, route of administration, and dosage form are equivalent in both drugs; (4) that the drug has the same active ingredients (its bioequivalence); and (5) that the labeling is the same, except in respect to the information about the manufacturer.<sup>92</sup> Pursuant to this section, the FDA also created the “Approved Drug Products With Therapeutic Equivalence Evaluations,” commonly known as the Orange Book.<sup>93</sup> The Orange Book is updated every thirty days with current information regarding newly approved drugs and revised patent information.<sup>94</sup>

In addition to the drug product-related certification required of generic drug manufacturers in Title I of the H-W Act, the Act requires a legal certification<sup>95</sup> regarding the status of the patents protecting the brand-name drug.<sup>96</sup> In a generic manufacturer’s ANDA application, the manufacturers must file one of the following four certifications for each Orange Book patent listing covering a relevant pioneer drug: (1) that no patents currently exist; (2) that previous relevant patents have expired; (3) that the generic manufacturer would wait until any relevant patents expired to market their version; or (4) that any current patent is not valid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted (known as a

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<sup>92</sup> See Flannery & Hutt, *supra* note 88, at 278.

<sup>93</sup> *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD AND DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cder/ob/>; see also Kelly, *supra* note 85, at 418.

<sup>94</sup> See Flannery & Hutt, *supra* note 88, at 293.

<sup>95</sup> *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, (July 2002), F.T.C., [https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy\\_0.pdf](https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf).

<sup>96</sup> *Id.*

“Paragraph IV certification”).<sup>97</sup> When the generic manufacturer seeks to market a generic equivalent of an innovator’s drug before the expiration of an Orange Book patent listing for the pioneer drug, the generic company submits a Paragraph IV certification.<sup>98</sup> Paragraph IV certifications come into play in reverse-payment agreements because they are the typical trigger for a brand manufacturer to file a patent infringement claim,<sup>99</sup> which is the first step towards what may culminate in an agreement for a reverse-payment settlement.

Under the Act, the first generic manufacturer to file a Paragraph IV certification<sup>100</sup> will be granted 180 days of generic marketing exclusivity—meaning that the FDA will not allow any other subsequent generic drugs to be marketed during this 180-day exclusivity period.<sup>101</sup> In a Paragraph IV certification, a generic manufacturer certifies that its drug either (1) does not infringe the patent of the relevant brand-drug, or that (2) the relevant brand-drug’s patents claims are invalid.<sup>102</sup> A generic manufacturer must file a Paragraph IV certification with the FDA in order to seek approval to put its generic drug on the market before the brand-drug’s patent has expired.<sup>103</sup> In other words, a Paragraph IV

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<sup>97</sup> Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?* 15 YALE J. HEALTH POL’Y, L. & ETHICS 293, 303 (2015).

<sup>98</sup> *See id.* (“To assist generic drug manufacturers in identifying patents that claimed the brand-name drug, or its uses, the FDA required brand-name manufacturers to list in the book of Approved Drug Products with Therapeutic Equivalence Evaluations—also known as the Orange Book—all relevant patents protecting their products.”).

<sup>99</sup> *See id.* (“When a generic manufacturer makes a Paragraph IV certification, it is required to provide notice to the brand-name manufacturer.”).

<sup>100</sup> *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).

<sup>101</sup> *See* § 355(j)(5)(B)(iv)(I) (2012) (“Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.”).

<sup>102</sup> *See* § 355(j)(2)(A)(vii)(IV) (2012).

<sup>103</sup> *Id.*

certification is a generic manufacturer's ticket to enter the market early.

Once the brand-name manufacturer has received notice that the generic manufacturer has submitted a Paragraph IV certification with the FDA, the Act provides that the brand manufacturer (or whoever holds the patent—usually the manufacturer is also the patent holder) has forty-five days in which to file a patent infringement lawsuit, claiming that the generic drug infringes its patent claims.<sup>104</sup> In theory, the two companies would then engage in patent litigation and would either reach a settlement in which the generic company would have to pay damages to the brand (if it was infringing the brand's patent), or in the alternative, the litigation would go to trial for a determination of infringement.<sup>105</sup> The original goal of creating the Paragraph IV challenge process was to provide a mechanism through which generic manufacturers could challenge weak patents.<sup>106</sup> However, many brand and generic manufacturers abuse the system by entering into closed-door settlement negotiations that divide the market for the drug, increasing their joint profits at the expense of consumers.<sup>107</sup> These settlements are referred to as “reverse-payment” settlements, because of the nature of the payment flow: instead of the payment flowing from the alleged infringer (the generic) to the patent holder (the brand), the payment flow is reversed—the generic receives a benefit from the brand in return for their agreement to not enter the market.<sup>108</sup>

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<sup>104</sup> See 35 U.S.C. § 271(e)(2) (2012).

<sup>105</sup> See generally § 271(a) (“[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent therefor, infringes the patent.”).

<sup>106</sup> Patent strength is generally measured by the probability that it would be found valid and infringed upon if tested in court. See generally Joseph Farrell and Carl Shapiro, *How Strong Are Weak Patents?* 98 AMERICAN ECON. REV. 4, 1347–1369 (2008).

<sup>107</sup> See Keith M. Drake, Martha A. Starr & Thomas McGuire, *Do “Reverse Payment” Settlements of Brand-Generic Patent Disputes in the Pharmaceutical Industry Constitute an Anticompetitive Pay for Delay?* (Nat'l Bureau of Econ. Research, Working Paper No. 20292, 2014).

<sup>108</sup> See Balto, *supra* note 16, at 335.

A typical reverse-payment settlement takes a form similar to this:<sup>109</sup> Company A is a manufacturer of Drug X, a brand-name drug, and its patent on Drug X still has a duration of ten years. Company B, a generic manufacturer, files a Paragraph IV certification in order to put its drug, Drug Z, on the market. Drug Z is a generic form of Drug X. After Company B files its ANDA and the accompanying Paragraph IV certification asserting that Drug Z is the bioequivalent of Drug X and that Drug X's patent is either invalid or is not infringed by Drug Z, patent litigation would normally commence, with Company A bringing a patent infringement suit against Company B. However, in a situation involving a reverse-payment settlement, Company A would agree to drop its patent infringement suit against Company B, and would also agree to pay Company B \$10,000,000 per year for the remaining term of A's patent (ten years). In exchange, Company B would agree to refrain from bringing Drug Z to the market until the patent on Drug X had expired. In this scenario, Company B, the initial infringer, was awarded a significant amount of money, referred to as a "cash" reverse-payment settlement.

The FTC, among other critics, has condemned reverse-payment settlements as anticompetitive and illegal under antitrust doctrines, asserting that the delay of new products hurts customers who could benefit from the lower market prices that generic drugs offer.<sup>110</sup> In *FTC v. Actavis*,<sup>111</sup> the Supreme Court ruled that cash reverse-payment settlements between patent holders and generic manufacturers violate antitrust laws.<sup>112</sup> However, the Court ignored the possibility that a settlement could be of non-monetary value, opening up a world of confusion for circuit courts.

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<sup>109</sup> *But see* Andrew E. Podgorny, *Supporting the Rationale Behind the Hatch-Waxman Act and Patent Law: How Reverse Payment Settlements Under FTC v. Actavis Can Be Procompetitive*, 12 IND. HEALTH L. REV. 423, 424-26 (2015) (arguing a contrary position to this Recent Development, but including a thoughtful and descriptive illustration of the reverse-payment settlement process, upon which this illustrative example is loosely based).

<sup>110</sup> Balto, *supra* note 16, at 334.

<sup>111</sup> *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

<sup>112</sup> *Id.*

### III: HINDSIGHT: WHAT THE SUPREME COURT LEFT OUT IN *FTC v. ACTAVIS*

The story of the *Actavis* case involves a suspicious agreement between pharmaceutical companies, a contemporaneous case decided in a different circuit that used a different test, and, most importantly, a granting of certiorari by the Supreme Court—all of which will be detailed in Section III. This section will explain the facts leading up to the *Actavis* Case and the lower court’s treatment of the complaint. It will then highlight the circuit split that occurred around the same time as the *Actavis* case was first heard, and finally will detail the Supreme Court’s Holding in *Actavis*, including its troublesome silence regarding the legality non-cash reverse-payment settlements.

#### *A: Factual and Lower Circuit Background*

The factual background of *Actavis* is quite similar to the hypothetical scenario between Company A and Company B.<sup>113</sup> In 2003, respondent Solvay Pharmaceuticals (“Solvay”) obtained a patent for its approved brand-name drug, AndroGel.<sup>114</sup> Later that year, respondents<sup>115</sup> Actavis, Inc.<sup>116</sup> (“Actavis”) and Paddock Laboratories, two different generic drug manufacturers, each filed an ANDA for their own generic drugs, each stipulated to be the bioequivalent of AndroGel.<sup>117</sup> As part of the ANDA requirements, the respondents certified under Paragraph IV<sup>118</sup> that Solvay’s patent was invalid and/or that its drugs did not infringe it.<sup>119</sup> Solvay then

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<sup>113</sup> See *supra* Part II.B.

<sup>114</sup> AndroGel is used to treat adult males who have low or no testosterone due to certain medical conditions. See ANDROGEL, <https://www.androgel.com>; *FTC v. Actavis, Inc.*, 133 S.Ct. 2223, 2229 (2013).

<sup>115</sup> A fourth manufacturer and respondent, Par Pharmaceutical, did not file an ANDA of its own, but joined forces with Paddock, agreeing to share the patent litigation costs in return for a share of Paddock’s profit if its generic drug was approved. See *Actavis*, 133 S.Ct. at 2229.

<sup>116</sup> Actavis, Inc. was incorporated as Watson Pharmaceuticals at the time it filed this ANDA. See *id.*

<sup>117</sup> *Id.*

<sup>118</sup> 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).

<sup>119</sup> *Actavis*, 133 S. Ct. at 2224-25.

initiated patent infringement litigation against Actavis and Paddock.<sup>120</sup> In the meantime, the FDA approved Actavis's first-to-file generic drug, but in 2006 the parties settled out of court.<sup>121</sup> Under the terms of the settlement Actavis agreed that it would not bring its generic to market until August 31, 2015, sixty-five months before Solvay's patent expired and also that it would promote AndroGel to urologists.<sup>122</sup> In return, Solvay agreed to pay millions of dollars to each generic—\$12 million in total to Paddock; \$60 million in total to Par; and an estimated \$19–\$30 million annually, for nine years, to Actavis.<sup>123</sup> The companies described these payments as compensation for other services the generics promised to perform, but the FTC contended the other services had little value.<sup>124</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>125</sup>

On January 29, 2009, the FTC filed suit against the settling parties, alleging that the respondents violated Section 5 of the Federal Trade Commission Act<sup>126</sup> by unlawfully agreeing “to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years” in their settlement agreement.<sup>127</sup> The district court held that these allegations did not set forth an antitrust law violation.<sup>128</sup> It accordingly dismissed the FTC's complaint, and on appeal, the Eleventh Circuit affirmed,<sup>129</sup> stating that “absent sham litigation or fraud in obtaining the patent, a

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<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

<sup>123</sup> See Complaint at 77, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

<sup>124</sup> *Actavis*, 133 S. Ct. at 2229.

<sup>125</sup> See Complaint at 81–85, *FTC v. Actavis*, 133 S. Ct. 2223 (2013).

<sup>126</sup> 15 U.S.C. § 45 (2012); see generally *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447 (1986) (“Section 5 encompass[es] . . . practices that violate the Sherman Act and other antitrust laws.”).

<sup>127</sup> App. 29, Complaint ¶ 5.

<sup>128</sup> See *In re AndroGel Antitrust Litig.* (No. II), 687 F. Supp. 2d 1371, 1379 (N.D. Ga. 2010).

<sup>129</sup> *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012).



reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”<sup>130</sup>

*B: Circuit Splits*

Meanwhile, the Third Circuit diverged from the Eleventh Circuit shortly afterwards by refusing to adopt its “scope of the patent” rule.<sup>131</sup> In its *In re K-Dur*<sup>132</sup> decision (decided prior to the Supreme Court’s grant of certiorari for *Actavis*), the Third Circuit favored the application of a “quick-look” rule of reason test (also favored by the FTC), based on the common-sense conclusion that “[a] payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties entering the agreement . . . .”<sup>133</sup> This “quick-look” rule of reason test assumed that the existence of a reverse payment settlement was prima facie evidence of an unreasonable restraint on trade.<sup>134</sup> It also provides that an in-depth analysis, such as the “scope of the patent” test, is not necessary when a clear nexus exists between (a) an agreement from the patent holder to pay a generic manufacturer and (b) a benefit for the patent holder (to the economic detriment of consumers)—absent another legitimate purpose of the payment.<sup>135</sup>

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<sup>130</sup> *Id.* at 1312.

<sup>131</sup> *See In re K-Dur Antitrust Litig.* 686 F.3d 197, 223 (3d Cir. 2012).

<sup>132</sup> *See id.*

<sup>133</sup> *Andrx Pharm. Inc., v. Biovail Corp. Int’l*, 256 F.3d 799, 809 (D.C. Cir. 2001).

<sup>134</sup> The Third Circuit did clarify that a patent holder may attempt to rebut a plaintiff’s prima facie case of an unreasonable restraint of trade by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit. *See In re K-Dur Litigation*, 686 F.3d at 223.

<sup>135</sup> *In re K-Dur Litig.*, 686 F.3d 197, 218 (3d Cir. 2012) (“For example, a modest cash payment that enables a cash-starved generic manufacturer to avoid bankruptcy and begin marketing a generic drug might have an overall effect of increasing the amount of competition in the market . . .”).

*C: Certiorari and the “Sliding Scale” Test*

The Supreme Court granted certiorari to *FTC v. Actavis*, in light of the circuit split below.<sup>136</sup> The Court, in a 5-3 decision written by Justice Breyer, overturned the Eleventh Circuit’s no-antitrust-violation ruling.<sup>137</sup> However, even though the Court cautioned that this “unusual” type of agreement could have anticompetitive effects,<sup>138</sup> it did not endorse a strict prohibition on reverse-payment settlements<sup>139</sup> and declined to adopt the Third Circuit’s “quick-look” rule that the reverse payments are prima facie evidence of unreasonable restraints on trade.<sup>140</sup> It also refused to endorse the Eleventh Circuit’s “scope of the patent” test.<sup>141</sup> Instead, the Supreme Court promulgated a new approach to assessing the anticompetitive nature of reverse-payment agreements: the sliding scale test.<sup>142</sup>

The Court based its new approach on the holding from a previous Supreme Court case, which quoted a leading antitrust scholar: “[t]here is always something of a sliding scale in appraising reasonableness . . . [and] the quality of proof required

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<sup>136</sup> *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2230 (2013).

<sup>137</sup> *Actavis*, 133 S.Ct. at 2237.

<sup>138</sup> *Id.* at 2231.

<sup>139</sup> *Id.*

<sup>140</sup> *Id.*

<sup>141</sup> *Id.* at 2234-37; see also Michael F. Werno, *More Questions Than Answers? The Uncertainties Surrounding Reverse-Payment Settlements in the Post-Actavis World*, 21 B.U. J. SCI. & TECH. L. 200, 206-07 (“[The Supreme Court] based its rejection of the scope of the patent test on ‘five sets of considerations.’ First, these payments have the ‘potential for genuine adverse effects on competition.’ Second, the anticompetitive effects may sometimes be unjustified even in light of any pro-competitive effects. Third, in cases where there is strong anticompetitive damage, the ‘patentee likely possesses the power to bring that harm about in practice.’ Fourth, the Court believed that antitrust litigation is more efficient and ‘more feasible administratively than the Eleventh Circuit believed.’ The Court held that consideration of the payment in an antitrust action avoids ‘the need to litigate the patent’s validity (and also, any question of infringement).’ Finally, ‘the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuits.’”).

<sup>142</sup> *Actavis*, 133 S. Ct. at 2237.

should vary with the circumstances.”<sup>143</sup> The *Actavis* Court set forth the following test:

In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects . . . the 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.<sup>144</sup>

The Court thus refused to classify reverse-payment settlements as illegal *per se* and refused to be more specific on how lower courts should interpret its sliding scale test. Instead, it merely stated that it would “leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.”<sup>145</sup> Circuit courts have subsequently agreed that reverse-payment settlements in the form of cash are violations of antitrust laws,<sup>146</sup> but due to the Supreme Court’s lack of any substantial guidance in *Actavis*, the issue of non-cash “pay-for-delay” agreements continue to perplex the circuit courts.

#### **IV: THE CURRENT CRISIS: HOW DIFFERENT CIRCUITS HAVE STRUGGLED TO APPLY THE “SLIDING SCALE” TEST TO NON-CASH REVERSE SETTLEMENTS IN THE POST-ACTAVIS WORLD**

Following the Supreme Court’s *Actavis* decision, a new debate emerged: whether non-cash payments are unreasonable restraints

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<sup>143</sup> Cal. Dental Ass’n v. FTC, 526 U.S. 756, 780 (1999) (quoting P. Areeda, ANTITRUST LAW ¶ 1507, p. 402 (1986)).

<sup>144</sup> *Actavis*, 133 S.Ct. at 2237.

<sup>145</sup> *Id.* at 2238.

<sup>146</sup> See, e.g., *In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at 13 (S.D.N.Y. 2015); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015); *In re Effexor XR Antitrust Litig.*, 2014 WL 4988410, at 19 (D.N.J. 2014); *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 710 (E.D. Pa. 2014); *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 543 (D.N.J. 2014); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

on trade.<sup>147</sup> District courts now grapple with questions on how to value non-cash payments and whether they meet the vague “large and unjustified” standard in the sliding scale test.<sup>148</sup> It is problematic when lower courts are left with interpretation questions following a Supreme Court ruling. In this instance, the Supreme Court’s silence on whether a non-cash payment constitutes an antitrust violation, coupled with the vague factors it gave for determining whether a settlement is anticompetitive, created an environment where circuit courts have to determine—on their own—what the Supreme Court really intended. This absence of a clear precedent has created tensions between circuits that have interpreted *Actavis* differently. This section will first explain the logistics behind a non-cash reverse-payment settlement in Part A and will highlight the different problems lower courts have encountered while attempting to determine the legality of these non-cash payments in Part B.

*A: What Is a Non-Cash Reverse-Settlement?*

The term “non-cash payment” may seem like an oxymoron on its face, but there are varieties of ways in which a brand patent holder can give some form of valuable consideration to a generic manufacturer in exchange for the generic manufacturer’s agreement to withhold bringing its product to market that do not involve a monetary exchange. The most commonly used non-cash payment is a no-authorized generic agreement (“No-AG” or “No-AG agreement”).<sup>149</sup>

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<sup>147</sup> Robin A. van der Muelen & Rudi Julius, *Cash or No Cash—That is No Longer the Question!*, ANTITRUST HEALTH CARE CHRONICLE, 12 (2016), <http://www.labaton.com/blog/upload/Chronicle-Article.pdf>.

<sup>148</sup> *Actavis*, 133 S.Ct. at 2237.

<sup>149</sup> See *Authorized Generic Drugs: Short-Term Effects and Long Term Impacts* (2011), F.T.C., [https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf](https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf).

A No-AG involves the patent holder agreeing to not bring an authorized generic (or “AG”) product to market, so that the generic manufacturer’s drug can have exclusivity upon its (delayed) entry to the market.<sup>150</sup> An authorized generic is chemically identical to its counterpart brand drug, but sold by the brand company or its representatives as a generic product under the same regulatory approval as the brand-name drug.<sup>151</sup> Under a No-AG agreement, the brand manufacturer agrees not to launch its own authorized generic alternative when the first generic company begins to compete in exchange for the generic company delaying its entry.<sup>152</sup>

While a first-to-file generic manufacturer is entitled to no generic competition during its 180-day exclusivity period, in the absence of a No-AG agreement, a brand manufacturer is legally allowed to market its own generic product (called an authorized generic) during that same 180-day period, creating competition for the generic manufacturer.<sup>153</sup> However, if a No-AG agreement is created, the brand manufacturer will withhold from marketing its AG during the 180-day exclusivity period (or any other agreed-upon period), leading to valuable returns for the generic manufacturer (because its generic drug would be the only generic on the market).<sup>154</sup>

A non-cash payment such as a No-AG agreement can be harder to quantify because it is not a monetary amount, but it can also be

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<sup>150</sup> See *In re Effexor XR Antitrust Litigation*, 2014 WL 4988410 (D.N.J. 2014). Brief of the Federal Trade Commission as amicus curiae before the United States District Court for the District of New Jersey, addressing the question of whether a branded company’s commitment not to launch an authorized generic in competition with a generic company can be a reverse payment under the Supreme Court’s ruling in *FTC v. Actavis*, 133 S. Ct. 2223 (2013).

<sup>151</sup> *FTC Submits Proposed Amicus Brief Concerning “No-Authorized-Generic” Commitments in Drug Companies’ Patent Settlements* (August 16, 2013), F.T.C., <https://www.ftc.gov/news-events/press-releases/2013/08/ftc-submits-proposed-amicus-brief-concerning-no-authorized>.

<sup>152</sup> *Id.*

<sup>153</sup> See *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005).

<sup>154</sup> See *In re Effexor XR Antitrust Litig.*, 2014 WL 4988410 (D.N.J. 2014).

just as anticompetitive as a cash-based settlement.<sup>155</sup> An FTC empirical study of the competitive effects of authorized generics found that when a brand company does not launch an authorized generic during the exclusivity period reserved for the first-filing generic manufacturer under the Hatch-Waxman Act, the generic company's revenues are substantially increased, because consumers pay higher prices for the generic product.<sup>156</sup> Clearly there is a substantial economic value attached to a No-AG agreement, and because of that characteristic, brand and generic manufacturers have increasingly attempted to include No-AG agreements as part of non-cash reverse-payment settlements.<sup>157</sup>

*B: Subsequent Circuit Struggles in the Post-Actavis World:*

Different circuit courts have attempted to transfer the vague *Actavis* sliding scale test to contemporary anticompetitive concerns in the post-*Actavis* era, with mixed success. Two such attempts occurred in the Third Circuit and the First Circuit in 2015<sup>158</sup> and 2016<sup>159</sup> respectively, both of which are highlighted below to demonstrate the difficulties circuit courts face in applying the *Actavis* factors in a consistent, determinative manner.

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<sup>155</sup> *Authorized Generic Drugs: Short-Term Effects and Long Term Impacts* (2011), F.T.C., <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf> (“Because generics often are priced substantially below the price of brand-name drugs, even a few additional months without generic competition can significantly increase overall prescription drug costs.”).

<sup>156</sup> *See id.*

<sup>157</sup> *See id.* (“[T]here is strong evidence that agreements not to compete with an authorized generic have become a way for brand-name companies to compensate generic competitors for delaying entry.”).

<sup>158</sup> *King Drug Co. of Florence, Inc., v. Smithkline Beechman Co.*, 791 F.3d 388 (3rd Cir. 2015).

<sup>159</sup> *In re Loestrin 24 Fe Antitrust Litigation*, No. 1402071, 15-1250, 2016 WL 698077 (1st Cir. 2016).

### 1. Third Circuit

A No-AG agreement was the exact type of settlement in dispute in *King Drug Co. v. Smithkline Beecham Corp.* (“King Drug”),<sup>160</sup> which forced the Third Circuit to consider whether a reverse-payment settlement constituted an antitrust violation where there was no monetary payment involved.<sup>161</sup> The respondents, Smithkline Beecham (“GSK”)<sup>162</sup> and Teva Pharmaceuticals Industries, Ltd., entered into a No-AG agreement after Teva challenged the validity and enforceability of GSK’s patent on lamotrigine, the active ingredient in GSK’s brand drug Lamictal.<sup>163</sup> GSK originally filed a patent infringement suit against Teva, but the two companies settled out of court in February 2005.<sup>164</sup> Their settlement included Teva’s agreement to end its challenge to GSK’s patent in exchange for early entry into the market and GSK’s commitment not to produce its own AG version of Lamictal tablets until January 2009.<sup>165</sup> The plaintiff, a direct purchaser of Lamictal from GSK called King Drug Co., brought suit against both companies, contending that their no-AG agreement qualified as a “reverse payment” under *Actavis* because it violated Section 1 of the Sherman Act<sup>166</sup> by conspiring to delay generic competition for Lamictal tablets, and it violated Section 2<sup>167</sup> by conspiring to

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<sup>160</sup> *King Drug Co. of Florence, Inc.*, 791 F.3d.

<sup>161</sup> *Id.*

<sup>162</sup> At the time it entered into the No-AG agreement with respondent Teva, Smithkline Beecham was doing business as GlaxoSmithKline, or “GSK.” See *King Drug Co.*, 791 F.3d.

<sup>163</sup> *King Drug Co.*, 791 F.3d at 393.

<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

<sup>166</sup> A settlement in which the patentee drug manufacturer agrees to relinquish its right to produce an “authorized generic” of the drug to compete with a first-filing generic’s drug during the generic’s statutorily guaranteed 180 days of market exclusivity under the Hatch–Waxman Act, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason. Sherman Act, 15 U.S.C.A. §§ 1, 2.

<sup>167</sup> *Id.*

monopolize the lamotrigine tablet market.<sup>168</sup> GSK and Teva moved to dismiss, countering that, under the Third Circuit’s decision *in re K-Dur*,<sup>169</sup> only cash payments constitute actionable “reverse payments.”<sup>170</sup> The district court granted GSK and Teva’s motion to dismiss for failure to state a claim, concluding the settlement was “not subject to antitrust scrutiny” under *K-Dur*,<sup>171</sup> and that, “from a policy perspective, this settlement did introduce generic products onto the market sooner than what would have occurred had GSK’s patent not been challenged.”<sup>172</sup>

On appeal, the Third Circuit reversed the district court, holding that No-AG agreements should be subject to antitrust scrutiny under the sliding scale test to determine whether a reverse payment settlement “could have an anticompetitive effect or, alternatively, whether it was reasonable compensation for litigation costs or the value of services.”<sup>173</sup> In the opinion of the Third Circuit, an illegal “payment” for delay does not have to be cash-based.<sup>174</sup> Specifically, one potential non-cash way to pay off a generic-drug company is to remove competition from an authorized generic drug, thus allowing the generic to demand higher prices upon entry, just as was found in the agreement between GSK and

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<sup>168</sup> *King Drug Co. of Florence, Inc., v. Smithkline Beechman Co.*, 791 F.3d 388, 398 (3rd Cir. 2015).

<sup>169</sup> The Supreme Court later vacated *K-Dur* and remanded for reconsideration in light of *Actavis*. See *Merck & Co. v. La. Wholesale Drug Co.*, 133 U.S. 2849, 186 L.Ed.2d 904 (2013); *Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co.*, 133 U.S. 2849, 186 L.Ed.2d 904 (2013); *FTC v. Actavis, Inc.* 133 S.Ct. 2223, 2237–38 (finding that *K-Dur* was inconsistent with *Actavis* in that [the court] had directed application of “quick look rule of reason analysis,” rather than the traditional, full-fledged rule of reason standard that the Supreme Court subsequently decided is proper for reverse payment settlement agreements).

<sup>170</sup> *King Drug Co.*, 791 F.3d at 398.

<sup>171</sup> *Id.* (quoting *in re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-0995, 2012 WL 6725580, at 6 (D.N.J. 2012)).

<sup>172</sup> *Id.* (quoting *in re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-0995, 2012 WL 6725580, at 7 (D.N.J. 2012)).

<sup>173</sup> *Id.*

<sup>174</sup> *Id.*



Teva.<sup>175</sup> The Third Circuit accordingly found that the *Actavis* holding should not be limited to reverse payments of cash where a “No-AG agreement . . . represents an unexplained large transfer of value from the patent holder to the alleged infringer.”<sup>176</sup> Acknowledging the limited guidance provided by *Actavis*, the Third Circuit noted that “the thrust of the [Supreme] Court’s reasoning [in *Actavis* was] not that it is problematic that money is used to effect an end to the patent challenge, but rather that the patentee leverages some part of its patent power (in *Actavis*, its supracompetitive profits) to cause anticompetitive harm—namely, elimination of the risk of competition.”<sup>177</sup>

Most recently, the Supreme Court denied GSK’s petition for certiorari, which requested the highest court<sup>178</sup> to finally address whether non-cash settlement agreements were included in the realm of the *Actavis* opinion.<sup>179</sup> In its petition for certiorari, GSK stated:

[The Supreme] Court’s review is necessary to resolve disagreement and confusion among the lower courts about the breadth and meaning of *Actavis*, and to correct the Third Circuit’s erroneous conclusion that traditional

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<sup>175</sup> Jeff Zalesin, *FTC Puts No-Authorized-Generic Pharma Deals in Crosshairs*, LAW360 (2016) <http://www.law360.com/articles/778893/ftc-puts-no-authorized-generic-pharma-deals-in-crosshairs>.

<sup>176</sup> *King Drug Co. of Florence, Inc., v. Smithkline Beechman Co.*, 791 F.3d 388, 406 (3rd Cir. 2015).

<sup>177</sup> *Id.*

<sup>178</sup> See Petition for certiorari, *SmithKline Beecham Corp. v. King Drug Co. of Florence, Inc., et al.*, 791 F.3d 388 (2016) (“[T]he Third Circuit’s ruling is indicative of the confusion that has permeated the lower courts faced with interpreting *Actavis*. Numerous courts within the First, Second, Third, Seventh, and Ninth Circuits have considered what constitutes a potentially improper ‘reverse payment’ that is subject to antitrust review under *Actavis*, and those courts have adopted divergent tests and have reached conflicting results. Judges are asking for guidance, as are litigants. Those engaged in patent litigation need to know whether formerly routine settlement and licensing agreements are now at risk of being deemed antitrust violations.”).

<sup>179</sup> Tony Dutra, *No Second Look for Pay-For-Delay Drug Patent Settlements*, BLOOMBERG BNA PATENT, COPYRIGHT, AND TRADEMARK JOURNAL—DAILY EDITION, Nov. 8, 2016.

licensing arrangements that Congress authorized to promote innovation can be attacked as anticompetitive under the antitrust laws. The Third Circuit is not alone in expanding *Actavis* well beyond its intended bounds and misinterpreting the decision such that little, if anything, remains of the patentee's express power to license.<sup>180</sup>

The Supreme Court remanded the case back to the district court, on the advice of an amicus curiae brief written by the Office of the Solicitor General<sup>181</sup> which said that GSK and Teva's actions were subject to the same level of scrutiny, the "rule of reason" that was applied in *Actavis*.<sup>182</sup> While some optimists may view this as an indirect signal from the Supreme Court that non-cash settlements are violations of antitrust law, the ultimate decision lies once again with the district court, who will be again forced to act without any guiding precedence from the highest court, and its interpretation will likely be inconsistent with that of other district court's past rulings, or even subsequent rulings on the issue.<sup>183</sup>

## 2. First Circuit

The First Circuit also attempted to address a dispute regarding a non-cash reverse payment settlement in the case *in re Loestrin*,<sup>184</sup> where it extrapolated on the uncertain meaning of the *Actavis* holding and corrected what it felt was an inaccurate district court holding. This effectively overturned the lower court's ruling that *Actavis* did not apply to non-cash payments.<sup>185</sup>

The dispute in *Loestrin* arose from two reverse payments made by a brand manufacturer, Warner Chilcott ("Warner"), to resolve litigation concerning its patent covering the oral contraceptive

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<sup>180</sup> See Petition for Certiorari, *SmithKline Beecham Corp. v. King Drug Co. of Florence, Inc., et al.*, 791 F.3d 388 (2016).

<sup>181</sup> Brief for FTC as Amici Curiae Supporting Respondents, *SmithKline Beecham Corp. v. King Drug Co. of Florence, Inc., et al.*, 791 F.3d 388 (No. 15-1055, cert. denied 11/7/16).

<sup>182</sup> See Dutra, *supra* note 179.

<sup>183</sup> See *id.*

<sup>184</sup> *In re Loestrin* 24 Fe Antitrust Litig., No. 1402071, 15-1250, 2016 WL 698077 (1st Cir. 2016).

<sup>185</sup> *Id.*

Loestrin Fe.<sup>186</sup> The first litigation arose when a generic manufacturer, Watson Pharmaceuticals, Inc. (“Watson”), attempted to introduce a generic version of Loestrin Fe to the market through an ANDA filed in 2006.<sup>187</sup> Warner brought suit against Watson for patent infringement.<sup>188</sup> The two parties settled in January, agreeing that Watson would delay entry of its generic version of Loestrin Fe until January 22, 2014, in exchange for Warner agreeing to not market, supply, or license an AG version of Loestrin Fe during Watson’s 180-day generic exclusivity period.<sup>189</sup> Warner also agreed not to grant any licenses to any other generic manufacturers during those 180 days.<sup>190</sup>

Almost immediately after Watson and Warner made their agreement, another manufacturer, Lupin Pharmaceuticals, Inc. (“Lupin”) also filed an ANDA to market a generic version of Loestrin Fe.<sup>191</sup> A very similar no-AG agreement quickly arose between Warner and Lupin in October 2010.<sup>192</sup> Two putative classes of plaintiffs subsequently brought antitrust claims alleging that the two settlement agreements were violations of Section 1 of the Sherman Act.<sup>193</sup> The district court declined to extend *Actavis* to non-cash reverse payment settlements and granted the defendant’s motion to dismiss, setting the decision up for immediate appeal.<sup>194</sup>

The Court of Appeals for the First Circuit subsequently reversed and made several clarifications to the vague *Actavis* ruling.<sup>195</sup> In its ruling, the First Circuit was quick to point out that the district court was mistaken in believing that *Actavis* involved

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<sup>186</sup> *Id.* at 540.

<sup>187</sup> *Id.* at 545.

<sup>188</sup> *Id.*

<sup>189</sup> *In re* Loestrin 24 Fe Antitrust Litig., No. 1402071, 15-1250, 2016 WL 698077, at 545 (1st Cir. 2016).

<sup>190</sup> *Id.*

<sup>191</sup> *Id.*

<sup>192</sup> *Id.*

<sup>193</sup> *Id.*

<sup>194</sup> *Id.*

<sup>195</sup> *In re* Loestrin 24 Fe Antitrust Litig., No. 1402071, 15-1250, 2016 WL 698077, at 542 (1st Cir. 2016).

only cash payments.<sup>196</sup> Further, it acknowledged that “the value of non-cash reverse payments may be much more difficult to compute than that of their cash counterparts,” but ultimately determined that complexity and difficulty of proof were not justifications for avoiding antitrust scrutiny.<sup>197</sup>

### *C. Analyzing the Difficulties of Valuing Non-Cash Payments*

While the First and Third Circuits seem to agree that non-cash reverse payment settlements should be included in the prohibited class of settlements set forth by *Actavis*, the resulting questions facing district and circuit courts now include the most pertinent: how do plaintiffs sufficiently—and more importantly, successfully—plead a reverse payment case that does not involve a cash payment?<sup>198</sup> Although it remains to be seen whether other appellate courts will follow the First and Third Circuit’s lead, it seems likely that pharmaceutical manufacturers will face increased exposure to significant liability from private antitrust plaintiffs claiming that the parties entered into noncash reverse payment settlements.<sup>199</sup>

Not only are there difficulties in valuing non-cash agreements at the pleading stage, plaintiffs also may not have access to much, if any, information about certain settlement terms, particularly side agreements, which will further limit their discovery.<sup>200</sup> Thus, valuing such deals becomes nearly impossible, especially at the pleading stage, which is a crucial hurdle to overcome in any litigation suit.<sup>201</sup> Further, some pharmaceutical companies are not U.S. public companies and therefore are not required to report

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<sup>196</sup> *Id.*

<sup>197</sup> *Id.* at 545.

<sup>198</sup> Robin A. van der Muelen & Rudi Julius, *Cash or No Cash- That is No Longer the Question!*, ANTITRUST HEALTH CARE CHRONICLE 12, 21 (2016), <http://www.labaton.com/blog/upload/Chronicle-Article.pdf>.

<sup>199</sup> *Id.*

<sup>200</sup> *Id.*

<sup>201</sup> *Id.*; see also *In re Effexor*, 2014 WL 4988410 at 21 (2014) (“Simply alleging some sort of value of a no-authorized generic agreement, absent a reliable foundation supporting that value, does not establish the plausibility required by Rule 12(b)(6).”).

deals they make with other companies.<sup>202</sup> So, while a plaintiff (or a class of plaintiffs) may suspect that a secret side deal is the underlying, substantial part of a settlement agreement, unless it is first discovered by other means, such as an independent FTC investigation, these plaintiffs will not have access to the terms of those agreements and will be unable to adequately plead their value.<sup>203</sup> This effectively limits their chances of success in court.<sup>204</sup>

In several recent instances,<sup>205</sup> district courts have agreed that *Actavis* applied to non-cash reverse payments, but nonetheless dismissed the cases because the plaintiffs did not adequately allege that the payments were “large” or “unjustified.”<sup>206</sup> For example, in 2016 the District Court for the Southern District of New York dismissed a class of indirect purchasers’ claims that Takata Pharmaceutical Company and its subsidiaries engaged in anticompetitive conduct to restrict generic entry of ACTOS and ACTO*plus*, drugs used to treat diabetes, through alleged pay-for-delay agreements with five manufacturers (“the Takata settlements”).<sup>207</sup> The court held that the plaintiffs failed to allege anticompetitive conduct under the rule of reason that would amount to the type of “large and unjustified” payment that would raise antitrust concerns under *Actavis*.<sup>208</sup> In discussing the Takata settlements, the court concluded that even if the agreements were

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<sup>202</sup> Robin A. van der Muelen & Rudi Julius, *Cash or No Cash- That is No Longer the Question!*, ANTITRUST HEALTH CARE CHRONICLE 12, 21 (2016), <http://www.labaton.com/blog/upload/Chronicle-Article.pdf>.

<sup>203</sup> *Id.*

<sup>204</sup> *Id.*; see also *Effexor*, 2014 WL 4988410 at 22; *Lipitor*, 46 F. Supp. 3d at 546.

<sup>205</sup> See *Effexor*, 2014 WL 4988410, at 20; see also *Lipitor*, 46 F. Supp. 3d at 534 (“[A reverse payment] must be converted to a *reliable estimate* of its monetary value so that it may be analyzed against the *Actavis* factors.”) (emphasis added); *In re ACTOS*, 2015 WL 5610752, at 19-20 (holding that the plaintiffs failed to allege anticompetitive conduct under the rule of reason that would amount to the type of “large and unjustified” payment that would raise antitrust concerns under *Actavis*).

<sup>206</sup> See *Effexor*, 2014 WL 4988410, at 20; see also *Lipitor*, 46 F. Supp. 3d at 534; *In re ACTOS*, 2015 WL 5610752, at 19-20.

<sup>207</sup> *In re ACTOS*, 2015 WL 5610752, at 19-20 (2016).

<sup>208</sup> *Id.*

considered payments, the plaintiffs had failed to sufficiently prove to the court that the payments were “large” and “unjustified.”<sup>209</sup> The court stated that it required “[p]laintiffs [to] plausibly allege a factual basis for the court to reasonably estimate the value of the settlement terms.”<sup>210</sup> In their complaint, the plaintiffs alleged that the licensing terms in the settlements were of “substantial value” and worth “tens” and “hundreds of millions” of dollars, but did not provide any method of calculating the value of the licensing terms.<sup>211</sup> Further, the court was not persuaded by plaintiffs’ argument that a valuation method was unnecessary simply because the payments were sufficiently large.<sup>212</sup>

Clearly, many obstacles for challenging non-cash reverse payment settlements remain, lending to the conclusion that the Supreme Court ultimately failed its responsibility of providing clear precedence for circuit courts to follow in *Actavis*. Further, despite clear pleadings from courts, judges, and litigants, the Supreme Court has refused to clarify its position, causing further inconsistencies and confusion to permeate in the lower layers of the judicial system.<sup>213</sup>

### CONCLUSION

Because brand-name drug patent owners are easily able to utilize the loophole created in the Supreme Court’s ruling in *Actavis*, and because circuit and district courts are now faced with

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<sup>209</sup> *Id.*

<sup>210</sup> *Id.*

<sup>211</sup> *Id.*

<sup>212</sup> *Id.*

<sup>213</sup> See Petition for certiorari, *SmithKline Beecham Corp. v. King Drug Co. of Florence, Inc., et al.*, 791 F.3d 388 (2016) (“[T]he Third Circuit’s ruling is indicative of the confusion that has permeated the lower courts faced with interpreting *Actavis*. Numerous courts within the First, Second, Third, Seventh, and Ninth Circuits have considered what constitutes a potentially improper ‘reverse payment’ that is subject to antitrust review under *Actavis*, and those courts have adopted divergent tests and have reached conflicting results. Judges are asking for guidance, as are litigants. Those engaged in patent litigation need to know whether formerly routine settlement and licensing agreements are now at risk of being deemed antitrust violations.”).

the difficult task of determining which non-cash settlements meet the standard of an antitrust violation without any authority from the Supreme Court to help set forth that standard, the Supreme Court missed the mark by ignoring non-cash pay-for-delay reverse payment settlements in *FTC v. Actavis*. District courts and circuit courts alike have struggled in the post-*Actavis* world to apply the “large” and “unjustified” factors to increasingly complex agreements between major pharmaceutical companies, in which it is clear that the companies are benefitting to the detriment of the consumers, but there is not an easy cash trail to follow in order to prove an antitrust violation occurred. Drug prices affect the lives of virtually all American citizens at some point in their lifetime, and the Supreme Court has continuously—and erroneously—denied valuable opportunities to protect those citizens from the detrimental anticompetitive effects of non-cash reverse-payment settlements.