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## Update on Antitrust and Pay-for-Delay: Evaluating “No Authorized Generic” and “Exclusive License” Provisions in Hatch-Waxman Settlements

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# Update on Antitrust and Pay-for-Delay: Evaluating “No Authorized Generic” and “Exclusive License” Provisions in Hatch- Waxman Settlements

SAAMI ZAIN\*

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## I. INTRODUCTION

In *FTC v. Actavis*, the Supreme Court held that so-called “pay-for-delay” settlements—where a branded drug manufacturer settles patent litigation against a generic drug manufacturer by paying the generic to delay its entry until sometime prior to patent expiry—may violate the antitrust laws.<sup>1</sup> In

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

doing so, the Court rejected the “scope of the patent” test used by some appellate courts, which essentially held such settlements immune from antitrust liability absent claims that the litigation was a sham.<sup>2</sup> That test was based primarily on the rationale that because a patentee is granted the lawful right to exclude all others from practicing the patented invention, any anticompetitive effects resulting from such an agreement would be within the scope of the patent and thus immune from antitrust liability.<sup>3</sup> The Supreme Court rejected that logic, holding that “patent and antitrust policies are both relevant” in evaluating the settlement’s legality<sup>4</sup> and that “this Court’s precedents make clear that patent-related settlement agreements can sometimes violate the antitrust laws.”<sup>5</sup> Finally, the Court elaborated on “five sets of considerations” in support of its holding that pay-for-delay agreements may be unlawful.<sup>6</sup>

Although *Actavis* settled the controversy over whether pay-for-delay settlements may violate the antitrust laws, it lacked clear guidelines for evaluating their legality. As a result, lower courts have struggled in ascertaining when such agreements are illegal, particularly in situations when it was not obvious that a settlement contained an unlawful payment—for example, when the agreement only included non-cash benefits such as supply agreements, licenses, or extraneous collaborations.<sup>7</sup> A relatively new provision being challenged is when a settlement provides for not only a license to

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2. *Id.* at 2230.

3. *Id.*

4. *Id.* at 2231. The Court explained: “A *valid* patent excludes all except its owner from the use of the protected process or product . . . . And that exclusion may permit the patent owner to charge a higher-than-competitive price for the patented product. But an *invalidated* patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe. The paragraph IV litigation in this case put the patent’s validity at issue, as well as its actual preclusive scope. The parties’ settlement ended that litigation. The FTC alleges that in substance, the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for damages. That form of settlement is unusual. And, for reasons [previously] discussed . . . there is reason for concern that settlements taking this form tend to have significant adverse effects on competition. Given these factors, it would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well.” *Id.* (quoting *United States v. Line Materials, Co.*, 333 U.S. 287, 308 (1948)).

5. *Id.* at 2232.

6. *Id.* at 2234.

7. *See, e.g., In re Lipitor Antitrust Litig.*, 868 F.3d 231, 250 (3d Cir. 2017); *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 93 (2d Cir. 2017); *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 545 (1st Cir. 2016); *In re Opana ER Antitrust Litig.*, No. 14 C 10150, 2016 WL 738596, at \*2 (N.D. Ill. Feb. 25, 2016); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 242 (D. Conn. 2015); *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069 (N.D. Cal. 2014).

allow generic entry prior to patent expiry, but also an agreement by the branded company not to launch or separately license an “authorized generic”—a generic drug approved under the branded drug’s application that would compete for generic sales.<sup>8</sup> These “No Authorized Generic” provisions, as they are commonly referred to, can be quite lucrative to a generic manufacturer, particularly if it results in the drug being the sole generic on the market for a significant time period.<sup>9</sup> And because the agreement is between competitors—whether actual or potential—the provision is essentially a non-compete provision, which antitrust law tends to subject to greater scrutiny. Indeed, although agreements not to compete are not categorically prohibited, in circumstances where they appear facially anticompetitive they may be subject to an abbreviated analysis<sup>10</sup> or even condemned as *per se* illegal.<sup>11</sup> The increased prevalence of No Authorized Generic provisions in pharmaceutical settlements has accentuated concerns

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8. FED. TRADE COMM’N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 1 n.1 (“Authorized generic[s] . . . are drugs that are approved as brand-name drugs but are marketed as generic drugs.”), <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> [<https://perma.cc/2HYC-GBGA>].

9. See *Actavis*, 133 S. Ct. at 2229; *Mylan Pharm., Inc. v. FDA*, 454 F.3d 270, 273 (4th Cir. 2006) (“By selling an authorized generic during the exclusivity period enjoyed by the first paragraph IV ANDA applicant, the pioneer drug maker prevents that applicant from winning all of the customers who want to switch from the branded drug to a cheaper generic form.”).

10. See, e.g., *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 457–59 (1986) (finding agreement among physicians to refuse to provide x-rays to insurers for auditing purposes in conjunction with claims forms found to be illegal under quick-look); *NCAA v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 88, 100 (1984) (holding restrictions on members ability to negotiate television contracts, which limited output of televised sports programs, found illegal under a quick-look analysis); *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 362–63 (5th Cir. 2008) (finding an agreement by physician group that they would only collectively negotiate with insurers unlawful under quick-look); *Polygram Holdings v. FTC*, 416 F.3d 29, 31, 35 (D.C. Cir. 2005) (holding agreement between record labels to suspend advertising on recordings of two prior “The Three Tenors” concerts—which would compete with recordings of the newer concert—unlawful under quick-look).

11. See, e.g., *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49–50 (1990) (finding market allocation by competitors *per se* illegal); *Arizona v. Maricopa Cty. Med. Soc’y*, 457 U.S. 332, 347–48 (1982) (holding agreements among competing physicians setting maximum fees that may be claimed in full payment for health services provided to policyholders *per se* illegal); *United States v. Trenton Potteries Co.*, 273 U.S. 392, 397–98 (1927) (holding price fixing by competitors *per se* illegal).

over how such provisions are—and should be—evaluated under current antitrust jurisprudence.

*In re Lamictal Direct Purchaser Antitrust Litigation*, a case that was appealed to the United States Supreme Court in 2016, offers the most developed arguments for the legality of No Authorized Generic provisions post-*Actavis*.<sup>12</sup> While the primary focus in the lower courts concerned to what extent non-cash payments in Hatch-Waxman settlements were subject to *Actavis*, defendants advanced more substantive arguments before the Supreme Court. First, the *Lamictal* defendants characterized the provision as an “exclusive license” rather than a No Authorized Generic agreement.<sup>13</sup> According to defendants, such licenses are “common” and “procompetitive”; therefore, allowing antitrust liability would be both unwarranted and imprudent.<sup>14</sup> Second, defendants contend that *Actavis* does not apply to conduct expressly permitted under patent law, such as exclusive licenses.<sup>15</sup> Finally, defendants maintain that exclusive licenses are—or should be—afforded antitrust immunity.<sup>16</sup> Although the arguments are not meritless, the author concludes that none support antitrust immunity for the challenged provision.

#### A. Background on Hatch-Waxman

The Federal Food, Drug, and Cosmetics Act (Act), and its implementing regulations, governs, *inter alia*, the manufacturing, sale, and marketing of pharmaceuticals in the United States.<sup>17</sup> Under the Act, anyone seeking to bring a new drug to market must submit a New Drug Application (NDA) with the Food and Drug Administration (FDA) and provide scientific data demonstrating that the drug is safe and effective for its intended use.<sup>18</sup> Once an NDA is approved, FDA lists the drug, along with information about the claimed patents and periods of exclusivity, in its publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as the “Orange Book.”<sup>19</sup>

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12. *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 561–62 (D.N.J. 2014), *vacated and remanded sub nom.* King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp., 791 F.3d 388 (3d Cir. 2015).

13. *Id.* at 562.

14. Brief Amicus Curiae of the National Association of Manufacturers in Support of Defendants-Appellees Urging Affirmance at 14, 20–23, 29, King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp., 791 F.3d 388 (3d Cir. 2015) (No. 2:12-cv-00995).

15. Petition for a Writ of Certiorari at 3, *King Drug*, 791 F.3d 388 (No. 12-cv-00995).

16. *Id.* at 25–28.

17. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2012).

18. 21 U.S.C. § 355(b)(1); Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 404 (2012).

19. *Aaipharma Inc. v. Thompson*, 296 F.3d 227, 230 (4th Cir. 2002).

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act, amending the Act to encourage generic entry by permitting a quicker, easier means for generic drugs to come to market.<sup>20</sup> Under the Hatch-Waxman Act, companies seeking to market generic versions of a drug that has already been approved pursuant to an NDA may obtain FDA approval by submitting an Abbreviated New Drug Application (ANDA) to FDA and by demonstrating their generic version is “bioequivalent” to the NDA.<sup>21</sup> A company filing an ANDA must address every patent listed by the NDA in the Orange Book.<sup>22</sup> Specifically, the ANDA filer must certify that: (1) no patent information is listed in the Orange Book for the proposed generic drug, (2) the listed patents have expired, (3) the listed patents will expire before the generic product is marketed, or (4) the patents listed are invalid or will not be infringed by the generic.<sup>23</sup> When a generic company challenges a patent’s validity or asserts non-infringement—referred to as a “paragraph IV patent certification”<sup>24</sup>—it must also set forth “a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.”<sup>25</sup>

Upon receiving a paragraph IV certification, a branded drug company that has a drug approved under an NDA may file patent litigation against the generic that submitted the certification, which has the effect of automatically delaying FDA approval of the generic for thirty months or until the patent is held to be invalid or not infringed.<sup>26</sup> In contrast, if the NDA holder does not file suit within forty-five days, the FDA may approve the ANDA immediately, provided all other conditions for approval have been met—that is, the drug is deemed safe and efficacious and no other unexpired

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20. See Hatch-Waxman Act, Pub. L. No. 98-417, § 102, 98 Stat. 1585, 1594–95 (1984) (codified as amended at 21 U.S.C. § 355 (2012)); *Caraco*, 566 U.S. at 405 (explaining the Hatch-Waxman process was “designed to speed the introduction of low-cost generic drugs to market”).

21. 21 U.S.C. § 355(j)(2)(A). A generic is “bioequivalent” to a branded drug when the same dose is administered, and the rate and extent of absorption does not differ significantly between the two. See Definitions, 21 C.F.R. § 320.1 (2016).

22. 21 U.S.C. § 355(j)(2)(A)(vii).

23. *Id.*

24. *Patent Certifications and Suitability Petitions*, FDA (May 23, 2018), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm047676.htm> [<https://perma.cc/U97F-MF8G>].

25. 21 U.S.C. § 355(b)(3)(D).

26. 35 U.S.C. § 271(e)(2)(A) (2012); 21 U.S.C. § 355(j)(5)(B)(iii).

exclusivity has been granted.<sup>27</sup> The FDA awards exclusivity to the first generic drug manufacturer that files an ANDA challenging the branded drug's listed patents.<sup>28</sup> During this 180 day generic exclusivity period, the FDA may not approve any other ANDA for the same drug.<sup>29</sup>

### B. Background on Antitrust Law

Antitrust laws are the “Magna Carta of free enterprise,” with the purpose of protecting competition and consumers.<sup>30</sup> The Sherman Act<sup>31</sup> is the cornerstone of these laws and proscribes both joint conduct among firms that unreasonably harms competition,<sup>32</sup> as well as monopolization.<sup>33</sup> In examining whether conduct is unreasonable—and thus illegal—for antitrust purposes, courts typically apply a holistic, fact specific approach termed the “rule of reason,” which often entails evaluating the relevant industry, the firms involved in the litigation, the nature of the conduct being challenged, pro-competitive business justifications for the conduct, and the actual and likely effects of the conduct.<sup>34</sup> However, because this analysis is extensive

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27. 21 U.S.C. § 355(j)(5)(B)(iii) (2012); 21 C.F.R. § 314.107(f)(2); Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc., 552 F.3d 1033, 1037 (9th Cir. 2009) (“If a patent holder fails to bring an infringement suit within forty-five days of receipt of a Paragraph IV notification, it loses the right to the thirty-month automatic stay . . .”).

28. 21 U.S.C. § 355(j)(5)(B)(iv); Teva Pharm. USA, Inc. v. Sebelius, 595 F.3d 1303, 1305 (D.C. Cir. 2010).

29. 21 U.S.C. § 355(j)(5)(B)(iv); *Teva*, 595 F.3d at 1305.

30. *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972). Consumer welfare is the primary focus of antitrust laws. *See e.g.*, *Spanish Broad. System of Fla, Inc. v. Clear Channel Comm'ns, Inc.*, 376 F.3d 1065, 1071 (11th Cir. 2004); *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001); *K.M.B. Warehouse Distribs., Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 129 (2d Cir. 1995).

31. *See generally* Sherman Act, 15 U.S.C. §§ 1–7 (2012).

32. *Id.* § 1. Section 1 of the Sherman Act prohibits certain joint conduct that harms competition, providing in part, “[e]very 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.* Despite its broad, prohibitive terms, the Supreme Court has long held that section 1 only condemns “unreasonable restraint[s].” *Standard Oil Co. of N.J. v. United States*, 221 U.S. 1, 89 (1910).

33. 15 U.S.C. § 2. Section 2 of the Sherman Act provides in part, “[e]very 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.” *Id.*

34. *See, e.g.*, *Bd. of Trade of Chi. v. United States*, 246 U.S. 231, 238 (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.”).

and often very time consuming, courts have articulated circumstances when the analysis may be truncated or even obviated.<sup>35</sup> In *Actavis*, the Supreme Court applied the “rule of reason” to Hatch-Waxman patent settlements.<sup>36</sup>

### C. Lamictal Litigation

Lamotrigine is used primarily to treat epilepsy and bipolar disorder<sup>37</sup> and was first approved by the FDA in 1994.<sup>38</sup> GlaxoSmithKline (GSK) sells and markets the drug as Lamictal®, in both chewable and non-chewable tablet forms.<sup>39</sup> GSK claimed a patent on the drug’s active ingredient, U.S. Patent No. 4,602,017 (‘017 patent), which was filed on February 27, 1984 and expired on July 22, 2008.<sup>40</sup>

In April 2002, Teva was the first of several generic manufacturers to file an ANDA seeking to market generic lamotrigine, and was thereby awarded 180-day generic exclusivity.<sup>41</sup> After Teva submitted a Paragraph IV certification—asserting the ‘017 Patent was either invalid, unenforceable, or not infringed by its proposed generic—GSK timely filed suit, triggering the statutory thirty month stay of FDA approval for Teva’s generic lamotrigine ANDAs.<sup>42</sup> In late January 2005, the District Court “ruled that the patent’s main claim, for the invention of lamotrigine, was invalid.”<sup>43</sup> Shortly after—and prior to the court making a ruling on the validity of the patent’s remaining

35. N. Pac. R.R. v. United States, 356 U.S. 1, 5 (1958) (“[T]here are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use.”). See also Cal. Dental Ass’n v. FTC, 526 U.S. 756, 757 (1999); FTC v. Ind. Fed’n of Dentists, 476 U.S. 447, 457–58 (1986) (finding conduct unreasonable without an elaborate “Rule of Reason” inquiry).

36. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2226 (2013).

37. King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp., 791 F.3d 388, 396 (3d Cir. 2015).

38. *Lamictal—Approved Treatment for Epilepsy and Bipolar*, DRUG DEV. TECH., <https://www.drugdevelopment-technology.com/projects/lamictal-by-gsk/> [<https://perma.cc/5W7L3>].

39. See *King Drug*, 791 F.3d at 393. The non-chewable formulation has achieved far greater sales than the chewables, which are worth \$2 billion in annual sales, compared to chewables, which have less than \$50 million in annual sales. See *id.* As a result, this article focuses only on the non-chewable formulation.

40. *Id.* at 396.

41. *Id.* at 397.

42. *Id.*

43. *Id.*



claims—the parties settled.<sup>44</sup> Pursuant to the settlement, Teva was allowed to market “generic lamotrigine tablets on July 21, 2008, if GSK received a ‘pediatric exclusivity’ extension, or on March 1, 2008, if GSK did not.”<sup>45</sup> Thus, if GSK obtained pediatric exclusivity, as it did,<sup>46</sup> Teva agreed it would not launch its generic *until the day before the patent expired*, and GSK agreed that it would not launch an authorized generic for six months post patent expiry—thereby allowing Teva to be the sole provider of generic lamotrigine tablets during its 180 day exclusivity period.<sup>47</sup> Although it does not appear that GSK expressly promised not to launch an authorized generic,<sup>48</sup> the settlement provides Teva with an exclusive license, “including as to GSK and its Affiliates and Third Parties with respect to Generic Equivalents.”<sup>49</sup>

In February 2012, Lamictal Direct Purchasers filed an antitrust action against GSK and Teva, alleging their settlement contained an unlawful reverse payment in violation of sections 1 and 2 of the Sherman Act.<sup>50</sup> In the District Court, the primary legal dispute was whether *Actavis* applied to settlements that did not “involve an exchange of money.”<sup>51</sup> The District Court held that it did not and thus dismissed the case.<sup>52</sup> On June 26, 2015, the Court of Appeals for the Third Circuit reversed, holding that *Actavis* applies to non-cash consideration.<sup>53</sup> According to the Third Circuit, “no-

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44. *Id.*

45. *Id.* (footnote omitted) (“With a pediatric exclusivity extension [granted], the patent would still have expired on July 22, 2008, but the FDA would [not have been allowed to approve] ANDAs filed by competing generics until after January 22, 2009.”).

46. JACQUELINE H. WARE, OFFICE OF DRUG EVALUATION, NDA REGULATORY FILING REVIEW 2 (2008), [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2009/022251s000\\_Admincorres.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/022251s000_Admincorres.pdf) [<https://perma.cc/FN6Y-EJ2G>].

47. *King Drug*, 791 F.3d at 411. The settlement also granted Teva rights to an early—and exclusive—launch of generic lamotrigine chewables. *Id.* at 393. However, because revenues for the chewables were alleged to be negligible in comparison to the tablets—\$50 million in comparison to \$2 billion in annual sales—the real value and consideration given in the settlement related to the tablets. *See id.*

48. Because most of the settlement is private, it is not entirely clear whether or not GSK expressly promised to launch an authorized generic.

49. *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 562 (D.N.J. 2014), *vacated and remanded sub nom.* *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015).

50. *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-995(WHW), 2012 WL 6725580, at \*1, \*3 (D.N.J. Dec. 6, 2012).

51. *Lamictal*, 18 F. Supp. 3d at 568.

52. The district court actually ruled on the matter twice: once based on pre-*Actavis* circuit law in *Lamictal*, 2012 WL 6725580, at \*1, and then later under *Actavis*. *Lamictal*, 18 F. Supp. 3d at 563.

53. *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015) (“We believe this no-AG agreement falls under *Actavis*’s rule because it may represent an unusual, unexplained reverse transfer of considerable value from the

AG agreements are likely to present the same types of problems as reverse payments of cash” and may therefore be unlawful under *Actavis* “when it represents an unexplained large transfer of value from the patent holder to the alleged infringer.”<sup>54</sup>

In February 2016, defendants filed a writ of certiorari with the Supreme Court, framing the issue as to whether an exclusive license is subject to *Actavis*.<sup>55</sup> According to defendants, the challenged provision is merely a “routine” and “well accepted” early entry exclusive license permitted under *Actavis*, as well as expressly allowed under the patent laws, and thus not unlawful under the antitrust laws—either under *Actavis* or otherwise.<sup>56</sup> After being invited to weigh in, in October 2016, the Solicitor General submitted a brief recommending that the Court not review the case because it was not the best vehicle for addressing antitrust scrutiny of an exclusive license in the context of Hatch-Waxman settlements, as the challenged provision was not an exclusive license in form or substance.<sup>57</sup> On November 7, 2016 the Supreme Court denied certiorari.<sup>58</sup>

## II. ANALYSIS

Since *Actavis*, lower court review of Hatch-Waxman settlements involving non-monetary compensation has been mixed. Concerning exclusivity provisions in particular, most of the analysis has generally focused on

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patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition.”).

54. *Id.* at 403–04. “The anticompetitive consequences of this pay-for-delay may be as harmful as those resulting from reverse payments of cash. If the brand uses a no-AG agreement to induce the generic to abandon the patent fight, the chance of dissolving a questionable patent vanishes (and along with it, the prospects of a more competitive market). As with a reverse payment of cash, a brand agreeing not to produce an authorized generic may thereby have ‘avoided the risk of patent invalidation or a finding of noninfringement.’ In addition, when the parties’ settlement includes a no-AG agreement, the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted. And during this time, the brand’s monopoly remains in force. Once the generic enters, moreover, it faces no competition with other generics at all.” *Id.* at 405 (footnote omitted) (citation omitted) (quoting *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013)).

55. Petition for a Writ of Certiorari, *supra* note 15 (“What the Third Circuit termed a ‘no-AG’ clause . . . was in fact an exclusive license . . .”).

56. *Id.* at 2.

57. Brief for the United States as Amicus Curiae at 8, 19, 20, *SmithKline Beecham Corp. v. King Drug Co. of Florence, Inc.*, 137 S. Ct. 446 (2016) (No. 15-1055).

58. *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015), *cert. denied*, 137 S. Ct. 446 (2016).

how—and to what extent—*Actavis* applies. The *Lamictal* case is one of the few cases where substantive arguments were advanced on the antitrust analysis of such provisions.<sup>59</sup>

Throughout the *Lamictal* litigation, both the characterization and legality of the settlement’s exclusivity provision were disputed. Defendants argued that because the provision on its face provided Teva with an “exclusive license” to generic lamotrigine and contained no monetary compensation, it was merely a typical, unobjectionable early entry exclusive license.<sup>60</sup> According to defendants, not only was the settlement not a pay-for-delay agreement subject to *Actavis*, but it was immune from antitrust liability because exclusive licenses are expressly authorized by the Patent Act.<sup>61</sup> Plaintiffs, in contrast, contended that apart from lacking a cash payment, the settlement was a common pay-for-delay case: Teva agreed to dismiss its suit challenging GSK’s patent in exchange for, *inter alia*, GSK allowing Teva to launch during GSK’s exclusivity period and agreeing to forego its right to launch an authorized generic until after the expiration of Teva’s 180-day exclusivity—thereby making Teva the sole generic during that time period.<sup>62</sup> The parties’ conflicting views are largely due to three central issues, which will be address *infra*: (1) when is an exclusivity provision an “exclusive license,” (2) does *Actavis* apply to exclusive licenses or other conduct

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59. See *supra* Section I.C.

60. Memorandum in Support of the Teva Defendants’ Motion to Dismiss Direct Purchaser Plaintiffs’ Consolidated Amended Class Action Complaint at 22, *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-995(WHW), 2012 WL 6725580 (D.N.J. Dec. 6, 2012) (No. 12-995), 2012 WL 11921677 (“Read together, plaintiffs’ allegations amount to no more than the claim that Teva was permitted an exclusive early entry license for the sale of generic lamotrigine products. But such a license, without more, cannot be subject to antitrust scrutiny.”); Teva Defendants’ Reply in Support of Motion to Dismiss Direct Purchaser Plaintiffs’ Consolidated Amended Class Action Complaint at 5, *Lamictal*, 2012 WL 6725580 (No. 12-995) (“Exclusive early entry licenses are expressly *permitted* under the antitrust laws and such licenses are a commonplace element of the patent system.”).

61. Petition for a Writ of Certiorari, *supra* note 15, at 25–28. “Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.” 35 U.S.C. § 261 (2012). According to defendants, this provides antitrust immunity to the settlement. Petition for a Writ of Certiorari, *supra* note 15, at 25–28; see also Brief of Appellees Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc., 2014 WL 2206174 at \*34, *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015) (No. 14-1243) (“A patent licensing agreement that grants exclusivity to a particular market segment, even to the exclusion of the patent holder—which is all a so-called ‘no-AG’ provision does—is not actionable. Such exclusivity is a license term specifically authorized by the Patent Act.”) (emphasis omitted).

62. Petition for a Writ of Certiorari, *supra* note 15, at 6–10.

authorized by patent law, and (3) how are exclusive licenses evaluated under antitrust law?

As the Court of Appeals, Solicitor General, and plaintiffs in *Lamictal* noted, the exclusivity provision was likely not an “exclusive license,” notwithstanding the settlement’s characterization as one.<sup>63</sup> Rather, as only one day of the patent life remained at the time Teva was permitted to launch its generic, the vast majority of the agreed upon non-compete—or “exclusivity”—period was not protected by patent rights. And although defendants advance creative arguments for why the pediatric exclusivity granted for the drug is “equivalent” to an extension of the patent,<sup>64</sup> it certainly is not the best factual case. Nonetheless, given the increased prevalence of these provisions—and that future settlements could easily be drafted and structured so as to provide a better factual case—the issue is worth addressing.<sup>65</sup>

#### A. When is an Exclusivity Provision an “Exclusive License”?

Because many of the arguments made in *Lamictal* are predicated on representing the No Authorized Generic provision as an exclusive license, it is useful to examine that characterization. Unfortunately, none of the parties in the litigation addressed the issue in much depth but, rather, made their conclusion based on a rather superficial analysis.<sup>66</sup> However, relying

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63. *King Drug*, 791 F.3d at 406 n.27.

64. See e.g., Brief of Appellees Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc., *supra* note 61, at 37 (“Courts routinely view this blanket [pediatric] exclusivity as equivalent to a patent extension.”); *id.* at 41 (comparing pediatric exclusivity with patent exclusivity).

65. Indeed, at least one other case being currently litigated has made very similar arguments in defense of its Hatch-Waxman settlement. See, e.g., Actavis Defendants’ Memorandum in Support of Their Motion to Dismiss the Direct Purchaser Plaintiffs’ Amended Complaint Pursuant to Fed. R. Civ. P. 12(b)(6) at 20–21, *In re Intuniv Antitrust Litig.*, No. 1:16-cv-12653-ADB (D. Mass. filed Dec. 30, 2016) (“What DPPs characterize as a ‘no AG’ agreement would be nothing more than an exclusive license from Shire to Actavis to market the generic version of Intuniv for a certain period of time before Shire’s patents expire. . . . [B]ecause exclusive licenses *are* expressly authorized by the Patent Act, they cannot be challenged as reverse payments under *Actavis*.”).

66. In addition to the Agreement expressly granting an “exclusive license,” defendants argued that because it also prevented GSK from launching its own generic, the license was in fact exclusive. See Memorandum in Support of the Teva Defendants’ Motion to Dismiss Direct Purchaser Plaintiffs’ Consolidated Amended Class Action Complaint at 19, *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-995(WHW), 2012 WL 6725580 (D.N.J. Dec. 6, 2012) (No. 2:12-cv-00995-WHW-CLW), ECF No. 71-1 (“Teva was given an

solely on how the provision was characterized is clearly inadequate, as both antitrust and patent law eschew form over substance in such matters.<sup>67</sup> Rather, similar to an antitrust rule of reason analysis, determining one's property interest in a patent post-transfer typically requires evaluating various factors, including the intent of the transfer, the rights and obligations granted and retained, the legal context, business realities, and the purpose and manner in which the license was granted.<sup>68</sup>

Reflecting the flexibility of business needs, a license transfer can range from a bare-bones non-exclusive license to an outright assignment of all patent rights.<sup>69</sup> A non-exclusive license, which is essentially a promise not to sue for infringement,<sup>70</sup> places little, if any, restrictions on the patentee's rights vis-à-vis the patented invention.<sup>71</sup> With a "sole license," the patentee retains all rights subject only to the rights granted to the sole licensee.<sup>72</sup>

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exclusive license to market generic Lamictal . . . and an exclusive license by definition meant that GSK would not also launch a generic product in addition to its branded product.”). In contrast, plaintiffs averred that because GSK retained the right to practice the patent via selling Lamictal it *ipso facto* could *not* be exclusive. *See* Brief of Appellees Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc., *supra* note 61, at 42, 44.

67. *Am. Needle, Inc. v. NFL*, 560 U.S. 183, 193 (2010) (“[T]he Sherman Act . . . ‘is aimed at substance rather than form.’”) (quoting *United States v. Yellow Cab, Co.*, 332 U.S. 218, 227 (1947)); *Eastman Kodak Co. v. Imagine Tech. Servs.*, 504 U.S. 451, 466–67 (1992) (“Legal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law.”); *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998) (“Determining whether a licensee is an exclusive licensee or a bare licensee is a question of ascertaining the intent of the parties to the license as manifested by the terms of their agreement and examining the substance of the grant . . . . The use of the word ‘exclusive’ is not controlling; what matters is the substance of the arrangement.”).

68. *See, e.g., Azure Networks v. CSR PLC*, 771 F.3d 1336, 1343 (Fed. Cir. 2014) (“We must also consider a non-exhaustive list of rights for determining whether a licensor has transferred ‘all substantial rights’ to the licensee . . . .”); *Textile Prods.*, 134 F.3d at 1484.

69. *301 Ownership/Assignability of Patents and Applications [R-07.2015]*, USPTO.GOV (Jan. 24, 2018, 5:19 PM) [hereinafter *Patents and Applications*], [www.uspto.gov/web/offices/pac/mpep/s301.html](http://www.uspto.gov/web/offices/pac/mpep/s301.html) [<https://perma.cc/FX9N-92SQ>] (“As compared to assignment of patent rights, the licensing of a patent transfers a bundle of rights which is less than the entire ownership interest, e.g., rights that may be limited as to time, geographic area, or field of use.”).

70. *WiAV Sols. v. Motorola, Inc.*, 631 F.3d 1257, 1265 (Fed. Cir. 2010) (“[A] so-called ‘bare licensee’ holds nothing more than a promise from the patentee that the patentee will not sue the licensee for practicing the patented invention.”).

71. XUAN-THAO N. NGUYEN, ROBERT W. GOMULKIEWICZ & DANIELLE CONWAY-JONES, *INTELLECTUAL PROPERTY, SOFTWARE, AND INFORMATION LICENSING: LAW AND PRACTICE* § 2.III.E.2.B, at 5–56 (2018).

72. 2-15 ROGER M. MILGRIM & ERIC E. BENSON, *MILGRIM ON LICENSING* § 15.33 (Matthew Bender, rev. ed.) (“In a sole license situation, the licensor either retains the right to continue operating under the subject matter of the license or prior licenses granted are

Finally, in the prototypical exclusive license, “the licensor may not license to another or itself exercise the rights being licensed.”<sup>73</sup> As a practical matter, however, the distinctions between the varying license types are more nuanced. As explained by one treatise, although “[s]ome exclusive licenses are as limiting as their name suggests . . . [m]ost exclusive licenses, however, do not grant such encompassing exclusivity. They instead grant exclusive rights for a given use or context.”<sup>74</sup> Moreover, the above definitions may place too great an emphasis on the transfer and retention of rights, given that exclusive and non-exclusive licenses may transfer less than all rights, for example, it may be limited to a geographic region or field-of-use.<sup>75</sup>

Unfortunately, there is insufficient publicly available information to determine whether the challenged provision in *Lamictal* was in fact an exclusive license. However, the facts and business realities strongly suggest that it was not an exclusive license, as the license was of nominal value—being only for a single day—in contrast to the agreement not to launch an authorized generic, which lasted for Teva’s FDA-granted 180-day exclusivity period.

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preserved, but the licensor agrees to refrain from granting further licenses to any third party other than the sole licensee during the term of the sole license.”) (emphasis omitted).

73. NGUYEN, GOMULKIEWICZ & CONWAY-JONES, *supra* note 71; *see also* Patents and Applications, *supra* note 69 (“An exclusive license may be granted by the patent owner to a licensee. The exclusive license prevents the patent owner (or any other party to whom the patent owner might wish to sell a license) from competing with the exclusive licensee, as to the geographic region, the length of time, and/or the field of use, set forth in the license agreement.”).

74. NGUYEN, GOMULKIEWICZ & CONWAY-JONES, *supra* note 71; *see also* MILGRIM & BENSON, *supra* note 72, at § 15.08 (“The Federal Circuit has at times given ‘exclusive license’ a somewhat broader meaning in the context of determining standing to sue for patent infringement than the term is given in licensing practice.”).

75. *Compare* Textile Prods., Inc. v. Mead Corp., 134 F.3d 1481, 1485 (Fed. Cir. 1998) (finding the license was not exclusive due to the retention by licensee of certain rights), *with* *WiAV*, 631 F.3d at 1265–67 (holding the license grant was exclusive, despite retention of rights). *See also* MILGRIM & BENSON, *supra* note 72, at §15.08 (“A field of use license can be exclusive, and sufficient to bestow constitutional standing on the licensee to sue infringers acting *within* the field, even though other licensees can grant licenses *outside* the field of use.”); NGUYEN, GOMULKIEWICZ & CONWAY-JONES, *supra* note 71 (“Exclusive licenses may grant rights akin to an assignment of rights within the field of exclusivity.”).

## B. Evaluating the Scope and Application of *Actavis*

A central dispute post-*Actavis* is ascertaining the decision's scope and application. In *Lamictal*, defendants made two primary arguments to support their contention that *Actavis* was a "narrow decision" that only applies to "unusual" Hatch-Waxman patent settlements.<sup>76</sup> First, they averred that rather than rejecting the scope of the patent test, the opinion merely limited it.<sup>77</sup> Second, they maintained that *Actavis* does not apply to conduct "expressly authorized by the Patent Act," which they contended includes the challenged exclusivity provision.<sup>78</sup> Neither of these arguments are persuasive.

Although *Actavis* may not have provided the clearest guidance on how to evaluate the legality of Hatch-Waxman settlements, neither the developing lower court case law nor the opinion itself support a narrow interpretation. Indeed, although lower courts have been divided on numerous issues concerning the application of *Actavis*, the majority of courts have interpreted the decision broadly.<sup>79</sup> And this view is consistent with the opinion's broad language and purpose. The *Actavis* court took pains to explain it rejected the scope of the patent test because it failed to consider *both* antitrust and patent policy in evaluating the legality of the challenged agreement—a point broadly applicable to *all* patent settlements—not just to Hatch-Waxman cases.<sup>80</sup> As articulated by the Court of Appeals's decision in *Lamictal*, given *Actavis*' unambiguous rejection of antitrust immunity,<sup>81</sup> attempts to resuscitate or offer a modified version of the scope of the patent test are dubious at best.

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76. Petition for a Writ of Certiorari, *supra* note 15, at 4.

77. *Id.* at 23 ("Actavis applied two clear limits on the patentee's immunity from antitrust suit . . . [A]ctions may run afoul of the antitrust laws when they fall into one of two categories: (a) those that use the patent toward an *end* other than securing value from the patented discovery itself; and (b) those that use a *means* other than the patent to promote the monopoly of the patent.").

78. *Id.* at 4, 26.

79. For cases where the courts held *Actavis* is not limited to cash, see *supra* note 7.

80. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2225, 2231 (2013) ("It would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, and not against procompetitive antitrust policies as well. . . . And indeed, contrary to the Circuit's view that the only pertinent question is whether 'the settlement agreement falls within' the legitimate 'scope' of the patent's 'exclusionary potential,' this Court has indicated that patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent.") (citation omitted) (quoting *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1310 (11th Cir. 2012)).

81. *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 407 n.29 (3d Cir. 2015) ("The defendants' arguments are much like those rejected by the majority in *Actavis*. The disagreement in the Court was fundamental. In the dissenters' view, 'a patent claim *cannot possibly* impose unlawful anticompetitive harm if the patent holder is acting within the scope of a valid patent and therefore permitted to do precisely what the antitrust suit claims is unlawful.' The dissenters viewed the majority as 'imposing

The argument that *Actavis* is inapplicable to conduct expressly permitted under the patent statute is predicated upon a misreading of *Actavis* and the Patent Act. Defendants make much of the language in *Actavis* suggesting one reason antitrust immunity was rejected for pay-for-delay settlements is that patent law does not “expressly or by fair implication” grant a patentee the right to pay off a competitor to delay competition.<sup>82</sup> Arguing that because exclusive licenses are expressly authorized by the Patent Act, it is averred that they cannot be governed by *Actavis*.<sup>83</sup> Defendants make too much of this language, however, which was primarily to address one point made by the dissent. At most, this is but one consideration in evaluating the legality

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antitrust liability based on the parties’ subjective uncertainty about a legal conclusion,’ namely, whether a patent is valid (and it is one or the other), because ‘the majority seems to think that *even if* the patent is valid, a patent holder violates the antitrust laws merely because the settlement took away some chance that his patent would be declared invalid by a court.’”) (citations omitted) (quoting *Actavis*, 133 S. Ct. at 2244).

82. *Actavis*, 133 S. Ct. at 2233 (“What does appear novel are the dissent’s suggestions that a patent holder may simply ‘pay a competitor to respect its patent’ and quit its patent invalidity or noninfringement claim without any antitrust scrutiny whatever . . . . The dissent does not identify any patent statute that it understands to grant such a right to a patentee, whether expressly or by fair implication.”) (citation omitted) (quoting *id.* at 2243 (Roberts, J., dissenting)); see also *id.* at 2231 (“[T]he Court in *Line Materials* explained that ‘the improper use of a patent monopoly,’ is ‘invalid’ under the antitrust laws and resolved the antitrust question in that case by seeking an accommodation ‘between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act.’ To strike that balance, the Court asked questions such as whether ‘the patent statute specifically gives a right’ to restrain competition in the manner challenged; and whether ‘competition is impeded to a greater degree’ by the restraint at issue than other restraints previously approved as reasonable.”) (citation omitted) (quoting *United States v. Line Materials Co.*, 333 U.S. 287, 310–11 (1948)).

83. Petition for a Writ of Certiorari, *supra* note 15, at 3 (“Embedded in *Actavis* is a line between conduct that is authorized by patent law even though it might restrict competition in the near term (such as the grant of an exclusive license), which is not subject to antitrust challenge for that reason, and the alleged unusual reverse payments at issue there, which the Court emphasized were not authorized by law.”); see also *id.* at 4 (“[A]n indispensable part of [a patent] right is the ability to grant licenses, including those with exclusivity terms. *Actavis* preserved this bedrock of patent law when it amplified the line—already developed in this Court’s doctrine—between conduct that is authorized by patent law (such as the grant of an exclusive license) and the alleged unusual, large reverse cash payments at issue there. The alleged reverse payment in *Actavis* was subject to further examination under the antitrust laws precisely because of the absence of ‘any patent statute that . . . grants such a right to a patentee, whether expressly or by fair implication.’ That is not the case here, where the agreement merely reflected an exercise of the patentee’s express statutorily-granted right to grant an exclusive license.”) (citations omitted) (quoting *Actavis*, 133 S. Ct. at 2233).



of pay-for-delay agreements. The opinion’s unequivocal rejection of antitrust immunity militates against placing too much emphasis on this comment.

Similarly, reliance on Section 261 of the Patent Act<sup>84</sup> is mistaken. First, Section 261 does not expressly authorize the challenged provision in *Lamictal*, but rather merely grants patentees the right to grant a license “to the whole or any specified part of the United States”—in other words, a territorial license.<sup>85</sup> Second, even if section 261 were directly applicable to the challenged provision, any argument that this, by itself, confers antitrust immunity would be inconsistent with the prevailing views expressed by treatises,<sup>86</sup> case law,<sup>87</sup> and the enforcement guidelines<sup>88</sup> that territorial restrictions are evaluated under traditional antitrust principles. Finally, the argument proves too much, suggesting that an express authorization of conduct by one law thereby provides immunity under entirely separate, distinct laws having very different purposes.<sup>89</sup> But just as the grant of legal rights incident to ownership of real property does not provide blanket immunity for all uses of the property under any other applicable laws—

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84. 35 U.S.C. § 261 (2012) (“Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.”).

85. *Id.*; *see also* *Am. Indus. Fastener Corp. v. Flushing Enters., Inc.*, 362 F. Supp. 32, 36–37 (N.D. Ohio 1973) (“Section 261, strictly construed as these decisions mandate, permits a patentee to impose on the licensee territorial restrictions on the distribution of the product.”). While the exclusive license in *Lamictal* has territorial restrictions—being limited to the United States—the challenged provision of the license is the agreement by GSK not to launch a generic—not the territorial aspect—which is not covered under § 216.

86. *See* 1 HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 33.03[A], at 33–22 (3d ed. 2017).

87. *See, e.g.*, *White Motor Co. v. United States*, 372 U.S. 253, 272 (1963) (rejecting *per se* treatment for territorial allocation between manufacturer and distributors, requiring instead that the lower court “ascertain[] the effect upon competition of the particular territorial restraints in suit”); *Int’l Wood Processors v. Power Dry, Inc.*, 792 F.2d 416, 429 (4th Cir. 1986); *Mannington Mills, Inc. v. Congoleum Indus., Inc.*, 610 F.2d 1059, 1071 (3d Cir. 1979); *United States v. CIBA Geigy Corp.*, 508 F. Supp. 1118, 1150 (D.N.J. 1976).

88. U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, *ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY* 6 (2017).

89. *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 407 (3d Cir. 2015) (“[W]e believe the fact that the Patent Act expressly authorizes licensing does not necessarily mean it also authorizes reverse payments to prevent generic competition.”); *cf. United States v. Masonite Corp.*, 316 U.S. 265, 280 (1942) (“Since patents are privileges restrictive of a free economy, the rights which Congress has attached to them must be strictly construed so as not to derogate from the general law beyond the necessary requirements of the patent statute.”); *United States v. Microsoft Corp.*, 253 F.3d 34, 63 (D.C. Cir. 2001) (“Microsoft’s primary copyright argument borders upon the frivolous. The company claims an absolute and unfettered right to use its intellectual property as it wishes . . . . That is no more correct than the proposition that use of one’s personal property, such as a baseball bat, cannot give rise to tort liability.”).

for example, nuisance, tort, or environmental—rights granted by the Patent Act do not provide immunity under all other laws. Indeed, such deference would arguably be even more inappropriate for patent law, which primarily grants the *right to exclude others* from practicing the patented invention, rather than granting the patentee affirmative rights to *use* the invention.<sup>90</sup>

### C. Evaluating Exclusive Licenses under Antitrust Law

The primary failing in the arguments advanced by the *Lamictal* defendants is that *even if* the challenged provision were a bona fide exclusive license, it would not be exempt from antitrust scrutiny. Although various legal and policy arguments were advocated in support of the claim that “licensing agreements should not be second-guessed case-by-case under the antitrust laws,”<sup>91</sup>—many of which were made and rejected in *Actavis*—scant case law has been provided in support.<sup>92</sup>

There is no justification for granting antitrust immunity for exclusivity provisions in Hatch-Waxman settlements, regardless of how they are structured or characterized. First, given the *Actavis* court’s sweeping language and clear rejection of the scope of the patent test, continued advocacy for immunity seems rather unavailing and ineffectual.<sup>93</sup> Second, granting immunity for anticompetitive *use* of intellectual property is contrary to decades of

90. *Special Equip. Co. v. Coe*, 324 U.S. 370, 378 (1945) (“The patent grant is not of a right to the patentee to use the invention, for that he already possesses. It is a grant of the right to exclude others from using it. . . . By the very terms of the statute the grant is nothing more than a means of preventing others, except under license from the patentee, from appropriating his invention.”). Pharmaceuticals are a particularly illustrative example of this distinction. A patent provides no right to sell a drug in the United States, because—regardless of any patent rights one may claim—approval by the FDA is required prior to have any affirmative right to sell a drug in the United State. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2012).

91. Petition for a Writ of Certiorari, *supra* note 15, at 21; *see also* Brief of Appellees Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc., *supra* note 61, at 22 (stating that under *Actavis*, “absent such a large and unexplained payment, parties are expressly permitted—and even are encouraged—to settle their patent disputes via settlement containing an early-entry license.”).

92. Even the *Lamictal* defendants conceded that a valid patent may be *used* in an anticompetitive manner. *See* Brief of Appellees Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc., *supra* note 61, at 22 (“As the Court in *Actavis* stated, courts have struck down patent licenses only when those licenses are ‘overly restrictive patent licensing agreements’—including situations where parties *improperly used patent licenses to collude and pool patents, fix prices, and/or harm competitors.*”) (emphasis added).

93. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2225 (2013)

Supreme Court decisions. The Supreme Court has consistently evaluated antitrust liability for the exercise of intellectual property based on a review of the factual and legal basis of the conduct at issue, rejecting any categorical immunity.<sup>94</sup> And this is consistent with views expressed by lower courts,<sup>95</sup> academics<sup>96</sup> and the enforcement agencies.<sup>97</sup>

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94. See, e.g., *Am. Needle, Inc. v. NFL*, 560 U.S. 183, 186 (2010) (stating that exclusive trademark license between NFL and Reebok “must be judged under the [flexible] Rule of Reason”); *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 47, 50 (1990) (“[A]greement that gave BRG an exclusive license to market HBJ’s material [such that] HBJ would not compete with BRG in Georgia and that BRG would not compete with HBJ outside of Georgia . . . was unlawful on its face.”); *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 7 (1979) (stating that despite provisions in Copyright Act expressly permitting blanket licenses, blanket license would be judged under antitrust rule of reason); *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 136 (1969); *United States v. Sealy, Inc.*, 388 U.S. 350, 355 (1967); *United States v. Singer Mfg. Co.*, 374 U.S. 174, 195 (1963); *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 378 (1952); *Timken Roller Bearing Co. v. United States*, 341 U.S. 593, 598 (1951) (discussing that allocation of territories incidental to trademark licensing contracts were subject to antitrust scrutiny); *United States v. Line Materials Co.*, 333 U.S. 287, 308 (1948); *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 402 (1948) (Frankfurter, J., concurring).

95. See, e.g., *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 407 (3d Cir. 2015) (“[A]s we read the [*Actavis*] opinion, even exclusive licenses cannot avoid antitrust scrutiny where they are used in anticompetitive ways.”); *New York v. Actavis*, 787 F.3d 638, 660 (2d Cir. 2015) (“Defendants argue that their conduct does not violate antitrust law because they have merely ‘exercised rights afforded by the Patent Act.’ But patent law gives Defendants a temporary monopoly on individual drugs—not a right to use their patents as part of a scheme to interfere with competition ‘beyond the limits of the patent monopoly.’”) (citation omitted) (quoting *Line Materials*, 333 U.S. at 308); *United States v. Microsoft Corp.*, 253 F.3d 34, 63 (D.C. Cir. 2001); *CSU, LLC v. Xerox Corp. (In re Indep. Serv. Orgs. Antitrust Litig.)*, 203 F.3d 1322, 1325 (Fed. Cir. 2000) (“Intellectual property rights do not confer a privilege to violate the antitrust laws.”); *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997) (stating license restrictions “are contractual in nature and are subject to antitrust, patent, contract, and any other applicable law”); *Instructional Sys. Dev. Corp. v. Aetna Cas. & Sur. Co.*, 817 F.2d 639, 644–45 (10th Cir. 1987) (stating exclusive trademark licensing agreement subject to rule of reason, because “[e]ven constitutionally protected property rights such as patents may not be used as levers for obtaining objectives proscribed by the antitrust laws”) (quoting *Ford Motor Co. v. United States*, 405 U.S. 562, 576 n.11 (1972); *Krehl v. Baskin-Robbins Ice Cream Co.*, 664 F.2d 1348, 1355 (9th Cir. 1982) (applying rule of reason to exclusive trademark licensing scheme and citing the possibility that “licenses were merely facades to mask an allocation of markets by pre-existing competitors”); *Ohio-Sealy Mattress Mfg. Co. v. Sealy, Inc.*, 585 F.2d 821, 827 (7th Cir. 1978) (“[I]f Sealy’s license agreement and its conduct thereunder amounted to substantial limitations on manufacturers’ sales territories, a per se violation existed.”).

96. HOVENKAMP ET AL., *supra* note 86, at 7–26 (“Assuming the patent is valid, the Patent Act expressly permits exclusive licensing, but it seems clear that [this] fact alone does not render them immune from antitrust scrutiny.”) (footnote omitted).

97. U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, *supra* note 88, at 16 (“In the vast majority of cases, restraints in intellectual property licensing are evaluated under the rule of reason.”); *id.* at 20–21 (“[T]he licensor may grant an exclusive license, or one or more partially exclusive licenses (such as territorial or field-of-use licenses), which limit the

The few cases cited by the *Lamictal* defendants and others in support of immunity are dated, factually distinguishable, and have been mostly limited to their facts. A case from the early twentieth century seems to be the origin of the claimed legal authority.<sup>98</sup> *E. Bement & Sons v. National Harrow Co.* involved a patent pooling arrangement between various patentees of certain farming equipment that transferred their patents to a single, newly formed patent holding entity authorized to manage and grant licenses to the patents.<sup>99</sup> The primary issue before the *Bement* Court was the legality of a resale price restriction in one of the licenses provided by the patent holding entity.<sup>100</sup> Notwithstanding resale price restrictions being per se antitrust violations at the time, the Court held that the licenses were not unlawful because a patentee has an “absolute freedom in the use or sale of rights under the patent laws.”<sup>101</sup> While this absolutist view on the exercise of patent rights was reflected in a few subsequent cases,<sup>102</sup> it was short-lived.<sup>103</sup>

*United States v. General Electric Co.* seems to be the primary case cited in support of antitrust immunity for licensing practices, but it is far from convincing.<sup>104</sup> *General Electric* involved a distribution scheme for patented incandescent lights by means of offering conditional licenses to over 21,000

ability of the licensor to license others and possibly also to use the technology itself. Generally, such exclusive licenses may raise antitrust concerns only if there is a horizontal relationship among licensors, or among licensees, or between the licensors and its licensee(s).”).

98. See generally *E. Bement & Sons v. Nat’l Harrow Co.*, 186 U.S. 70 (1902).

99. *Id.* at 76–78, 85.

100. *Id.* at 88–89.

101. *Id.* at 91. Today, of course, all resale price restraints—whether patented or not—are subject to the rule of reason. See e.g., *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 877–78 (2007); *State Oil Co. v. Kahn*, 522 U.S. 3, 3–5 (1997).

102. *Cont’l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 424 (1908) (“The inventor is one who has discovered something of value. It is his absolute property. He may withhold the knowledge of it from the public, and he may insist upon all the advantages and benefits which the statute promises to him who discloses to the public his invention.”); *Henry v. A.B. Dick Co.*, 224 U.S. 1, 40 (1903) (“The patentee has the sole right of using and selling the articles, and he may prevent anybody from dealing with them at all. Inasmuch as he has the right to prevent people from using them or dealing in them at all, he has the right to do the lesser thing; that is to say, to impose his own conditions. It does not matter how unreasonable or how absurd the conditions are.”).

103. Beginning with *Motion Picture Patents v. Universal Film Manufacturing Co.*, 243 U.S. 502, 518 (1917)—which overruled *A.B. Dick*—and *Straus v. Victor Talking Machine Co.*, 243 U.S. 490 (1917), the Supreme Court began taking a more critical view of the use of patents to impede competition. See, e.g., *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942) (“[I]t will not do to say that since the patentee has the power to refuse a license, he has the lesser power to license on his own conditions.”).

104. See generally *United States v. Gen. Elec. Co.*, 272 U.S. 476 (1926).

agents.<sup>105</sup> Rejecting the government’s challenge that the licenses and agency distribution scheme were a *per se* illegal sham to control the downstream sales price of the product, the Supreme Court held that the licenses and the “genuine contracts of agency” did not violate the Sherman Act.<sup>106</sup> The Court, citing *Bement*, thus seemed to uphold the validity of nearly any license condition unilaterally imposed by a patentee that is within the “scope of his patent rights.”<sup>107</sup> However, *General Electric* has generally not been broadly interpreted, but rather limited to its facts.<sup>108</sup> Instead, subsequent Supreme Court cases have continued to evaluate antitrust challenges to the exercise of intellectual property rights under traditional antitrust principles.<sup>109</sup> For example, in *United States v. Line Materials Co.*, the Supreme Court rejected antitrust immunity for patents used to fix prices between competitors.<sup>110</sup> The *Line Materials* court also seemingly sought to harmonize *General Electric* with its antitrust jurisprudence by offering the following: “[W]here a *conspiracy to restrain trade or an effort to*

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105. *Id.* at 478.

106. *Id.* at 488.

107. *Id.* at 485 (“It is only when [a patentee] adopts a combination with others, by which he steps out of the scope of his patent rights and seeks to control and restrain those to which he has sold his patented article in their subsequent disposition of what is theirs, that he comes within the operation of the Anti-Trust Act.”). Given *Actavis*’s rejection of the scope of the patent test—one might question whether *General Electric* is still good law on this issue.

108. Over the years, the Supreme Court has both declined to expand upon the case and has limited its application. For example, as recently as May 2017, the Supreme Court held that the Federal Circuit had misread *General Electric* as supporting a limited view of the exhaustion doctrine. See *Impression Prod. v. Lexmark Int’l*, 137 S. Ct. 1523, 1534 (2017).

109. See, e.g., *Am. Needle, Inc. v. NFL*, 560 U.S. 183, 203 (2010) (deciding that exclusive trademark license between NFL and Reebok “must be judged according to the flexible Rule of Reason”); *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 50 (1990) (ruling that market allocation by competing bar review companies effectuated in part by exclusive licenses to copyrighted materials and trademarks *per se* illegal); *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 10, 15–16, 19 (1979) (stating that despite provisions in Copyright Act expressly permitting blanket licenses, blanket license would be judged under antitrust rule of reason); *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 101–03 (1969); *United States v. Sealy, Inc.*, 388 U.S. 350, 350 (1967) (ruling conspiracy to fix prices of trademark licenses *per se* illegal); *United States v. New Wrinkle, Inc.*, 342 U.S. 371 (1952); *Timken Roller Bearing Co. v. United States*, 341 U.S. 593, 598 (1951) (allocating territories incidental to trademark licensing contracts subject to antitrust scrutiny); *United States v. U.S. Gypsum Co.*, 333 U.S. 364 (1948) (finding unlawful conspiracy to fix prices of gypsum and control its sale and distribution via acquiring patents and granting licenses with similar terms and fixed prices); *United States v. Masonite Corp.*, 316 U.S. 265, 280, 282 (1942) (declining to follow *General Electric* and condemning agency agreements between various manufacturers of patented building material as *per se* illegal).

110. *United States v. Line Materials, Co.*, 333 U.S. 287, 308 (1948) (“[T]he possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly.”).

*monopolize is not involved*, a patentee may license to another to make and vend the patented device with a provision that the licensee's sale price shall be fixed by the patentee."<sup>111</sup> Lower courts have similarly largely rejected interpreting *General Electric* to afford any type of antitrust immunity for anticompetitive use of intellectual property.<sup>112</sup> Finally, *Actavis's* clear rejection of the scope of the patent test undermines the legal premise behind *Bement* and other cases relied upon in support of immunity based on a patent grant.

Second, even if one were to conclude that antitrust immunity for exclusive licenses may be appropriate in certain circumstances, Hatch-Waxman settlements are a poor candidate for such protection. As an initial matter, the mere fact that these are horizontal agreements between actual or potential competitors suggests immunity is improper.<sup>113</sup> Moreover, given that many—including the current FDA Commissioner—have criticized pharmaceutical companies for engaging in anticompetitive conduct to delay generic entry,<sup>114</sup>

111. *Id.* at 304 (emphasis added); *see also id.* at 308–10 (“During its term, a valid patent excludes all except its owner from the use of the protected process or product. . . . As we have pointed out, a patentee may license others to make and vend his invention and collect a royalty therefor. . . . The Sherman Act was enacted to prevent restraints of commerce but . . . [t]he monopoly granted by the patent laws is a statutory exception to this freedom for competition . . . . *It is not the monopoly of the patent that is invalid. It is the use of that monopoly, improperly.*”) (emphasis added) (citations omitted).

112. *See e.g.*, *New York v. Actavis PLC*, 787 F.3d 638, 660 (2d Cir. 2015) (“Defendants argue that their conduct does not violate antitrust law because they have merely ‘exercised rights afforded by the Patent Act.’ But patent law gives Defendants a temporary monopoly on individual drugs—not a right to use their patents as part of a scheme to interfere with competition ‘beyond the limits of the patent monopoly.’”) (citations omitted) (quoting *Line Materials*, 333 U.S. at 308); *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 407 (3d Cir. 2015); *United States v. Microsoft Corp.*, 253 F.3d 34, 63 (D.C. Cir. 2001); *CSU, LLC v. Xerox Corp. (In re Indep. Serv. Orgs. Antitrust Litig.)*, 203 F.3d 1322, 1325 (Fed. Cir. 2000); *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997); *Instructional Sys. Dev. Corp. v. Aetna Cas. & Sur. Co.*, 817 F.2d 639, 644–45 (10th Cir. 1987); *Krehl v. Baskin-Robbins Ice Cream Co.*, 664 F.2d 1348, 1355 (9th Cir. 1982); *Ohio-Sealy Mattress Mfg. Co. v. Sealy, Inc.*, 585 F.2d 821, 827 (7th Cir. 1978).

113. *See U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, supra* note 88, at 14 (“[T]he Agencies ordinarily will treat a relationship between a licensor and its licensee, or between licensees, as having a horizontal component when they would have been actual or potential competitors in a relevant market in the absence of the license, even if a vertical relationship also exists.”); *see also id.* at 21 (“Generally, such exclusive licenses may raise antitrust concerns only if there is a horizontal relationship among licensors, or among licensees, or between the licensors and its licensee(s).”).

114. Elizabeth Powell-Bullock, *Gaming the Hatch-Waxman System: How Pioneer Drug Makers Exploit the Law to Maintain Monopoly Power in the Prescription Drug*

immunity for Hatch-Waxman settlements would be especially inappropriate. Finally, a prominent treatise has even argued that No Authorized Generic agreements could potentially be *more harmful* than the cash payment in *Actavis*, even suggesting that such agreements should receive *more* rather than *less* scrutiny.<sup>115</sup>

### III. CONCLUSION

Ever since *Actavis* held that Hatch-Waxman patent settlements could violate antitrust laws, companies entering into such settlements have endeavored to structure and characterize settlements in ways that minimize potential antitrust liability. Thus, settlements involving significant cash payments are rare today. Rather, consideration from the branded drug manufacturer to the generic now tends to be more subtle and indirect, for example by: (1) entering into generous supply or distribution agreements—such as where the generic becomes a distributor or supplier at significantly higher rates than prior/other suppliers or distributors; (2) granting the generic additional, unrelated license(s) on favorable terms—for example, for other products or in other markets; or (3) entering into collateral agreements that may involve entirely different products or markets or ventures—for example, where the branded manufacturer agrees to fund or assist in a research or development collaboration that does not appear consistent with its own strategy.

This article evaluates No Authorized Generic provisions, a fairly recent but increasingly prevalent provision used in Hatch-Waxman settlements. In these provisions, the branded company typically both grants a license to the generic and agrees not to launch an authorized generic for a certain period of time. Although many have criticized these provisions as anticompetitive non-compete agreements, others have defended them as

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*Market*, 29 J. LEGIS. 21, 25–26, 29 (2002); Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, 4 INNOVATION POL'Y & ECON. 145, 155, 178 (2004); Jayne O'Donnell, *FDA Chief Says Drug Makers are Gaming the System to Slow Generic Competition; Vows Action*, USA TODAY (Aug. 15, 2017, 5:38 PM), <https://www.usatoday.com/story/news/politics/2017/08/15/fda-chief-says-drug-makers-gaming-system-slow-generic-competition-vows-action/568698001/> [<https://perma.cc/YX8F-Y7W6>].

115. See PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION, at pt. 2046 (Wolters Kluwer Supp. 2016) (“No Authorized Generic” agreements in fact place a second market exclusion agreement (i.e., generic vs generic, for 180 days) on top of the first one, which was at issue in *Actavis* itself (pioneer versus generic for the term of the settlement). The outcome is more anticompetitive than a large cash payment for delay. . . . provision compensates the generic with something far more troublesome [than cash]—namely a second market division that serves to keep prices higher during the 180-day period when other generic firms are unable to enter the market.”).

a procompetitive resolution to years of patent litigation. In the *Lamictal* litigation, defendants went even further in defending the legality of these provisions by (1) characterizing them as typical exclusive licenses rather than non-compete agreements, (2) arguing that such provisions are not subject to *Actavis*, and (3) arguing that because exclusive licenses are common and often procompetitive, that they should be immune from antitrust. Most of these arguments do not carry the day. Even if a particular No Authorized Generic provision were deemed a bona fide exclusive license, there is no legal support for immunizing it from antitrust scrutiny. Rather, as with most restrictions, it would be subject to standard antitrust rule of reason analysis. Nevertheless, even though the *Lamictal* defendants' arguments in favor of antitrust immunity should fail, the effort to characterize and structure Hatch-Waxman settlements using exclusive licenses may not be entirely in vain, as courts tend to give greater deference to patents—and thus patent licenses—than non-compete agreements between competitors.



