

# THE ROLE OF ANTITRUST PRINCIPLES IN PATENT MONOPOLIES: THE THIRD CIRCUIT APPLIES ANTITRUST SCRUTINY TO NO-AG PATENT SETTLEMENTS IN *SMITHKLINE*

**Abstract:** On June 26, 2015, in *King Drug Co. of Florence v. Smithkline Beecham Corp.*, the U.S. Court of Appeals for the Third Circuit held that no-authorized generic agreements (“no-AG agreements”), in which a pioneer pharmaceutical manufacturer agrees not to introduce a generic drug, are subject to antitrust scrutiny under the Sherman Act. This Comment argues that the Third Circuit correctly extended the U.S. Supreme Court decision in *Federal Trade Commission v. Actavis* to non-cash settlement agreements. In *Actavis*, the Court held that a “reverse-payment settlement,” which compensates a generic manufacturer to delay market entry, creates monopolistic consequences and is subject to antitrust scrutiny. To rule otherwise would deter manufacturers from introducing generic drugs into the pharmaceutical market and, consequently, restrict the amount of lower cost generic drugs available to consumers.

## INTRODUCTION

In 2005, Smithkline Beecham Corp., doing business as GlaxoSmithKline (“GSK”), a brand-name pharmaceutical manufacturer, settled a patent infringement lawsuit with Teva Pharmaceutical Industries (“Teva”), a generic pharmaceutical manufacturer.<sup>1</sup> Under the terms of the settlement agreement, the brand manufacturer agreed not to introduce an authorized generic (agreed to a “no-AG agreement”) for a limited period of time.<sup>2</sup> In effect, the no-AG agreement reduced the number of possible generics available from two—

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<sup>1</sup> *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 397 (3d Cir. 2015). GlaxoSmithKline (“GSK”) initiated the litigation to challenge Teva Pharmaceutical Industries (“Teva”)’s attempt to market a generic version of the drug before GSK’s patent expired. *Id.* at 396. Because the litigation settled, GSK’s patent retained its original expiration: July of 2008. *Id.*

<sup>2</sup> *Id.* at 397 (noting that GSK agreed not to market its authorized generic for a 180-day period of exclusivity). Although GSK brought the infringement suit against Teva, GSK risked losing its patent to Teva’s validity defense. *See id.* (noting that GSK lost its chief patent claim). An authorized generic is a generic drug that the brand manufacturer sells. Thomas Chen, Note, *Authorized Generics: A Prescription for Hatch-Waxman Reform*, 93 VA. L. REV. 459, 460 (2007). When parties sign an agreement not to market an authorized generic (a “no-AG agreement”), the brand manufacturer agrees not to market its own generic during the period of exclusivity granted to the first-filing generic manufacturer. Aaron Edlin et al., *The Actavis Inference: Theory and Practice*, 67 RUTGERS U. L. REV. 585, 596 (2015).

Teva's and GSK's—to one—Teva's alone.<sup>3</sup> In exchange, GSK avoided Teva's patent validity challenge and, consequently, retained the exclusive right to market its brand-name drug for the completion of the patent term.<sup>4</sup>

In 2015, in *King Drug Co. of Florence v. Smithkline Beecham Corp.*, the United States Court of Appeals for the Third Circuit held that the no-AG agreement was subject to antitrust scrutiny.<sup>5</sup> The Third Circuit relied on the United States Supreme Court's 2013 decision in *Federal Trade Commission v. Actavis* to reach its conclusion.<sup>6</sup> In *Actavis*, the Supreme Court held that a “reverse payment settlement,” where a brand pays the generic to delay entering the market, adversely affects competition and should be evaluated according to antitrust principles.<sup>7</sup>

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<sup>3</sup> See Michele M. Kang, *ANDA Reverse Payments and the Post-Actavis Landscape*, 8 HASTINGS SCI. & TECH. L.J. 73, 79 (2016) (explaining that no-AG agreements limit the number of possible generic drugs offered from two—authorized generic and generic—to one—generic). Under the Hatch-Waxman Act, a first-filing generic drug manufacturer is entitled to a 180-day exclusivity period, to be shared only with the brand-name manufacturer's authorized generic. See Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2012)) (providing a 180-day period of exclusivity to the first-filing generic manufacturer, but permitting the pioneer drug manufacturer to market its authorized generic drug during this time); Fed. Trade Comm'n v. Actavis, Inc., 133 S. Ct. 2223, 2229 (2013) (noting the 180-day period of exclusivity excludes competition from other generic manufacturers, but does not prevent the brand manufacturer from introducing its own generic, known as an authorized generic).

<sup>4</sup> *Smithkline*, 791 F.3d at 397. Had Teva won the patent suit in court in February of 2005, Teva would have been entitled to a first-filer's 180-day exclusivity period, shared with GSK, beginning on the day of the decision. See Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 430 (2011) (noting that the 180-day market exclusivity period commences at the earlier of a court decision regarding the validity of the patent or the date generic manufacturers enter the market). After this period, any later-filing generic manufacturer whose Abbreviated New Drug Application (“ANDA”) had been approved would have been allowed entry into the market. See 21 U.S.C. § 355(j) (providing 180-day period of exclusivity to the first to file an ANDA); *Smithkline*, 791 F.3d at 396 (stating that no other generic can enter during this exclusivity period); Kelly, *supra*, at 424 (noting that the FDA reviews subsequent ANDA applications after the completion of the 180-day period). In the end, the market would have opened in June of 2005. *Smithkline*, 791 F.3d at 397. Under the settlement agreement, the market remained closed to all manufacturers other than GSK and Teva during GSK's patent term and Teva's subsequent 180-day exclusivity period, ultimately opening in January of 2009. *Id.*

<sup>5</sup> *Smithkline*, 791 F.3d at 409 (stating that the settlement agreement creates a monopoly and consumers pay in the form of higher prices); see also Sherman Antitrust Act, ch. 647, 26 Stat. 209 (1890) (codified as amended at 15 U.S.C. §§ 1–7 (2012)) (prohibiting contracts or conspiracies that restrain or monopolize trade). Antitrust law protects consumers from anticompetitive arrangements in the marketplace. See A. Michael Ferrill et al., *Antitrust and Consumer Protection*, 60 SMU L. REV. 669, 670–71 (2007) (finding that antitrust laws are designed to promote competition between market players and prohibit price-fixing, so consumers benefit in the form of lower prices).

<sup>6</sup> See Fed. Trade Comm'n v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013) (noting that patent settlements can sometimes violate antitrust laws); *Smithkline*, 791 F.3d at 403 (applying the *Actavis* rule to find anticompetitive consequences in the no-AG agreement).

<sup>7</sup> See *Actavis*, 133 S. Ct. at 2227, 2237 (holding that the legality of a settlement where the brand pays a large and unjustified cash payment to the generic manufacturer to delay market entry should be evaluated with antitrust and patent law).

This Comment argues that the Third Circuit correctly extended the *Actavis* holding to include non-cash settlements because both forms of settlements represent a potential unreasonable restraint of trade.<sup>8</sup> Part I of this Comment discusses the legislative purpose of the Hatch-Waxman Act and reviews the factual and procedural history of *Smithkline*.<sup>9</sup> Part II explains the legal landscape set forth in *Actavis* and examines the *Smithkline* holding in light of the *Actavis* decision.<sup>10</sup> Finally, Part III argues that the Third Circuit correctly interpreted Congress's intent by holding that non-cash patent settlements are subject to antitrust scrutiny.<sup>11</sup>

## I. ENSURING ACCESS TO LOW COST PHARMACEUTICAL DRUGS

Congress enacted the Drug Price Competition and Patent Term Restoration Act (popularly the "Hatch-Waxman Act") in 1984 to protect consumers from excessive pharmaceutical prices.<sup>12</sup> By reducing the time and costs associated with introducing a generic drug, Congress hoped to encourage generic manufacturers to enter the market sooner.<sup>13</sup> The pro-competitive aim of the Hatch-Waxman Act saves consumers billions of dollars in pharmaceutical prices every year.<sup>14</sup> Section A of this Part examines the legislative history of the Hatch-Waxman Act and the procedure required to introduce pharmaceutical drugs to

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<sup>8</sup> See *infra* notes 116–119 and accompanying text.

<sup>9</sup> See *infra* notes 12–68 and accompanying text.

<sup>10</sup> See *infra* notes 69–115 and accompanying text.

<sup>11</sup> See *infra* notes 116–136 and accompanying text.

<sup>12</sup> See 21 U.S.C. § 355 (providing opportunities for generic entry before the expiration of a brand's patent life). The Act balances the competing goals of encouraging innovation and stifling unproductive monopolies by encouraging generic manufacturers to challenge weak or invalid patents. *Smithkline*, 791 F.3d at 394 (recognizing that the Hatch-Waxman Act accomplishes this balancing act by enabling generics to challenge patents); *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 204, 217 (3d Cir. 2012) (explaining that the congressional purpose of the Hatch-Waxman Act is to increase competition by encouraging generic manufacturers to challenge weak patents), *vacated and remanded sub nom. Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013). By challenging such patents, generic manufacturers can introduce pharmaceutical alternatives and the public can enjoy lower drug prices sooner. *Smithkline*, 791 F.3d at 394; see Brief for Rep. Henry A. Waxman as Amicus Curiae Supporting Petitioner at 11, *Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416) (stating that the Act was enacted to respond to the increasing problem of high prescription drug prices by increasing competition in the industry between brand and generic drugs).

<sup>13</sup> See *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404–05 (2012) (explaining that the Hatch-Waxman Act facilitates an abbreviated process for generic manufacturers to enter the market).

<sup>14</sup> See Brianna Ford, Comment, *Using Reverse Payment Agreements as an Effective Way to Maintain a Patent Monopoly in the Pharmaceutical Industry*, 21 AM. U. J. GENDER, SOC. POL'Y & L. 919, 949 (2013) (noting the congressional intent to lower pharmaceutical drug prices by increasing competition). The introduction of generic drugs in 1994 saved consumers \$10 billion. *Id.* at n.244. In 2010, consumers paid an average copayment of \$34.77 and \$6.06 per prescription for brand name and generic drugs, respectively. Kang, *supra* note 3, at 77.

the market.<sup>15</sup> Section B of this Part details the factual and procedural history in the U.S. Court of Appeals for the Third Circuit decision in *Smithkline*.<sup>16</sup>

### A. *The Legislative Purpose of the Hatch-Waxman Act*

A patent is the exception to the rule against monopolies.<sup>17</sup> The Constitution's Patent Clause grants inventors the exclusive right to their innovations for a limited period of time in order to promote arts and sciences.<sup>18</sup> This exclusive period prevents early imitation of the patent, because the presence of multiple market players can greatly reduce a pioneer's profits, and consequently, could discourage novel innovations.<sup>19</sup> Nevertheless, federal patent laws recognize that competition, and not monopoly, is integral to the availability of low cost goods and services in the open market system.<sup>20</sup>

Accordingly, Congress enacted the Hatch-Waxman Act to create access to low cost generic drugs.<sup>21</sup> The Hatch-Waxman Act expedites the approval process in order to quickly and efficiently introduce generic drugs to the market.<sup>22</sup> The Act also encourages generic manufacturers to challenge weak or invalid

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<sup>15</sup> See *infra* notes 17–46 and accompanying text.

<sup>16</sup> See *infra* notes 47–68 and accompanying text.

<sup>17</sup> *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). The rule against monopolies promotes access to a free market. *Id.* In turn, a patent, which grants access to an exclusive market, is the exception to the prohibition of monopolies because a patent is a monopoly. *Id.*

<sup>18</sup> U.S. CONST. art. I, § 8, cl. 8 (promoting the progress of arts and sciences by providing inventors the exclusive right to their inventions).

<sup>19</sup> See *Smithkline*, 791 F.3d at 394 (noting that prompt imitation from competitors would hinder valuable pharmaceutical development).

<sup>20</sup> See 15 U.S.C. § 1 (prohibiting contracts in restraint of free trade and competition); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (stating that patent laws reflect the balance between promoting inventions, while also encouraging imitation in order to create a thriving economy). See generally Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 762–63 (2002) (noting the tension between patent law, which allows for anticompetitive exclusion, and antitrust law, which prohibits such exclusion). The Patent Clause balances the need to promote innovation and stifle monopolies by imposing limitations on the grant of a patent. See *Bonito Boats*, 489 U.S. at 146 (explaining the limitations on a patent's monopoly). For example, Congress may not approve patent monopolies of unlimited duration, or patents that result in restricting access to readily available materials or removing existing knowledge from the public domain. *Id.* This is because the public is best served when patents do not exceed the scope of their lawful monopolies. *Precision Instrument Mfg. Co.*, 324 U.S. at 816.

<sup>21</sup> *Smithkline*, 791 F.3d at 394 (stating that the purpose of the Act is to increase the number of available generic drugs); see Drug Price Competition and Patent Term Restoration Act of 1984; Brief for Rep. Henry A. Waxman as Amicus Curiae Supporting Petitioner, *supra* note 12 (noting that the Act was designed to solve the issue of high pharmaceutical drug prices).

<sup>22</sup> See *Actavis*, 133 S. Ct. at 2228 (commenting that the Act allows generics to forego expensive and time-consuming studies that are necessary for a pioneer drug to obtain marketing approval). The Hatch-Waxman Act reduces the time and costs associated with introducing a generic drug. Ford, *supra* note 14, at 922–23 (explaining that generic manufacturers who produce a “bioequivalent” of an approved brand-name drug may forego the clinical testing requirements of a new drugs).

brand-name patents.<sup>23</sup> The Act safeguards the competitive economy by incentivizing manufacturers to create and market inexpensive pharmaceutical alternatives.<sup>24</sup>

The Supreme Court identified four features of the Hatch-Waxman Act that effectuate the legislative purpose of providing available low cost prescription drugs.<sup>25</sup> First, the Food and Drug Administration (“FDA”) must approve a pioneer or “brand-name” prescription drug before it is made available to the public.<sup>26</sup> The approval process is very lengthy and costly.<sup>27</sup> Brand-name drug manufacturers submit a New Drug Application (“NDA”) that includes investigative reports and comprehensive information about the drug.<sup>28</sup> If the NDA demonstrates the drug is safe and effective for use, the FDA will grant the patentee marketing approval.<sup>29</sup>

Second, a generic drug manufacturer who wishes to market a generic version of an already approved brand-name drug may obtain marketing approval through an expedited process.<sup>30</sup> Instead of an NDA, generic drug manufacturers file an Abbreviated New Drug Application (“ANDA”), certifying the generic is the “bioequivalent” of the brand-name drug.<sup>31</sup> The abbreviated process

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<sup>23</sup> *Smithkline*, 791 F.3d at 394. The FDA provides an expedited process to generic manufacturers in order to increase the number of available generics on the market. Kelly, *supra* note 4, at 421. On average, the approval process for a New Drug Application (“NDA”) lasts fifteen years and costs \$1.5 billion. *Id.* at 422. For this reason, the FDA found it unnecessary and wasteful to require generics to undergo the full NDA process. *Id.* at 421.

<sup>24</sup> See Ralph B. Kalfayan & Vic A. Merjanian, *Ensuring Access to Affordable Medication: The Supreme Court’s Opinion in F.T.C. v. Actavis, Inc., COMPETITION*, Fall 2013, at 121, 125–26 (noting the statutory options for generic manufacturers to enter the market before the expiration of a brand’s patent). Pharmaceutical prices increased by thirty-three percent from 2006 to 2010, and competition is essential to reduce the cost of pharmaceutical drugs. *Id.* The Hatch-Waxman Act provides incentives to increase competition for generic manufacturers and provide accessible healthcare. *Id.* at 121.

<sup>25</sup> *Actavis*, 133 S. Ct. at 2227–29.

<sup>26</sup> See 21 U.S.C. § 355(a) (stating that manufacturers need FDA approval to introduce a new drug); *Actavis*, 133 S. Ct. at 2228 (noting the approval process necessary for introducing a drug); *Smithkline*, 791 F.3d 388 at 394–95 (recognizing approval is required before a pharmaceutical drug is permitted market entry).

<sup>27</sup> *Actavis*, 133 S. Ct. at 2228; see 21 U.S.C. § 355(b)(1) (outlining required submissions for application).

<sup>28</sup> 21 U.S.C. § 355(b)(1); *Actavis*, 133 S. Ct. at 2228. The NDA requires, among other things, reports of investigations into safety and efficacy, a list of the drugs components, statement of composition, description of the facilities used in manufacturing, drug samples, and a proposed labeling sample. 21 U.S.C. § 355(b)(1); *Actavis*, 133 S. Ct. at 2228.

<sup>29</sup> 21 U.S.C. § 355(a) (restricting marketable drugs to those with approved applications and proven efficacy); *Actavis*, 133 S. Ct. at 2228.

<sup>30</sup> *Actavis*, 133 S. Ct. at 2228. Prior to the enactment of the Hatch-Waxman Act, generic manufacturers were required to spend millions of dollars completing separate NDAs. Ford, *supra* note 14, at 923 (stating that generic manufacturers had to undergo the costly NDA approval process before the Act was enacted).

<sup>31</sup> 21 U.S.C. § 355(j)(2)(A)(iv). A generic is the bioequivalent of a listed drug if there is no significant difference between the rate and extent of absorption under the same dose, conditions, and ingredients. *Id.* § 355(j)(8)(B).

promotes drug competition by allowing the generic to take advantage of the pioneer's approval efforts.<sup>32</sup>

Third, the Hatch-Waxman Act sets forth several methods for preventing and resolving patent disputes between brand and generic filers.<sup>33</sup> Generic filers are required to provide the FDA assurance that the generic drug will not infringe on a brand's patents by certifying that: (I) the brand-name manufacturer did not file a patent, (II) the brand's patent has expired, (III) the brand's patent will expire, or (IV) the patent is invalid and/or the generic will not infringe upon the patent.<sup>34</sup>

A paragraph IV certification, however, is a per se act of infringement and generally provokes patent litigation.<sup>35</sup> If the brand-name patentee sues the generic for infringement within forty-five days of the paragraph IV filing, the FDA must withhold approval of the generic for a thirty-month stay for litigation.<sup>36</sup> If the court makes a ruling within the thirty-month period, the FDA adheres to the determination regarding the patent's validity.<sup>37</sup> If the matter is not decided within thirty months, the FDA may grant the generic marketing approval.<sup>38</sup>

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<sup>32</sup> *Smithkline*, 791 F.3d at 395. The Hatch-Waxman Act speeds up the generic approval process by allowing bioequivalent generics to forego repeating clinical studies. David C. Kurlander, Note, *Rebalancing Pay-for-delay: Why No-authorized Generic Agreements Should Be Subject to Higher Antitrust Scrutiny*, 32 CARDOZO ARTS & ENT. L.J. 683, 688 (2014) (noting that the Hatch-Waxman Act enables generics to forego repeating the NDA clinical trials in order to increase the number of competitors and decrease pharmaceutical prices). ANDAs reduce the cost associated with introducing a generic drug from \$200 million to \$1 million. See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1564–65, 1564 n.36 (2006) (commenting that the cost of an ANDA is much less expensive than NDA clinical trials).

<sup>33</sup> See 21 U.S.C. § 355(b)(1) (requiring brand applicants to list the number and expiration date of relevant patents); *Actavis*, 133 S. Ct. at 2228 (noting that the Hatch-Waxman Act prevents patent disputes by requiring generic filers “to assure the FDA that the generic will not infringe the brand-name’s [listed] patents”) (citation omitted). Generic manufacturers verify whether their drug will infringe the brand’s patents by reference to the brand’s NDA, which provides information on all patents related to the pioneer drug. *Actavis*, 133 S. Ct. at 2228.

<sup>34</sup> 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV). A filer that elects the “paragraph IV” certification must provide a factual and legal basis stating why the patent is invalid or will not be infringed. *Id.* § 355(j)(2)(B)(iv)(II). In other words, so long as the brand name’s patent is valid and relevant, the generic will not be approved for market. *Id.*

<sup>35</sup> *Actavis*, 133 S. Ct. at 2228; see 21 U.S.C. § 355(j)(2)(B); *Smithkline*, 791 F.3d at 395 (explaining that “the patent statute treats paragraph IV certification as a per se act of infringement”). A filer is required to notify the patent holders that its paragraph IV certification claims the patents are invalid or will not be infringed upon. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (providing that the brand’s patent is invalid or will not be infringed).

<sup>36</sup> 21 U.S.C. § 355(j)(5)(B)(iii) (providing a forty-five-day window for the brand name to act in order to halt the generic approval process in a paragraph IV certification); *Actavis*, 133 S. Ct. at 2228; *Smithkline*, 791 F.3d at 395.

<sup>37</sup> 21 U.S.C. § 355(j)(5)(B)(iii); *Actavis*, 133 S. Ct. at 2228; *Smithkline*, 791 F.3d at 395–96.

<sup>38</sup> 21 U.S.C. § 355(j)(5)(B)(iii); *Actavis*, 133 S. Ct. at 2228; *Smithkline*, 791 F.3d at 395–96. A filer that markets its generic after the thirty-month stay, but before a court judgment, may be liable for infringement. Kurlander, *supra* note 32, at 689 n.43. If the brand patentee is successful in defending

Fourth, the Act encourages generic manufacturers to file ANDAs with paragraph IV certifications to challenge weak patents.<sup>39</sup> The first generic filer is granted 180 days of exclusive rights to the generic prescription drug market.<sup>40</sup> This exclusionary period is incredibly valuable, because generic manufacturers derive the majority of their profits during this time as the only market player.<sup>41</sup>

Nonetheless, the exclusivity period does not prohibit the pioneer patentee from introducing an “authorized generic.”<sup>42</sup> An authorized generic is a generic drug produced by the pioneer brand-name drug manufacturer.<sup>43</sup> Because the FDA has already approved the brand name, the pioneer drug manufacturer is granted entry to the generic market in order to recoup lost profits as a result of other generic’s entry.<sup>44</sup> The pioneer patentee, however, could choose to forego this right by entering into a “no-authorized generic” agreement with the first generic to file an ANDA.<sup>45</sup> If the brand name and generic enter a no-AG agreement, the first-filing generic would remain the only generic for the 180-day exclusivity period.<sup>46</sup>

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his or her patent claim, and the court finds that the generic has infringed the patent, the generic manufacturer may not market the generic. *Id.* at 689. If, however, the patentee is not successful in defending his or her patent claim or the court otherwise finds that the patent has not been infringed, the generic manufacturer may bring the generic to market under the ANDA rules. *Id.* (noting that the thirty-month stay is lifted at the earlier of the court rendering a verdict regarding the validity of the patent or the expiration of thirty months).

<sup>39</sup> *Actavis*, 133 S. Ct. at 2228–29; *In re K-Dur Antitrust Litig.*, 686 F.3d at 217; see 21 U.S.C. § 355(j)(5)(B)(iv) (granting the first-filing generic a 180-day period of exclusivity).

<sup>40</sup> *Actavis*, 133 S. Ct. at 2229 (noting that no other generic manufacturers can compete during the period of exclusivity). The first-filing generic manufacturer is the only generic eligible to receive the exclusivity period, even if the first filer withdraws, settles, or loses the infringement lawsuit and never introduces its generic drug. Kurlander, *supra* note 32, at 689.

<sup>41</sup> See *Actavis*, 133 S. Ct. at 2229 (stating that the majority of the first-filing generic’s profits are derived during the 180-day period of exclusivity). The entry of another generic manufacturer forces the first-filing generic to reduce its prices by fifty percent. Ford, *supra* note 14, at 949 n.243.

<sup>42</sup> *Smithkline*, 791 F.3d at 396 (commenting that the period of exclusivity only excludes other generic manufacturers and does not exclude the brand patentee from introducing his or her own generic). There is a duopoly between the brand and the first-filing generic during the exclusivity period. Kurlander, *supra* note 32, at 689.

<sup>43</sup> *In re Nexium (Esomeprazole) Antitrust Litig. (Esomeprazole I)*, 968 F. Supp. 2d 367, 379 (D. Mass. 2013) (explaining that an authorized generic is the equivalent of the brand-name drug marketed under a generic label).

<sup>44</sup> See *id.* (noting that the authorized generic need not satisfy FDA approval because the FDA already approved the brand-name drug and the generic is its equivalent).

<sup>45</sup> *Id.* A no-AG agreement enables the first-filing generic to enjoy the 180-day exclusivity period sans competition from the patentee’s authorized generic. *Id.* Brand-name manufacturers agree not to introduce an authorized generic and generics agree to drop their claim. Kurlander, *supra* note 32, at 693.

<sup>46</sup> Kurlander, *supra* note 32, at 695–96. In exchange, the brand retains its patent for its natural life, protecting the brand’s monopoly until the summation of the patent’s term and the first-filing generic’s 180 days. *Id.*

*B. District Court Approves Settlement Agreement in Which Pioneer Manufacturer Agrees Not to Introduce an Authorized Generic*

In *Smithkline*, plaintiffs, direct purchasers of the brand-name drug Lamictal, a drug used to treat epilepsy and bipolar disorder, commenced a putative class action lawsuit against defendant Smithkline Beecham Corp. (“GSK”).<sup>47</sup> Plaintiffs alleged that the settlement agreement between GSK, Lamictal’s producer, and Teva Pharmaceutical Industries Ltd. (“Teva”), a Lamictal generic manufacturer, violated Sections 1 and 2 of the Sherman Act.<sup>48</sup>

GSK pioneered Lamictal and sells the brand-name drug in chewable and non-chewable tablet form.<sup>49</sup> In order to obtain marketing approval, GSK obtained patent No. 4,602,017 (“’017 patent”) on lamotrigine, the active ingredient in Lamictal.<sup>50</sup> The ‘017 patent expired on July 22, 2008.<sup>51</sup>

In April 2002, Teva filed an ANDA to market generic lamotrigine chewables and non-chewable tablets.<sup>52</sup> As assurance to the FDA, Teva certified in paragraph IV that the generic would not infringe upon GSK’s ‘017 patent and/or that the ‘017 patent was unenforceable.<sup>53</sup> In response, GSK sued Teva for patent infringement, thereby delaying the FDA’s generic approval process for the anticipated thirty-month litigation period.<sup>54</sup> A jury-waived trial commenced in federal court in January 2005.<sup>55</sup> District Judge Bissell ruled that GSK’s main patent claim for the invention of lamotrigine was invalid.<sup>56</sup> The parties settled, howev-

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<sup>47</sup> *Smithkline*, 791 F.3d at 393, 396–98. King Drug Co. of Florence Inc. and Louisiana Wholesale Drug Co. Inc. led the putative class. *Id.* at 396. Defendant is referred to as GSK because SmithKline Beecham Corp. does business as GlaxoSmithKline following the merger between GlaxoWellcome and SmithKline Beecham in 2001. *Id.* at 393; *Our History*, GSK, <http://www.gsk.com/en-gb/about-us/our-history/> [<https://perma.cc/ZYP3-CBKE>].

<sup>48</sup> 15 U.S.C. §§ 1–2 (prohibiting unreasonable restraints on trade); *Smithkline*, 791 F.3d at 393, 405 (noting that antitrust law is intended to protect consumers from anticompetitive market arrangements).

<sup>49</sup> *Smithkline*, 791 F.3d at 396–97. Although GSK sells both chewable and non-chewable tablets, the majority of Lamictal prescriptions are for non-chewable tablets. *Id.* Indeed, between March 2007 and 2008, tablet sales measured in excess of \$2 billion whereas chewable sales in 2005 were around \$50 million. *Id.*

<sup>50</sup> *Smithkline*, 791 F.3d at 396; see 21 U.S.C. § 355(a), (b) (requiring the NDA application to include the patent number, among other things, before the brand drug can be approved for sale).

<sup>51</sup> *Smithkline*, 791 F.3d at 396.

<sup>52</sup> *Id.* at 397. Teva was the first generic to file an ANDA. *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> *Id.* As part of the ANDA process, generic manufacturers are required to notify brand-name patent holders of their paragraph IV certification. See 21 U.S.C. § 355(j)(2)(B) (stating that the ANDA application requires the generic manufacturer to submit notice to the brand-name manufacturer).

<sup>55</sup> See *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 561 (D. N.J. 2014) (laying out the facts of the patent dispute underlying the antitrust claim), *vacated*, *Smithkline*, 791 F.3d at 397 (noting that the parties settled the patent dispute before the conclusion of the trial).

<sup>56</sup> *Smithkline*, 791 F.3d at 397.

er, in February 2005 before Judge Bissell could enter judgment on the validity of the patent.<sup>57</sup>

In the February 2005 settlement, GSK agreed to allow Teva to market generic lamotrigine chewable and non-chewable tablets.<sup>58</sup> According to the agreement, Teva was permitted to sell generic chewables no later than June 1, 2005, thirty-seven months before the '017 patent's expiration date on July 22, 2008.<sup>59</sup> GSK also permitted Teva to market generic tablets on July 21, 2008 or March 1, 2008.<sup>60</sup> As part of the "no-AG agreement," GSK also agreed to withhold marketing its authorized generic until January 2009, after Teva's 180-day exclusivity period ended.<sup>61</sup> The settlement agreement ensured that Teva could take advantage of its entire statutory exclusivity period without any generic competition.<sup>62</sup>

In exchange, Teva dropped the lawsuit challenging the validity of the '017 patent.<sup>63</sup> Plaintiffs allege that Teva agreed to delay introducing their own generic lamotrigine tablet in exchange for the no-AG agreement.<sup>64</sup> Otherwise, plaintiffs allege, Teva would have proceeded to market a lamotrigine generic tablet "at risk" in the unlikely event the district judge found the remaining patent claims valid.<sup>65</sup> Teva confirmed the allegations by noting that GSK's no-AG agreement was an integral part of the settlement and induced Teva to abandon its patent

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<sup>57</sup> See *id.* (stating that the parties settled the patent dispute before District Judge Bissell issued a ruling on the remaining patent claims). Plaintiffs alleged Teva would be successful with the remaining patent claims given District Judge Bissell's finding that the first patent claim was invalid. See *id.* (noting that the remaining patents were extremely weak given District Judge Bissell's ruling that the main patent was invalid).

<sup>58</sup> *Id.*

<sup>59</sup> *Id.* GSK agreed to supply Teva with lamotrigine chewables because the FDA had not yet approved Teva's ANDAs. *Id.* at 397 n.12.

<sup>60</sup> 21 U.S.C. § 355(a)(c)(2)(B); *Smithkline*, 791 F.3d at 397. GSK agreed to permit Teva to market generic tablets on July 21, 2008, if the FDA granted GSK a "pediatric exclusivity" extension, which stays the FDA generic approval process for six months so long as the brand-name patentee submits studies relating to the pediatric population. *Smithkline*, 791 F.3d at 397 & 397 n.13. If GSK did not receive a pediatric exclusivity extension, GSK agreed to allow Teva to introduce generic tablets five months prior on March 21, 2008. *Id.*

<sup>61</sup> *Smithkline*, 791 F.3d at 397.

<sup>62</sup> See *id.* (noting that the 180-day period would have begun upon a final court judgment, regardless of whether Teva was ready to market its generic at that time). The period of exclusivity was particularly advantageous to Teva, because the 180 days would have commenced as soon as the court issued a final judgment, even though the FDA could not approve Teva's ANDAs until after the thirty-month stay. *Id.* The FDA could not approve Teva's ANDAs for thirty months because GSK commenced litigation within forty-five days of Teva's paragraph IV certification. *Id.* at 395, 397.

<sup>63</sup> *Id.* at 397

<sup>64</sup> *Id.*

<sup>65</sup> *Smithkline*, 791 F.3d at 397; see 21 U.S.C. § 355(j)(5)(B)(iii). A pharmaceutical manufacturer launches a generic drug "at risk" if the manufacturer markets the generic with FDA approval after the thirty-month stay, but before the patent litigation is completed. *In re Nexium (Esomeprazole) Anti-trust Litig. (Esomeprazole II)*, 309 F.R.D. 107, 113 (D. Mass. 2015). Teva received FDA approval in August 2006. *Smithkline*, 791 F.3d at 397.

litigation.<sup>66</sup> The district judge approved the settlement and the case was dismissed on April 4, 2005.<sup>67</sup> As a result of the settlement, GSK maintained its patent-protected monopoly, based on a putatively invalid patent claim, for three years.<sup>68</sup>

## II. THE ROLE OF ANTITRUST PRINCIPLES IN PATENT SETTLEMENT AGREEMENTS

In 2015, in *King Drug Co. of Florence v. Smithkline Beecham Corp.*, the United States Court of Appeals for the Third Circuit vacated the United States District Court for the District of New Jersey's dismissal of the action.<sup>69</sup> The Third Circuit held that no-AG agreements are subject to antitrust scrutiny because of their monopolistic consequences.<sup>70</sup> The court relied on *Federal Trade Commission v. Actavis*, a 2013 decision in which the United States Supreme Court held that patent settlements involving cash payments to alleged infringers are subject to antitrust scrutiny.<sup>71</sup> Section A of this Part discusses the U.S. Supreme Court decision in *Actavis*.<sup>72</sup> Section B of this Part discusses the extension of the *Actavis* reasoning to non-cash settlements in *Smithkline*.<sup>73</sup>

### A. Reverse Payment Settlement Agreements Are Subject to Antitrust Scrutiny Under the Rule of Reason

Antitrust and intellectual property law are often in conflict, given their competing goals of prohibiting and protecting monopolies.<sup>74</sup> Antitrust laws pro-

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<sup>66</sup> *Smithkline*, 791 F.3d at 397.

<sup>67</sup> *Id.* at 398.

<sup>68</sup> *Id.* at 397.

<sup>69</sup> *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 399, 404, 413 (3d Cir. 2015).

<sup>70</sup> *Id.* at 405 (explaining the anticompetitive consequences of no-AG settlement agreements).

<sup>71</sup> 133 S. Ct. 2223, 2237 (2013); *Smithkline*, 791 F.3d at 394. In *Actavis*, a generic manufacturer initiated paragraph IV litigation to market a generic version of the brand drug. *Id.* at 2229. The parties settled in 2006, the generic manufacturers agreed to delay entering the generic market until 2015, and the brand-name manufacturer paid the three generic manufacturers \$12 million, \$60 million, and \$19–30 million annually, respectively. *Id.*

<sup>72</sup> See *infra* notes 74–102 and accompanying text.

<sup>73</sup> See *infra* notes 103–115 and accompanying text.

<sup>74</sup> See Christina Bohannon & Herbert Hovenkamp, *IP and Antitrust: Reformation and Harm*, 51 B.C. L. REV. 905, 919–20 (2010) (articulating the conflict that arises due to the differing statutory goals to prohibit and promote monopolies); Hemphill, *supra* note 32, at 1556–57 (noting that drug manufacturer settlements typically present antitrust violations); Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813, 1817 (1984) (“A practice is typically deemed to violate the antitrust laws because it is anticompetitive. But the very purpose of a patent grant is to reward the patentee by limiting competition . . .”).

scribe various anticompetitive arrangements in the marketplace.<sup>75</sup> Sections one and two of the Sherman Act prohibit unreasonable restraints on trade and the monopolization of trade or commerce.<sup>76</sup> The sections work in conjunction to condemn concentrated market power and wealth.<sup>77</sup> Conversely, patent law expressly endorses monopolizing the market.<sup>78</sup> Patent holders are provided the exclusive right to their inventions and corresponding profits in order to encourage innovation.<sup>79</sup> Deciphering the appropriate intersection between antitrust and patent law is a question many courts and scholars grappled with until the United States Supreme Court decision in *Actavis*.<sup>80</sup>

The Court in *Actavis* held that “reverse payment” settlement agreements are subject to antitrust scrutiny.<sup>81</sup> Reverse payment settlements typically occur when a brand-name manufacturer files a lawsuit against a generic manufacturer for patent infringement.<sup>82</sup> Instead of litigating the validity of the brand’s patent, the parties settle.<sup>83</sup> Under the terms of the settlement agreement, the patentee pays the alleged infringer to abstain from introducing a generic until the

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<sup>75</sup> See Sherman Act, 15 U.S.C. §§ 1–2 (2012) (prohibiting unreasonable restraints on trade and monopolies in the marketplace); *Smithkline*, 791 F.3d at 404 (stating that antitrust law promotes competition and protects consumers from anti-competitive monopolies).

<sup>76</sup> See 15 U.S.C. § 1 (“Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.”); *id.* § 2 (“Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony . . .”).

<sup>77</sup> See Maurice E. Stucke, *Reconsidering Antitrust’s Goals*, 53 B.C. L. REV. 551, 560 (2012) (stating that the Sherman Act was a response to concentrated wealth). The Sherman Act has many purposes: to prevent the concentration of markets, to protect freedom of trade, to promote consumer welfare, and to prohibit anticompetitive practices. *Id.* at 560–61. Due to the overall policy of promoting freedom of trade, the Sherman Act is often regarded as “the Magna Carta of free enterprise.” Hemphill, *supra* note 32, at 1555 (quoting *United States v. Topco Assoc., Inc.*, 405 U.S. 596, 610 (1972)).

<sup>78</sup> U.S. CONST. art. I, § 8, cl. 8 (granting inventors the exclusive right to their inventions).

<sup>79</sup> See Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 87 (2010) (noting that patent owners are afforded exclusive rights to their inventions in order to encourage innovation); Hemphill, *supra* note 32, at 1562 (“[A] patent is considered necessary to recoup an initial investment.”).

<sup>80</sup> See Tejas N. Narechania, *Patent Conflicts*, 103 GEO. L. J. 1483, 1489 (2015) (acknowledging that the intersection of antitrust and intellectual property law is a common source of conflict). Prior to *Actavis*, some scholars suggested a patent was an absolute right to exclude, whereas others argued patent rights must remain within the confines of antitrust law. *Id.*

<sup>81</sup> *Actavis*, 133 S. Ct. at 2227; see 15 U.S.C. § 1 (prohibiting contracts in restraint of trade or commerce). The Sherman Act protects consumers from unfair trade practices that impede competition. *Smithkline*, 791 F.3d at 405.

<sup>82</sup> *Actavis*, 133 S. Ct. at 2227; *Supreme Court 2012 Term: Leading Cases: Hatch-Waxman Act—Reverse-Payment Settlements—FTC v. Actavis, Inc.*, 127 HARV. L. REV. 358, 358 (2013) (noting that reverse payment settlements compensate generic drug manufacturers for staying out of the market).

<sup>83</sup> *Actavis*, 133 S. Ct. at 2227.

patent expires.<sup>84</sup> Thus, the agreement is referred to as a reverse payment settlement agreement because the patentee, who initiated the lawsuit to defend the validity of its patent, pays the alleged patent infringer.<sup>85</sup>

Prior to the landmark decision in *Actavis*, lower courts generally applied the “scope of the patent” test and found that Hatch-Waxman related settlements were immune from antitrust scrutiny.<sup>86</sup> The scope of the patent test assumes that, because a patent holder is entitled to a monopoly within the scope of its patent, liability under the Sherman Act for monopolistic behavior is in-

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<sup>84</sup> See *id.* (stating that the brand pays the generic “millions of dollars”). The Federal Trade Commission (“FTC”) has determined that reverse settlement amounts range from \$1.75 million to \$132.5 million. Marlee P. Kutcher, Comment, *Waiting Is the Hardest Part: Why the Supreme Court Should Adopt the Third Circuit’s Analysis of Pay-for-Delay Settlement Agreements*, 44 LOY. U. CHI. L.J. 1093, 1102–03 n.54 (2013) (stating that nine out of twenty settlements involved payments from the brand to the generic). For example, Bayer paid a generic paragraph IV filer a total of \$398.1 million, including an initial \$49.1 million payout to drop its litigation. Gregory Dolin, *Reverse Settlements as Patent Invalidation Signals*, 24 HARV. J. L. & TECH. 281, 299 (2011).

<sup>85</sup> *Actavis*, 133 S. Ct. at 2227. Reverse payment agreements are also referred to as pay-for-delay settlement agreements, because the brand-name manufacturer compensates the generic drug manufacturer to delay market entry. Peter Picht, *New Law on Reverse Payment Settlements—The Agenda for Courts and the Legislature After the Supreme Court’s Actavis Ruling*, 16 TUL. J. TECH. & INTELL. PROP. 105, 107 (2013). In general, a brand manufacturer agrees to pay the generic manufacturer in order to protect the length of its patent, and consequently, the brand’s expected profits in a monopoly setting. Kendyl Hanks et al., “Pay-for-Delay” Settlements: Antitrust Violation or Proper Exercise of Pharmaceutical Patent Rights? AM. B. (Jan. 2011), [http://www.americanbar.org/publications/blt/2011/01/02\\_hanks.html](http://www.americanbar.org/publications/blt/2011/01/02_hanks.html) [<https://perma.cc/BZB5-JPQS>]. Although costly, these arrangements provide the brand-name manufacturer higher expected profits, because the presence of a generic provides consumers a lower cost option, and therefore, forces the brand to reduce its inflated costs. See *id.* (commenting that reverse payments extend the brand’s patent term and expected profits without generic competition).

<sup>86</sup> *Actavis*, 133 S. Ct. at 2230–31; see *Fed. Trade Comm’n v. Watson Pharm., Inc.*, 677 F.3d 1298, 1307–09 (11th Cir. 2012) (acknowledging that paying a potential competitor to refrain from entering the market violates antitrust principles, but holding that the agreement was lawful within the scope of the patent because a patent grants the right to exclude others from the marketplace), *rev’d*, *Actavis*, 133 S. Ct. 2223; *Andrx Pharm., Inc. v. Elan Corp., PLC*, 421 F.3d 1227, 1233–34 (11th Cir. 2005) (noting that a settlement agreement is immune from antitrust attack unless there is proof of sham litigation or fraudulence). The scope of the patent test originated in the Sixth Circuit’s 2003 decision in *In re Cardizem CD Antitrust Litigation*, where the court rejected a settlement arrangement to pay the brand’s only competitor \$40 million per year not to enter the generic market, because the agreement restricted market entry of the generic and other drugs unrelated to the generic’s ANDA. 332 F.3d 896, 905–08 (6th Cir. 2003) (discussing various scenarios that would be per se illegal as restrictions on market entry beyond the scope of the patent); Michael A. Carrier, *Why the “Scope of the Patent” Test Cannot Solve the Drug Patent Settlement Problem*, 16 STAN. TECH. L. REV. 1, 2 (2012). The court characterized the arrangement as per se illegal because the restrictions on trade were plainly outside the scope of the patent. *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 900. The scope of the patent test evolved in 2006 in *In re Tamoxifen Citrate Antitrust Litigation*, where the Second Circuit appeared to immunize behavior within the scope of the patent, as opposed to proscribing behavior outside the scope of the patent. Carrier, *supra*, at 3; see *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212–13 (2d Cir. 2006) (noting that exclusionary behavior within the scope of a patent is not unlawful), *abrogated by Actavis*, 133 S. Ct. 2223.

appropriate.<sup>87</sup> The scope of the patent analysis considered the exclusionary potential of the patent, the extent to which the terms of the settlement exceed the scope, and any resulting anticompetitive consequences.<sup>88</sup> Thus, a reverse payment settlement did not result in antitrust liability if the anticompetitive consequences fell within the rights and privileges conferred by patent.<sup>89</sup>

In *Actavis*, the U.S. Supreme Court rejected this view and held that reverse payment agreements can violate antitrust principles, notwithstanding the agreement is in accord with the patent's scope.<sup>90</sup> Justice Breyer, writing for the Court, adopted the "rule-of-reason" test that considers both patent and antitrust factors to determine whether the settlement imposes an unreasonable restraint on trade.<sup>91</sup> The analysis balances the exclusionary privileges afforded to the patentee with the prohibition of monopolies under the Sherman Act.<sup>92</sup> If the anticompetitive effects outweigh the benefits conferred by the patent, the settlement is subject to antitrust liability.<sup>93</sup>

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<sup>87</sup> See *Carrier*, *supra* note 86, at 1–2 (stating that the analysis for the scope of the patent test considers whether a settlement arrangement is within the scope of the patent, and if it is, the arrangement does not violate antitrust laws).

<sup>88</sup> See *Smithkline*, 791 F.3d at 399, 401 (noting that a patent's scope is ascertained by reference to patent law).

<sup>89</sup> See *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1310–11 (11th Cir. 2003) (recognizing that patents are the exception to the rule against monopolies, but limiting the exception to the terms of the patent grant and statutory rights).

<sup>90</sup> See *Actavis*, 133 S. Ct. at 2227, 2237, 2239 (acknowledging that reverse payment settlements are not per se unlawful, but lawfulness should be assessed by considering all of the circumstances under the rule of reason test). The scope of the patent test has also been subject to criticism due to the fact that it presumes validity. See *Carrier*, *supra* note 86, at 6 (condemning the test's simplistic nature in assuming validity). For instance, if a patent is invalid, as is often the case in these settlement arrangements, it should not be entitled to the scope of the patent test, because the patent itself is invalid and thus does not have any scope. See *id.* (commenting that courts ignore the likely possibility that the patent is invalid, and therefore, inappropriately apply a scope analysis to an invalid patent).

<sup>91</sup> *Actavis*, 133 S. Ct. at 2237; *Smithkline*, 791 F.3d at 401. The Court explicitly rejected the FTC's proposition of a per se test where the settlement is presumed unlawful, and the settling parties must offer evidence to the contrary to show precompetitive effects. *Actavis*, 133 S. Ct. at 2237. In rejecting this approach and adopting the rule of reason test, however, the Court left open the question of how to apply the rule of reason standard for lower courts. See *id.* at 2238 (instructing lower courts to decide how to construct the rule of reason analysis). In response, Joshua D. Wright, the Commissioner of the FTC, noted that the *Actavis* holding is not a complete victory for the FTC and remarked on the difficult task ahead for lower courts in applying the rule of reason test without an exhaustive list of factors to consider. Joshua D. Wright, Commissioner, FTC, Intellectual Property Rights, Truncation, and *Actavis*: Who's Afraid of the Rule of Reason?, Remarks at the Competition Review Live 2d Annual IP & Antitrust USA (Apr. 14, 2015).

<sup>92</sup> *Actavis*, 133 S. Ct. at 2231. The rule of reason inquiry balances the economic benefits resulting from the agreement and the detrimental anticompetitive consequences. *In re Nexium (Esomeprazole) Antitrust Litig. (Esomeprazole I)*, 968 F. Supp. 2d 367, 387 (D. Mass. 2013).

<sup>93</sup> *Smithkline*, 791 F.3d at 401.

The Court articulated several considerations in favor of adopting the rule-of-reason test over the scope of the patent test.<sup>94</sup> First, reverse payment settlements can adversely effect competition.<sup>95</sup> The generic manufacturer is compensated to forgo its Hatch-Waxman right to enter the market prior to the patent expiration date.<sup>96</sup> As such, the brand manufacturer remains the only market player and consumers do not have a choice but to pay the patentee's supracompetitive prices.<sup>97</sup> Second, the settlement's anticompetitive consequences may be unjustified.<sup>98</sup> A payment is unjustified if it proportionally exceeds the benefits of settlement, because this suggests the patent holder is compensating the alleged infringer to stay out of the market.<sup>99</sup> Third, the size of the payment is a strong indicator that the patentee possesses the market power to deter the generic from entering the market.<sup>100</sup> Fourth, a large payment may imply the patentee lacks confidence in the patent's validity and is over-compensating to

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<sup>94</sup> *Actavis*, 133 S. Ct. at 2234; *Smithkline*, 791 F.3d at 402. The brand and generic maximize their profits by delaying entry because monopoly profits are greater than duopoly profits. Edlin et al., *supra* note 2, at 590–91.

<sup>95</sup> *Actavis*, 133 S. Ct. at 2234; *Smithkline*, 791 F.3d at 402. The payment to delay market entry is anticompetitive because it preserves a monopoly. Edlin et al., *supra* note 2, at 590–91. The Court noted that the purpose of the Hatch-Waxman Act is to increase competition, not deny it. *Actavis*, 133 S. Ct. at 2234. Accordingly, the Act was enacted to deter pharmaceutical companies from engaging in collusive agreements that delay the introduction of lower cost generic drugs. *Id.*

<sup>96</sup> *Actavis*, 133 S. Ct. at 2234. Earlier entry by the generic manufacturer benefits consumers because it creates competition. Lars P. Taavola, *Jumping into the Actavis Briar Patch—Insight into How Courts May Structure Reverse Payment Antitrust Proceedings and the Questions That Actavis Left Unanswered*, 40 WM. MITCHELL L. REV. 1370, 1381–82 (2014) (recognizing the anticompetitive effects when a generic agrees not to enter the market).

<sup>97</sup> *Actavis*, 133 S. Ct. at 2234–35. According to the FTC, “reverse payment settlements cost consumers about \$3.5 billion per year” as a result of higher drug prices. *Watson*, 677 F.3d at 1302. A pay-for-delay agreement eliminates the possibility of competition during the patent's lifetime. Edlin et al., *supra* note 2, 589–91 (explaining that a generic agrees not to enter the market for a set period of time in a reverse payment settlement).

<sup>98</sup> See *Actavis*, 133 S. Ct. at 2235–36 (explaining that a settlement's anticompetitive consequences are unjustified if the purpose of the settlement is to exclude competition).

<sup>99</sup> *Id.* at 2236. In *Actavis*, the parties would have saved an estimate \$2.75 million in litigation expenses by settling versus the \$20–30 million per year that Actavis received from the settlement. Taavola, *supra* note 96, at 1383. Such an arrangement raises antitrust concerns because the settlement provides a private benefit at the consumers' expense. See Hemphill, *supra* note 32, at 1572 (discussing the FTC's concern that pay-for-delay settlement arrangements violate antitrust principles because the agreement privately benefits the parties involved and imposes significant costs to consumers in the form of high pharmaceutical prices). A brand name, when faced with possible generic competition, could choose to lower prices or improve design. *Id.* at 1568. Instead, in a pay-for-delay settlement, the brand limits generic entry and, correspondingly, any possible benefit to consumers. See *id.* at 1572 (noting that these characteristics of a pay-for-delay settlement constitute a quintessential example of a Sherman Act violation).

<sup>100</sup> *Actavis*, 133 S. Ct. at 2236. Market power can be inferred if the payment exceeds the anticipated cost of litigation. Edlin et al., *supra* note 2, at 590. The Court also inferred market power by relying on FTC studies that found that reverse payment agreements correspond with “higher-than-competitive profits.” Taavola, *supra* note 96, at 1384.

prevent the risk of invalidation.<sup>101</sup> These considerations promote competition and, the Court reasoned, outweigh the single consideration of promoting settlement.<sup>102</sup>

*B. The Third Circuit's Decision to Apply Antitrust Scrutiny to No-Authorized Generic Agreements in Accordance with the Supreme Court Decision*

In 2015, in *Smithkline*, the U.S. Court of Appeals for the Third Circuit ruled that no-AG agreements are also subject to antitrust scrutiny under the rule of reason.<sup>103</sup> Judge Scirica, writing for the court, extended *Actavis*'s holding to include no-AG agreements, despite the fact that no-AG agreements do not include cash payments.<sup>104</sup> Nevertheless, the *Smithkline* court analogized no-AG agreements to reverse-payment settlements because both represent an unjustifiably large transfer of value from the patentee to the alleged patent infringer.<sup>105</sup>

For instance, the no-AG agreement in *Smithkline* provided Teva the exclusive right to the 180-day period without competition from both the brand manufacturer and other generic manufacturers.<sup>106</sup> Thus, the no-AG agreement affords the first generic the brand's unrealized generic profits and opportunity to set supracompetitive prices as the only generic market player.<sup>107</sup> Indeed, the exclusivity period is the primary source of the first filer's profits, which can amount to several hundred million dollars.<sup>108</sup> Therefore, the no-AG agreement represents a large transfer of value, albeit non-monetary.<sup>109</sup>

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<sup>101</sup> See *Actavis*, 133 S. Ct. at 2236–37 (explaining that a patentee who doubts the patent's survival may compensate the generic to avoid the risk that litigation will invalidate the patent, thus allowing the brand and generic to enjoy supracompetitive prices rather than face a competitive market).

<sup>102</sup> *Id.* at 2237. The rule of reason test results in more litigation and less settlement than the scope of the patent test. Ford, *supra* note 14, at 928–29. The latter benefits the patent holder because it involves only patent, and not antitrust, principles. *Id.* at 928.

<sup>103</sup> *Smithkline*, 791 F.3d at 403.

<sup>104</sup> *Id.* Unlike the cash payments made by the brand manufacturer in *Actavis*, no-AG agreements are characterized as non-cash settlements, because the value exchanged in the settlement is intangible and not a cash payment. Edlin et al., *supra* note 2, at 592–93 (commenting that though the “cash payment” in *Actavis* dealt with the exchange of money, there are other forms of payment, such as a stock transfer). Chief Justice Roberts, dissenting in *Actavis*, opined regretfully that the Court's rule of reason test could subject non-cash as well as cash settlements to antitrust. See *Actavis*, 133 S. Ct. at 2245 (Roberts, C.J., dissenting).

<sup>105</sup> *Smithkline*, 791 F.3d at 403–04 (stating that no-AG agreements, although non-cash, present similar problems as reverse-payment cash settlements).

<sup>106</sup> *Id.* at 404.

<sup>107</sup> *Id.* at 405.

<sup>108</sup> *Id.* The *Smithkline* court noted that the presence of another market player would adversely impact Teva's sales and require Teva to reduce the price of its generic. *Id.* at 404 n.21. On average, a first-filing generic enters the market at a twenty percent discount, but after the period of exclusivity ends, the generic is priced at an eighty to eighty-five percent discount from the brand's price. Robin

In addition, the *Smithkline* court reasoned that no-AG agreements result in monopolistic consequences.<sup>110</sup> Similar to reverse payments, a brand manufacturer can leverage the value of a no-AG agreement to induce the generic manufacturer to abandon its claim disputing the patent's validity.<sup>111</sup> This eliminates the risk that the patent is invalidated, and, consequently, the patentee continues to benefit from a brand monopoly.<sup>112</sup> Similarly, the generic manufacturer reaps the profits of a generic monopoly.<sup>113</sup> Thus, the no-AG agreement enables the brand and generic to share in the monopoly profits, but prevents consumers to benefit from a more competitive market.<sup>114</sup> In conclusion, the *Smithkline* court ruled that the no-AG agreement represents a large, unexplained transfer of value with antitrust effects that should be evaluated under the rule of reason.<sup>115</sup>

### III. ANTITRUST SCRUTINY EFFECTUATES THE LEGISLATIVE PURPOSE TO PROMOTE COMPETITION AND PROTECT CONSUMERS FROM HIGH PHARMACEUTICAL DRUG PRICES

In June 2015, the United States Court of Appeals for the Third Circuit in *King Drug Co. of Florence v. Smithkline Beecham Corp.* correctly held that no-AG agreements are subject to antitrust scrutiny under the rule of reason test.<sup>116</sup> First, this Part argues that the *Smithkline* decision is in line with Congress's

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Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 500–01 (2016).

<sup>109</sup> *Smithkline*, 791 F.3d at 405.

<sup>110</sup> *Id.* In no-AG agreements, the first-filing generic is able to set generic prices higher than would be possible with the presence of two generic drugs. Kang, *supra* note 3, at 79. The arrangement ensures the brand retains its patent period for the length of the agreement, which would be in jeopardy if the parties continued to litigate. See Michael A. Carrier, *Eight Reasons Why "No-Authorized-Generic" Promises Constitute Payment*, 67 RUTGERS U. L. REV. 697, 719 (2015) (arguing that no-AG agreements provide the brand an extended period of exclusive profits). In turn, the generic is entitled to a 180-day period of exclusivity. *Id.* The settlement thus violates antitrust principles because the arrangement decreases competition and increases profits for the parties involved at the expense of consumers. *Id.*

<sup>111</sup> Carrier, *supra* note 110, at 719.

<sup>112</sup> *Id.* The brand maintains its monopoly to continue marketing the brand drug. Feldman & Frondorf, *supra* note 108, at 522.

<sup>113</sup> *Smithkline*, 791 F.3d at 405; Feldman & Frondorf, *supra* note 108, at 500–01 (stating that a first-filing generic enters the market at a twenty percent discount and an eighty to eighty-five percent discount from the price of the brand-name drug during and after the period of exclusivity, respectively).

<sup>114</sup> *Smithkline*, 791 F.3d at 405.

<sup>115</sup> *Id.* at 409.

<sup>116</sup> See Fed. Trade Comm'n v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013) (stating that a large and unjustified payment to an alleged infringer risks anticompetitive effects and is subject to antitrust liability); *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 403 (3d Cir. 2015) (holding that *Actavis* is not limited to cash settlements).

intent to promote competition in the passage of the Hatch-Waxman Act.<sup>117</sup> Next, this Part argues that no-AG agreements should be evaluated in the same manner as cash reverse-payments at issue in the 2013 United States Supreme Court decision *Federal Trade Commission v. Actavis*.<sup>118</sup> Finally, this Part argues that the economic benefits derived from a competitive pharmaceutical market outweigh the potential benefits of promoting settlement.<sup>119</sup>

First, the *Smithkline* ruling effectuates the congressional intent to increase competition with the Hatch-Waxman Act.<sup>120</sup> The Third Circuit correctly held that no-AG agreements are subject to antitrust scrutiny because, similar to reverse payment agreements, no-AG agreements limit the number of available generics in the market to one.<sup>121</sup> In the reverse payment context, generics agree not to enter the market.<sup>122</sup> In no-AG agreements, brands agree not to enter the

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<sup>117</sup> See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 217 (3d. Cir. 2012) (explaining that the goal of the Hatch-Waxman Act is to promote competition by encouraging generic manufacturers to challenge weak or invalid patents), *vacated and remanded sub nom.* *Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013); *infra* notes 120–125 and accompanying text. The Hatch-Waxman Act incentivizes the production of low-cost drugs by streamlining the generic approval process and encouraging generics to challenge brand patents. Kurlander, *supra* note 32, at 690.

<sup>118</sup> See 133 S. Ct. at 2237 (holding that a reverse payment, when large and unjustified, is subject to antitrust review under the rule of reason); *Smithkline*, 791 F.3d at 404 (noting that the exclusivity period and authorized generics are worth several hundreds of millions of dollars); Taavola, *supra* note 96, at 1389 (noting that some courts interpret *Actavis* to include non-monetary payments); *infra* notes 126–132 and accompanying text.

<sup>119</sup> See *Actavis*, 133 S. Ct. at 2234, 2237 (recognizing the value of settlements but nonetheless concluding that the antitrust concerns outweigh the benefits of settlement); *infra* notes 133–136 and accompanying text. In *Actavis*, the Court reasoned that the general policy to promote settlement of disputes is not dispositive to resolving the antitrust issue. See *id.* at 2237 (holding that the anticompetitive consequences outweigh the single consideration of desirability of settlements); Kurlander, *supra* note 32, at 692–93 (noting the *Actavis* Court held that the general policy of promoting settlements should not solely determine the result of whether the settlement arrangement violates antitrust principles).

<sup>120</sup> See *In re K-Dur Antitrust Litig.*, 686 F.3d at 217 (noting that the Hatch-Waxman Act encourages patent challenges in order to increase the availability of generic drugs in the market). The Act protects consumers from excessive pharmaceutical drug prices by incentivizing generics to challenge weak patents. See Allison A. Schmitt, *Competition Ahead? The Legal Landscape for Reverse Payment Settlements After Federal Trade Commission v. Actavis, Inc.*, 29 BERKELEY TECH. L.J. 493, 498–99 (2014) (stating that the Act is designed to increase competition and decrease the price of pharmaceutical drugs). No-AG agreements limit competition, because the brand agrees not to market an authorized generic in exchange for the generic's willingness to delay market entry. See Carrier, *supra* note 110, at 717–20 (“[T]hese reciprocal market-division promises are even more anticompetitive than cash payments for delayed entry . . . [C]ash payments (1) delay generic entry. But no-AG agreements (1) delay generic entry and (2) reduce generic competition after entry.”).

<sup>121</sup> See *Actavis*, 133 S. Ct. at 2227 (explaining that reverse payment settlement agreements compensate the generic manufacturer to delay entering the market); *Smithkline*, 791 F.3d at 393 (explaining that brand-name manufacturers refrain from introducing their own generic in no-AG agreements).

<sup>122</sup> *Actavis*, 133 S. Ct. at 2227 (“Company A sues Company B for patent infringement. The two companies settle under the terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent’s term expires, and (2) Company A, the patentee, to pay B many millions of dollars.”).

generic market.<sup>123</sup> Though the terms of the agreements may differ, the result is the same—less competition and consequently higher prices for the consumer.<sup>124</sup> Therefore, antitrust scrutiny is appropriate because no-AGs stifle the congressional purpose of increasing the number of available low cost generic drugs on the market.<sup>125</sup>

Second, no-AG agreements represent a large transfer of value that should be evaluated under the rule of reason.<sup>126</sup> The 180-day exclusivity period can be worth several hundred million dollars and comprises the majority of the first-filer's profits.<sup>127</sup> In fact, in *Smithkline*, Teva's generic sales were an astounding \$671 million during the length of the no-AG agreement.<sup>128</sup> Reduced competition from the brand name further compensates the generic manufacturer.<sup>129</sup> The presence of an authorized generic drug reduces the generic manufacturer's expected revenues by forty to fifty percent.<sup>130</sup> Even though no cash is exchanged, no-AG agreements represent a large transfer of value because the generic manufacturer is able to enjoy generic monopoly profits.<sup>131</sup> To rule otherwise would disservice *Actavis* and allow pharmaceutical drug manufacturers to

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<sup>123</sup> *Smithkline*, 791 F.3d at 393.

<sup>124</sup> *Id.* at 403–04 (noting that reverse settlement and no-AG agreements prevent competition and negatively affect consumer welfare). No-AG agreements and reverse settlements both eliminate competition and result in higher generic prices. Kurlander, *supra* note 32, at 695. The settlements enable the brand to charge higher prices until the generic enters the market at the agreed upon date, at which time the generic is able to charge higher prices free from generic or authorized generic competition. *Id.*

<sup>125</sup> *See Actavis*, 133 S. Ct. at 2234 (explaining that the Hatch-Waxman Act facilitates competition and was not designed to encourage deals between brand and generics that delay competition).

<sup>126</sup> *Smithkline*, 791 F.3d at 404. Even though cash is not exchanged, no-AG agreements represent a large transfer of value. Kang, *supra* note 3, at 90–92 (recognizing that pharmaceutical settlements often involve non-cash consideration as value); *see Carrier*, *supra* note 110, at 706 (arguing that the *Actavis* holding did not limit its application to “cash,” and instead used “millions of dollars” on a number of occasions to anticipate its broader application to non-cash payments).

<sup>127</sup> *Smithkline*, 791 F.3d at 405. Brand-name manufacturers estimate generic deterrence is worth \$3.9 billion and generics estimate their right to market entry at \$748.6 million. Schmitt, *supra* note 118, at 498 n.37.

<sup>128</sup> *Smithkline*, 791 F.3d at 404.

<sup>129</sup> *See id.* at 404–05 & 404 n.21 (commenting that no-AG agreements create a generic monopoly instead of a generic duopoly).

<sup>130</sup> *See id.* at 404 n.21 (stating that the presence of an authorized generic forces a generic to reduce its price and revenues decline by as much as fifty-two percent). The generic's entry into the market causes the brand to lose eighty to ninety percent of its market share within a year. Feldman & Frondorf, *supra* note 108, at 501 (commenting that, because a generic is priced at an eighty percent discount to the brand name, a brand manufacturer loses an average of eighty to ninety percent of its market share within one year of generic introduction).

<sup>131</sup> *Smithkline*, 791 F.3d at 404; *see* Brief for Petitioner at 11, *Smithkline Beecham Corp. v. King Drug Co. of Florence*, 137 S. Ct. 446 (2016) (No. 15-1055) (noting that both a reverse settlement and no-AG agreement restrict competition and the anticompetitive risk is the same whether the consideration is made in cash or non-cash form).

creatively avoid antitrust scrutiny by disguising valuable compensation through non-cash means.<sup>132</sup>

Third, the congressional intent to promote competition clearly outweighs the need for settlement.<sup>133</sup> It is undeniable that the risk of antitrust scrutiny may deter settlements, thereby requiring some parties to fully litigate their disputes.<sup>134</sup> Indeed, consumers benefit from the quick resolution of disputes, but consumers do not benefit from settlements that promote monopolies and supracompetitive prices.<sup>135</sup> Therefore, antitrust scrutiny ultimately promotes efficiency by ensuring settlements do not eliminate beneficial competition.<sup>136</sup>

### CONCLUSION

In 2015, in *King Drug Co. of Florence v. Smithkline Beecham Corp.*, the Third Circuit Court of Appeals correctly ruled that no-AG agreements are subject to antitrust scrutiny under the rule of reason. Allowing such scrutiny effectuates the congressional objective of promoting competition under the Hatch-Waxman Act and increasing the number of affordable generic drugs on the market. Although a patent grants the patentee the right to exclude, it does not afford the patentee unlimited rights to the market. Accordingly, a patent settlement, cash or non-cash, that limits the number of available drugs on the market obliterates the purpose of the Hatch-Waxman Act and potentially violates antitrust principles. Therefore, the Third Circuit in *Smithkline* correctly applied antitrust principles to determine whether the no-AG agreement was an unreasonable restraint on trade.

MEGHAN FAY

Preferred Citation: Meghan Fay, Comment, *The Role of Antitrust Principles in Patent Monopolies: the Third Circuit Applies Antitrust Scrutiny to no-AG Patent Settlements* in *Smithkline*, 58 B.C. L. REV. E. SUPP. 128 (2017), <http://lawdigitalcommons.bc.edu/bclr/vol58/iss6/11>.

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<sup>132</sup> See Kang, *supra* note 3, at 90–92 (reciting Joshua Wright’s, the former Commissioner of the Federal Trade Commission, statements that *Actavis* includes non-cash compensation). Consideration in patent settlements takes form in a variety of complex ways, and it would be arbitrary to draw a distinction between cash and non-cash settlements. *Id.*

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

<sup>134</sup> See *In re K-Dur Antitrust Litig.*, 686 F.3d at 217 (acknowledging that the rule of reason test may limit parties’ ability to reach settlements because such settlements are subject to antitrust scrutiny).

<sup>135</sup> See *id.* (noting that monopolistic settlement agreements benefit the parties but are detrimental to the consumer). According to the FTC, pay-for-delay settlements cost consumers and the federal government \$3.5 billion to \$12 billion a year. Schmitt, *supra* note 118, at 502.

<sup>136</sup> See *In re K-Dur Antitrust Litig.*, 686 F.3d at 217 (explaining that anticompetitive settlements undermine the congressional purpose of the Hatch-Waxman Act).