

# THE CURIOUS CASE OF *WELLBUTRIN*: HOW THE THIRD CIRCUIT MISTOOK ITSELF FOR THE SUPREME COURT

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## INTRODUCTION

*FTC v. Actavis*<sup>1</sup> was one of the most important antitrust cases of the modern era. In one fell swoop, the Supreme Court ensconced antitrust’s role in analyzing settlements by which brand firms pay generics to delay entering the market. The Court underscored the harms presented by large and unjustified payments and rejected some of the prized justifications that settling parties had previously offered.

Since *Actavis*, the lower courts have begun to flesh out the antitrust analysis of drug patent settlements. In particular, the federal appellate courts have held that payment extends beyond cash to noncash forms of consideration<sup>2</sup> and have liberally interpreted the pleading requirements for noncash conveyances.<sup>3</sup>

A recent opinion, however, threatens the orderly development of the post-*Actavis* case law. In analyzing plaintiffs’ claim of antitrust injury in *In re Wellbutrin XL Antitrust Litigation*,<sup>4</sup> a Third Circuit panel mistook itself for the Supreme Court. The plaintiffs had alleged that the generic

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<sup>1</sup> 570 U.S. 136 (2013).

<sup>2</sup> *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538 (1st Cir. 2016); *King Drug Co. v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015).

<sup>3</sup> *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017).

<sup>4</sup> 868 F.3d 132 (3d Cir. 2017).

would have entered the market earlier if not for the settlement, but the Third Circuit found that they could not make such a showing because they did not definitively prove that the patent was invalid or not infringed. The panel only reached this conclusion, however, by studiously ignoring the evidence of a large and unjustified payment that the Supreme Court had indicated was a surrogate for the patent's weakness and accepting a defense based on avoiding risk that the Supreme Court had rejected.

This Essay first provides a background on pharmaceutical patent settlements. It then discusses the *Actavis* and *Wellbutrin* cases. Finally, it shows how the Third Circuit panel issued a ruling that was based on inappropriate assumptions and is inconsistent with Supreme Court case law, Third Circuit precedent, and relevant regulatory policies.

## I

### SETTLEMENT BACKGROUND

Brand and generic firms often settle patent infringement cases. Most of these settlements do not present antitrust concerns. Some do not delay entry at all. For example, in its most recent annual report, the Federal Trade Commission ("FTC") found that 20 out of 160 settlements between brands and generics in 2013 and 2014 did not restrict generic entry.<sup>5</sup>

Other settlements do not involve payment. The FTC report found that 111 settlements contained a restriction on entry but did not provide compensation.<sup>6</sup> Courts and the FTC have concluded that these "patent-term split agreements" do not violate the antitrust laws because they involve the parties dividing the patent term by selecting a date for generic entry based on the strength of the patent.<sup>7</sup> The greater the likelihood that the patent is valid and infringed, the later in the period generic entry would be expected.

It is the last category of payment and delayed entry (21 settlements<sup>8</sup>) that presents concern. These payments have

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<sup>5</sup> Bureau of Competition, Fed. Trade Comm'n, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2014, at 2 (2016) [hereinafter 2014 Report], available at <https://www.ftc.gov/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement-0> [https://perma.cc/66PM-XL3Z].

<sup>6</sup> *Id.*

<sup>7</sup> Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 60 (2009).

<sup>8</sup> 2014 Report, *supra* note 5, at 1.

been called “reverse payments” because the consideration flows from patentee to alleged infringer (unlike typical settlements in which alleged infringers pay patentees).<sup>9</sup> A brand is likely to gain additional exclusivity not warranted by the strength of the patent by supplementing the parties’ entry-date agreement with a payment to the generic. And the quid pro quo for the payment would appear to be the generic’s agreement to stay out of the market beyond the date that otherwise reflects the parties’ assessment of the patent’s strength and likely outcome of litigation.

The antitrust analysis of reverse-payment settlements has varied. In 2003, in the first federal appellate ruling, *In re Cardizem CD Antitrust Litigation*,<sup>10</sup> the Sixth Circuit concluded that a settlement that prevented a generic from marketing products not covered by the patent was “a horizontal agreement to eliminate competition[,] . . . a classic example of a per se illegal restraint of trade.”<sup>11</sup>

Courts, however, quickly retreated from such analysis, turning to a test that essentially immunized activity falling within the “scope of the patent.” The Federal Circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*,<sup>12</sup> for example, found that settlements fell “well within” the patentee’s rights, that patents bestowed “the right to exclude others,” and that the crucial inquiry was “whether the agreements restrict competition beyond the exclusionary zone of the patent.”<sup>13</sup> In addition to relying on the scope of the patent, courts upheld the agreements by emphasizing the importance of settlements, the link between settlements and innovation, the presumption of patent validity, and the “natural” status of reverse payments.<sup>14</sup> In July 2012, however, in *In re K-Dur Antitrust Litigation*,<sup>15</sup> the Third Circuit rejected the scope-of-the-patent test, explaining that it assumed the validity at issue in the case and was not relevant when the issue is infringement (on which

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<sup>9</sup> Carrier, *supra* note 7, at 60.

<sup>10</sup> 332 F.3d 896 (6th Cir. 2003).

<sup>11</sup> *Id.* at 908.

<sup>12</sup> 544 F.3d 1323 (Fed. Cir. 2008).

<sup>13</sup> *Id.* at 1332–33, 1336; *see also* Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1076 (11th Cir. 2005); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006); F.T.C. v. Watson Pharms., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012) (holding, in each case, that exclusion within the scope of the patent does not constitute unlawful restraint).

<sup>14</sup> Carrier, *supra* note 7, at 60–67.

<sup>15</sup> 686 F.3d 197 (3d Cir. 2012), *judgment vacated sub nom.* Merck & Co. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013).

the patentee bears the burden of proof).<sup>16</sup>

In 2013, in *FTC v. Actavis*,<sup>17</sup> the Supreme Court resolved the split among the courts by rejecting the scope-of-the-patent test. The Court found it “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.”<sup>18</sup>

The Court found that the settlement at issue had the “potential for genuine adverse effects on competition” because “payment in return for staying out of the market . . . keeps prices at patentee-set levels . . . .”<sup>19</sup> In addition, the Court highlighted the harms from a payment to a generic, which “in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product.”<sup>20</sup>

The Court revealed its strong preference for determining patent strength by examining the payment rather than the patent. The “size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”<sup>21</sup> Even strong patents are not immune from the concern with payments, because an unexplained payment on a “particularly valuable patent . . . likely seeks to prevent the risk of competition,” with this consequence “constitut[ing] the relevant anticompetitive harm.”<sup>22</sup> Finally, the Court found that the policy in favor of settlement did not immunize the agreements because of five arguments that centered on reverse payments’ (1) anticompetitive effects, (2) lack of justification, and (3) market power, along with (4) the feasibility of judicial analysis and (5) parties’ ability to settle without payment.<sup>23</sup>

The Court concluded that “the FTC must prove its case as in other rule-of-reason cases.”<sup>24</sup> And it instructed future courts to analyze payments’ “size, . . . scale in relation to the payor’s anticipated future litigation costs, . . . independence

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<sup>16</sup> *Id.* at 214.

<sup>17</sup> 570 U.S. 136 (2013).

<sup>18</sup> *Id.* at 137.

<sup>19</sup> *Id.* at 153–54.

<sup>20</sup> *Id.*

<sup>21</sup> *Id.* at 158.

<sup>22</sup> *Id.* at 157.

<sup>23</sup> *Id.* at 153–58.

<sup>24</sup> *Id.* at 159.

from other services for which it might represent payment, and . . . lack of any other convincing justification.”<sup>25</sup>

## II

### WELLBUTRIN: BACKGROUND

In *In re Wellbutrin XL Antitrust Litigation*,<sup>26</sup> purchasers of Wellbutrin XL, a drug treating depression, challenged conduct that delayed generic entry. Some of the conduct, targeting sham litigation and sham citizen petitions, lies outside the scope of this Essay. But the plaintiffs also alleged that the generic delayed entering the market because of a settlement involving payment from the brand company.<sup>27</sup>

One of the Court’s central concerns in *Actavis* was that the brand would pay the generic to “prevent the risk of competition”<sup>28</sup> and “induce the generic challenger to abandon its claim.”<sup>29</sup> Along these lines, the district court addressed an atypical settlement by which the generic “did not ‘abandon its claim’ and continued to litigate the patent litigation[,] . . . maintaining the risk of a finding of patent invalidity or non-infringement . . . .”<sup>30</sup> As a result, the district court found that the settlement did not “present the same antitrust concerns that motivated the court in *Actavis* to subject the settlement to antitrust scrutiny” and granted defendants’ motion for summary judgment.<sup>31</sup>

The Third Circuit appropriately reversed the district court on this point, finding that agreements that do “not end [patent] litigation . . . nevertheless implicate the kinds of concerns articulated in *Actavis* . . . .”<sup>32</sup> Although the correct result, the court’s level of remorse at reaching this outcome was striking: “The view of the law espoused by the FTC, adopted by the majority in *Actavis*, and followed by our Court in *King*, has been subject to cogent criticism, . . . but the controlling precedent is what it is.”<sup>33</sup>

The Third Circuit then addressed the issue of antitrust standing, which requires a showing of antitrust injury, or

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<sup>25</sup> *Id.*

<sup>26</sup> 868 F.3d 132 (3d Cir. 2017).

<sup>27</sup> *Id.* at 142.

<sup>28</sup> 570 U.S at 157.

<sup>29</sup> *Id.* at 154.

<sup>30</sup> *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 752 (E.D. Pa. 2015).

<sup>31</sup> *Id.*

<sup>32</sup> *In re Wellbutrin*, 868 F.3d at 152 n.50.

<sup>33</sup> *Id.* at 152–53 n.50.

“injury of the type the antitrust laws were intended to prevent and that flows from that which makes [the] defendants’ acts unlawful.”<sup>34</sup> To establish antitrust injury, the plaintiffs “must show that the harm they say they experienced—increased drug prices for Wellbutrin XL (and its generic equivalents)—was caused by the settlement they are complaining about.”<sup>35</sup> The plaintiffs introduced evidence showing that the generic would have entered the market before the date allowed under the settlement.<sup>36</sup> But the court found that such a showing “does not take into account [the] blocking patent.”<sup>37</sup> And “if the launch were stopped because it was illegal,” then the injury “would be caused not by the settlement but by the patent laws prohibiting the launch.”<sup>38</sup>

The plaintiffs responded that the generic would have been able to launch because, pursuant to its “litigation-based scenario,”<sup>39</sup> “in the absence of the challenged agreements, [the generic] would have prevailed against [the brand] in litigation.”<sup>40</sup> The court rejected this argument, but only after making a number of unsupported assumptions.

### III

#### WELLBUTRIN: UNSUPPORTED ASSUMPTIONS

The Third Circuit dismissed plaintiffs’ litigation-based scenario in two paragraphs.<sup>41</sup> Though not lengthy, the potential for mischief from this condensed discussion is significant. For starters, the section consisted of six unsupported assumptions.

First, while conceding that “the size of a reverse payment

<sup>34</sup> *Id.* at 164 (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)).

<sup>35</sup> *Id.* at 164–65.

<sup>36</sup> *Id.* at 165.

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

<sup>38</sup> *Id.* For a powerful critique of the assertion that a plaintiff must prove the legality of an at-risk launch that highlights its formalistic nature and contrasts it with *Actavis*’s direction to not litigate patent validity, see Kevin Soter, Note, *Causation in Reverse Payment Antitrust Claims*, 70 STAN. L. REV. (forthcoming 2018) (manuscript at 29–32) ([https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3026787](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3026787)) [<https://perma.cc/3XHN-Z7LK>].

<sup>39</sup> *In re Wellbutrin*, 868 F.3d at 166.

<sup>40</sup> *Id.* The plaintiffs also contended that the generic would have obtained a license to the patent, a position that the court dismissed. *Id.*

<sup>41</sup> The discussion in this section focuses on the general argument that a payment’s size acts as a surrogate for a patent’s weakness rather than the more specific discussion of an expert’s testimony on the likelihood of proving noninfringement, invalidity, and inequitable conduct. *Id.* at 167–69.

may have some relevance in determining how confident a litigant is in the strength of its case,” the panel averred that this was “far from dispositive.”<sup>42</sup> That, however, is not the standard—certainly not for a party opposing summary judgment. The role of an appellate court reviewing a summary judgment grant is not to make dispositive findings, but only to determine, viewing the facts in the light most favorable to the non-moving party, that “there is no genuine dispute as to any material fact.”<sup>43</sup>

Second, the panel carved out special rules for “complex and multi-faceted” settlements, claiming that such arrangements are particularly likely to lack a connection between a payment and the patent’s weakness.<sup>44</sup> But such a rule was nowhere articulated—or even intimated—in *Actavis*, which *itself* addressed a complex settlement involving agreements with multiple generics over varied time periods for unrelated services.<sup>45</sup>

Third, the panel hypothesized reasons for payment based on the brand’s “improper[] evaluat[ion]” of the patent.<sup>46</sup> But such hypothesis does not bear support in *Actavis*, which made clear that an “unexplained large reverse payment . . . suggests that the payment’s objective is to maintain supracompetitive prices to be shared among the patentee and the challenger . . . .”<sup>47</sup> In fact, earlier in its opinion, the panel conceded that the \$233 million payment “can be said to be large” and “unjustified in the sense of being unexplained.”<sup>48</sup>

Fourth, and relatedly, the panel found “multiple plausible ways” to interpret the brand’s payment.<sup>49</sup> But it did so only by adopting justifications that—even if long advocated by settling parties and some economists—*Actavis* rejected.

Fifth, the panel was “persuaded” by an argument in an amicus brief submitted by economists that resuscitated the

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<sup>42</sup> *Id.* at 168.

<sup>43</sup> FED. R. CIV. P. 56(a); *see, e.g.*, *Van Orden v. Borough of Woodstown New Jersey*, 703 F. App’x 153, 156 (3d Cir. 2017) (explaining that summary judgment is only appropriate when there is no factual dispute between the parties).

<sup>44</sup> *In re Wellbutrin*, 868 F.3d at 168.

<sup>45</sup> *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 144–45 (2013); *cf.* Aaron Edlin et al., *Activating Actavis*, 28 ANTITRUST 16, 18 (2013) (“The parties to a payment for delay have ample reason to pack complexities into the deal . . . to conceal its genuine nature.”).

<sup>46</sup> *In re Wellbutrin*, 868 F.3d at 168.

<sup>47</sup> *Actavis*, 570 U.S. at 157.

<sup>48</sup> *In re Wellbutrin*, 868 F.3d at 162.

<sup>49</sup> *Id.* at 168.

risk-aversion defense rejected in *Actavis*.<sup>50</sup> This brief offered a “lottery” example that showed nothing more than brand firms’ desire for certainty rather than taking the chance of losing the patent case.<sup>51</sup> Again, the Supreme Court rejected this argument in *Actavis*.

And sixth, the panel conveniently found the economists’ reasoning to “effective[ly] rebut[]” the argument that a payment’s size is a surrogate for the patent’s weakness.<sup>52</sup> But it is difficult to see how a panel of a lower court can employ an argument the *Actavis* majority *rejected* to “rebut” an argument the majority *accepted*.

In short, the Third Circuit panel’s ruling is unsupported on multiple grounds. At the same time, it also is inconsistent with the case law.

#### IV

##### INCONSISTENCY WITH *ACTAVIS*

As discussed above,<sup>53</sup> the importance of the Supreme Court’s *Actavis* decision cannot be overstated. The Court made clear that antitrust has a role to play within the scope of the patent and found that the policy in favor of settlement did not dictate the outcome because of multiple contravening factors.<sup>54</sup>

In opposition to other courts, the Court found that it was “feasible” for a court to evaluate the antitrust effects of settlements because “it is normally not necessary to litigate patent validity to answer the antitrust question.”<sup>55</sup> The reason is that “[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival.”<sup>56</sup> Such doubts “suggest[] that the payment’s objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market . . . .”<sup>57</sup> In fact, “the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity

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<sup>50</sup> *Id.* Even if there were a defense based on risk aversion, that would present only a question of fact, not a basis on which to grant summary judgment.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 168–69.

<sup>53</sup> *See supra* Part I.

<sup>54</sup> *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 153–58 (2013).

<sup>55</sup> *Id.* at 157.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

of the patent itself.”<sup>58</sup>

Not only did the Court make clear that a large unexplained payment can serve as a proxy for the patent’s weakness, but it also specifically jettisoned one of the settling parties’ prized defenses: that a brand might pay a generic to obtain certainty on a “particularly valuable patent.”<sup>59</sup> The Court explained that this certainty (despite its obvious benefits for the brand firm) has a steep price. In particular, it blocks the “risk of competition,” which (for the consumer, the focus of antitrust law) “constitutes the relevant anticompetitive harm.”<sup>60</sup>

In rejecting arguments based on avoiding the risk of competition, the Court dispensed with the “risk aversion” defense long advocated by settling parties (and some economists), including in *Actavis* itself. For example, in *Actavis*, a group of economists filed an amicus brief that asserted that reverse payments “may . . . be necessary for brand companies to overcome bargaining disadvantages caused by risk aversion.”<sup>61</sup> The brief also stated that “[b]rand companies are likely to be more risk averse than their generic challengers because they usually have significantly more to lose from a negative trial outcome.”<sup>62</sup> And it contended that “the size of a reverse payment generally does not provide a reliable benchmark to determine whether the payment is anticompetitive.”<sup>63</sup> Faced squarely with these justifications, the Court refused to accept them.<sup>64</sup>

In short, the Supreme Court’s landmark holdings in *Actavis* cannot be reconciled with the Third Circuit’s ruling, which downplayed the connection between payment and patent weakness and resuscitated the defense based on risk that the Supreme Court had rejected.

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<sup>58</sup> *Id.* at 158; see also Aaron Edlin et al., *The Actavis Inference: Theory and Practice*, 67 RUTGERS UNIV. L. REV. 585, 618 (2015) (“The best information the antitrust court has regarding the parties’ *ex ante* beliefs about patent validity and infringement is likely to come from the terms of the agreement they reached.”).

<sup>59</sup> *Actavis*, 570 U.S. at 157.

<sup>60</sup> *Id.* Preventing the risk of competition constitutes anticompetitive harm even if a plaintiff is not able to show that the generic was more likely than not to win the patent litigation.

<sup>61</sup> Brief of Antitrust Economists as Amici Curiae in Support of Respondents at 3, *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013) (No. 12-416).

<sup>62</sup> *Id.* at 20.

<sup>63</sup> *Id.* at 21.

<sup>64</sup> See *supra* note 57 and accompanying text; see generally HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 16.01[D], at 16–26 (3d ed. 2017) (“[T]he Court did not accept as a justification risk aversion or the patentee’s desire to convert an uncertain patent right into a certain one without litigation.”).

## V

## INCONSISTENCY WITH THIRD CIRCUIT CASE LAW

The panel's opinion also is inconsistent with Third Circuit precedent. The Third Circuit in *King Drug Co. v. Smithkline Beecham Corp.*<sup>65</sup> appropriately recognized the Supreme Court's holding in *Actavis* that "it is the prevention of th[e] risk of competition—eliminating 'the risk of patent invalidation or a finding of noninfringement' by 'paying the challenger to stay out' of the market . . . that 'constitutes the relevant anticompetitive harm.'"<sup>66</sup> The Third Circuit found that no-authorized-generic agreements threaten "the same types of problems" as cash payments, each of which arises from the elimination of the risk of competition.<sup>67</sup>

In *King Drug*, the Third Circuit recognized that "[i]f the brand uses a no-[authorized-generic] 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)."<sup>68</sup> As a result, "a brand agreeing not to produce an authorized generic may thereby have 'avoid[ed] the risk of patent invalidation or a finding of noninfringement.'"<sup>69</sup>

Nor is that the only inconsistency between the opinion and other law in the Third Circuit. Less than two weeks after the panel decision, the Third Circuit issued another opinion that cannot be reconciled with the ruling. In *In re Lipitor Antitrust Litigation*,<sup>70</sup> the court highlighted the importance of "the size of the reverse payment," which "serves at least two functions in assessing that payment's lawfulness": showing market power and "signify[ing] that the payment seeks to avoid invalidation of the disputed underlying patent."<sup>71</sup>

The Third Circuit, appropriately following *Actavis*'s teachings (which apply to determinations of liability and causation), explained in *Lipitor* that "[a] patent holder may be concerned about the validity of its patent, and so the size of the payment may very well correspond with the magnitude of that concern."<sup>72</sup> Applying such principles to the case at hand, the court found that the brand's forgiveness of damages in a

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<sup>65</sup> 791 F.3d 388 (3d Cir. 2015).

<sup>66</sup> *Id.* at 404 (quoting *Actavis*, 133 S. Ct. at 2236–37).

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

<sup>68</sup> *Id.* at 405.

<sup>69</sup> *Id.* (quoting *Actavis*, 133 S. Ct. at 2236).

<sup>70</sup> 868 F.3d 231 (3d Cir. 2017).

<sup>71</sup> *Id.* at 251.

<sup>72</sup> *Id.*

separate case (which, incidentally, was at least as complicated as the arrangement in *Wellbutrin*) “was ‘large’ enough to permit a plausible inference that [the brand] possessed the power to bring about an unjustified anticompetitive harm through its patents *and had serious doubts about the ability of those patents to lawfully prevent competition.*”<sup>73</sup> Such a ruling, firmly rooted in *Actavis*, cannot be reconciled with the *Wellbutrin* opinion.

## VI

### INCONSISTENCY WITH RELEVANT POLICY

Finally, the ruling is not consistent with the relevant regulatory policies. As the Supreme Court in *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP*<sup>74</sup> made clear, “[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue,” and courts must take “careful account” of “the pervasive federal and state regulation characteristic of the industry.”<sup>75</sup>

One central objective of the Hatch-Waxman Act, Congress’s comprehensive legislation balancing competition and innovation in the pharmaceutical industry, was to promote generic competition. The drafters permitted generics to experiment on brand drugs during the patent term and allowed generics to avoid the expensive and lengthy process of receiving “new drug” approval by demonstrating equivalence to the brand and relying on the brand’s clinical studies.<sup>76</sup> Congress was so motivated to encourage patent challenges that it granted a valuable 180-day period of exclusivity—potentially “worth several hundred million dollars” according to the Supreme Court<sup>77</sup>—to the first generic to file a “Paragraph IV” certification, seeking to enter before the end of the patent term on the grounds that the patent was invalid or not infringed.<sup>78</sup>

The policy of encouraging patent challenges finds support not only in the Hatch-Waxman Act but also in patent law. As the Supreme Court recognized in *Actavis*, a crucial “patent-related policy” is to “eliminat[e] unwarranted patent

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<sup>73</sup> *Id.* at 255 (emphasis added).

<sup>74</sup> 540 U.S. 398 (2004).

<sup>75</sup> *Id.* at 411.

<sup>76</sup> 35 U.S.C. § 271(e)(1) (2012); 21 U.S.C. § 355(j)(2)(A) (2012).

<sup>77</sup> *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 144 (2013).

<sup>78</sup> 21 U.S.C. § 355(j)(5)(B)(iv) (2012).

grants so the public will not ‘continually be required to pay tribute to would-be monopolists without need or justification.’<sup>79</sup>

As it turns out, patent challenges are critical in the context of settlements, with a comprehensive empirical study concluding that the vast majority—89%—of patents in settled litigation are secondary patents covering ancillary aspects of drug innovation (such as formulation or composition) rather than the active ingredient.<sup>80</sup> The brand firm is far less likely to win on these secondary patents (32%) than it is on active ingredient patents (92%).<sup>81</sup>

#### CONCLUSION

In the wake of the landmark *Actavis* decision, lower courts have addressed multiple nuanced issues. But while certain topics, such as the precise form of antitrust analysis, are appropriate for debate, relitigating matters decided in *Actavis* is not.

In analyzing the litigation-based scenario, the Third Circuit panel relied on unsupported assumptions and offered an opinion inconsistent with Supreme Court case law, Third Circuit precedent, and the policies at the heart of the Hatch-Waxman Act and patent law. As the law develops after *Actavis*, this is not a promising development.

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<sup>79</sup> *Actavis*, 570 U.S. at 151 (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).

<sup>80</sup> C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013).

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