

# Welcome to the Wild, Wild West: *Actavis* Five Years Later

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**F**IVE YEARS AGO, THE U.S. SUPREME Court altered the antitrust analysis that applies to settlements of pharmaceutical patent litigation. In its landmark 2013 decision in *FTC v. Actavis*, the Supreme Court held that such a settlement is subject to antitrust scrutiny under the rule of reason if it contains a “reverse payment”—that is a “large and unjustified” payment flowing from the patentee brand company to the alleged generic infringer.<sup>1</sup> In so doing, the Court left the task of structuring the rule of reason in this context to the lower courts—a task for which Chief Justice Roberts famously wished “good luck to the district courts.”<sup>2</sup>

Five years later, uncertainty shrouds the post-*Actavis* landscape as the decision has sown a disorderly mishmash of lower court opinions.<sup>3</sup> Three aspects of *Actavis* have consumed courts’ attention: what constitutes a “large and unjustified” reverse payment; how to structure the rule of reason framework; and the role of the patent in antitrust injury.<sup>4</sup> Though some limited consensus has emerged regarding these issues, the overall status was perhaps best described by defense counsel in *Apotex, Inc. v. Cephalon, Inc.*, the second case to go to trial since *Actavis*: “The truth of the matter is . . . you can read [*Actavis*] over again, you can read the subsequent cases, it’s the wild, wild west.”<sup>5</sup>

## What Is a “Large and Unjustified” Payment Under *Actavis*?

The lion’s share of uncertainty post-*Actavis* has centered on what qualifies as a “large” and “unjustified” payment. In fact, nearly every decision since *Actavis* has analyzed some aspect of the issue—from what it means for a payment to be “large and unjustified,” to even what constitutes a “payment”

in the first place. Though some consensus has emerged regarding the latter, the former still engenders discord. Subsequent decisions, for example, have emphasized that whether a payment was “large and unjustified” “requires viewing the payment in the context of the facts of the case, which may include business considerations that are less tangible or quantifiable.”<sup>6</sup>

## What Is a “Payment”?

A threshold question tackled by courts in the immediate aftermath of *Actavis* was what form an alleged reverse “payment” must take. Although some district courts initially limited *Actavis*’ application to cash payments only,<sup>7</sup> the reversal of those decisions has paved a consensus to the contrary. That is, antitrust scrutiny attaches to cash and non-cash payments alike.<sup>8</sup> Non-cash reverse payments that are now subject to antitrust scrutiny under *Actavis* include, among others, so-called No-AG agreements (short for No-Authorized Generics, it is an agreement by the brand not to launch an authorized generic version of the drug during the generic’s 180-day exclusivity period),<sup>9</sup> other business arrangements like product development and co-promotion agreements,<sup>10</sup> and settlements of other litigation.<sup>11</sup>

## What Is a “Large” Payment?

The Court in *Actavis* did not expressly define what constitutes a “large” payment. As a result, the decisions since *Actavis* generally make clear that what is “large” is a circumstance and fact-driven inquiry devoid of bright lines.<sup>12</sup>

To date, the guidepost that has received the most analysis is the brand company’s saved litigation costs. This is a product of *Actavis* itself. As the Court made clear, “The likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”<sup>13</sup> Though specifically identified as a factor by the Court, the weight of post-*Actavis* decisions has tilted heavily against an analysis that is simply a comparison to saved litigation costs. Indeed, the majority of decisions that analyze “large” hold that saved litigation costs are not dispositive and must be accompanied by additional considerations.<sup>14</sup>

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In *Aggrenox*, the district court reasoned that “[e]ven if the payments exceed avoided litigation costs, the *Actavis* factors . . . still matter.”<sup>15</sup> Similarly, in *Opana*, the court stated in no uncertain terms: “A ‘large’ payment is anything more than the value of the avoided litigation costs *plus* any other services provided from the generic to the brand manufacturer.”<sup>16</sup> Even more, the court in *K-Dur* held on summary judgment that a large payment exists if “the brand-name company paid the generic company consideration of some kind” in the settlement and that consideration “exceeded the estimated cost of litigation *and* the costs of other services and products.”<sup>17</sup> Thus, courts are generally in agreement on the lower bound of what is large. As the court in *Aggrenox* aptly put: “payments smaller than avoided litigation costs,” are presumptively valid payments under *Actavis*, and “represent a *de facto* safe harbor,” and “payments exceeding avoided litigation costs are not automatically deemed unlawful for that reason alone.”<sup>18</sup>

Given the open-ended nature of the inquiry, the issue of what goes into the “large” analysis has been hotly disputed in two of the three post-*Actavis* cases put before a jury—*Modafinil* and *Solodyn*.<sup>19</sup> Each offers a helpful window into “how in the heck a trial judge (and a jury) is supposed to apply the *Actavis* decision to an actual case.”<sup>20</sup>

In *Modafinil*, the court first instructed the jury that “[w]hether a payment is large depends on the specific facts and circumstances of this case.”<sup>21</sup> Then, consistent with its analysis at summary judgment,<sup>22</sup> the court instructed the following: “[f]irst, you must ask whether the payment exceeds the patent holder’s . . . anticipated future litigation costs,” and “[s]econd, you must consider whether the payment was significant enough to induce a generic challenger . . . to abandon its patent claim and stay off the market.”<sup>23</sup> To illuminate the second question, the court added: “you may consider . . . whether the payment comes close to or exceeds the expected profit to be earned by [the generic] if it had prevailed in the patent litigation.”<sup>24</sup>

*Modafinil* is also noteworthy because the defendant was permitted to offer evidence comparing the alleged size of the reverse payment to the brand’s profits for the patented product. Such a comparison finds support in *Actavis* itself. For example, the Court in *Actavis* recognized the relevance of a patent’s value when it said that it is inappropriate to measure whether a reverse payment is legal based “solely against the length of the patent’s term or its earning potential,” and that “traditional antitrust factors” must be considered.<sup>25</sup> Though such evidence regarding the size of the payment relative to the brand company’s potential earnings under its patent does not “immunize” a reverse payment agreement “from antitrust attack,”<sup>26</sup> it does appear to be relevant to whether the payment is “large.”

More recently, the court in *Solodyn* agreed that a comparison between the alleged size of the reverse payment and the brand’s profits is relevant to the “large” inquiry. The plaintiffs in that case—based in part on what happened in *Modafinil*—filed a motion in limine seeking to exclude certain

arguments and evidence regarding “large,” including comparisons between the amount of the alleged reverse payment to the brand’s “sales or profits” from *Solodyn*, or to the “potential profits” the brand “stood to lose” upon generic entry.<sup>27</sup> The court declined the invitation to “narrow the evidence at trial as to whether the payment from [the brand] to the [the generic] . . . was ‘large.’”<sup>28</sup> Instead, the court made clear that “whether a reverse payment was ‘large and unjustified’ *requires* viewing the payment in its factual context, which may include certain business realities,” and such evidence was introduced to the jury.<sup>29</sup>

### What Is an “Unjustified” Payment Under *Actavis*?

*Actavis* arguably provides more detail regarding what payments are likely considered “unjustified.” The Court offered several examples of payments that escape antitrust scrutiny. They include: (1) payments that are “no more than rough approximation” of avoided litigation expenses; (2) payments that “reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item;” (3) payments that reflect “traditional settlement considerations;” or (4) payments that offer “any other convincing justification.”<sup>30</sup> And, importantly, as the Third Circuit has held, the preceding list “do[es] not exclude other possible legitimate explanations from also justifying reverse payment settlement agreements.”<sup>31</sup> The sum of post-*Actavis* decisions on this point make clear that whether a payment is unjustified is an open-ended inquiry that may be assessed separately or shoehorned into the “amorphous” rule of reason and battled over in the burden-shifting framework.<sup>32</sup> As a consequence, *Actavis* offers litigants flexibility in proffering justifications for the payment. The permissibility of particular justifications has been largely case-specific.

Recently, the Third Circuit shed light on the meaning of “unjustified” in the context of determining whether a challenged settlement posed the potential anticompetitive harm identified by the Supreme Court in *Actavis* (such that the rule of reason analysis applied).<sup>33</sup> Specifically, the court in *Wellbutrin* stated that a No-AG agreement included in the challenged settlement “could [] be said to be unjustified in the sense of being unexplained.”<sup>34</sup> The No-AG at issue could be unexplained, according to the court, because it (1) “was not tied to the merits of the litigation” and (2) its duration was “fixed at 180 days, regardless of who prevailed in the case.”<sup>35</sup> The court, however, noted that it was making no “comment on whether a no-AG promise could be justified in the sense of being a sound exercise of business judgment and consonant with good public policy.”<sup>36</sup>

*Solodyn* is another recent example of note demonstrating the breadth of the “unjustified” inquiry. There, the court declined to exclude the defendant’s expert, who opined on the commercial reasonableness of a joint product development agreement executed contemporaneously to the patent litigation settlement.<sup>37</sup> The court credited the defendant’s argument

that “whether [the joint product development agreement] was commercially reasonable is relevant to whether the reverse payment was justified.”<sup>38</sup> That holds true, the court reasoned, because “antitrust litigation often requires an elaborate inquiry into the reasonableness of a challenged business practice.”<sup>39</sup> And, as stated in its denial of the motion in limine, answering the “large and unjustified” question “requires viewing the payment in the context of the facts of the case, which may include business considerations that are less tangible or quantifiable.”<sup>40</sup>

The court in *Solodyn* also wrestled with another common explanation to justify a reverse payment: “fair value” for services. Such a justification can be relevant where, in addition to resolving patent litigation, the parties enter into contemporaneous business agreements. Examples of such arrangements that have been challenged as reverse payments include product distribution agreements, pharmaceutical ingredient supply agreements, product development collaborations, and intellectual property licenses.<sup>41</sup> A “fair value” exchange for those services is considered a “traditional settlement consideration” under *Actavis* because “there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement.”<sup>42</sup>

Although fair payment for goods and services may not be a “silver bullet against antitrust scrutiny,” evidence that such payments are for fair value can justify a payment under *Actavis*.<sup>43</sup> Conversely, evidence that such payments exceed fair value can rebut a defendant’s explanation used to justify the payment.<sup>44</sup> But, not surprisingly, what is considered “fair value” is disputed. The court’s decision in *Solodyn* on this point is instructive. There, the court rejected plaintiffs’ “narrow definition” that fair value “requires ‘arms-length, objective, market based measurement’ of the services [the generic] promised to perform.”<sup>45</sup> The court made clear that other “acceptable methods” exist for calculating fair value and remained unconvinced that a focus on “the brand’s perspective of future earnings [under the joint development agreement] is irrelevant to the question of fair value.”<sup>46</sup>

Other courts have similarly considered a broad range of evidence in assessing “fair value” for services, including, for example, the economic value to the brand, the brand’s need for the services/products it is buying from the generic, and the typicality of the transaction.<sup>47</sup>

### The Rule of Reason

After concluding that antitrust scrutiny attaches to reverse payment settlement agreements, the Supreme Court concluded that such agreements are subject to the rule of reason. In so doing, the Court specifically rejected the “quick look” approach, which, the Court reasoned, is “appropriate only where ‘an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.’”<sup>48</sup> Reverse payment settlements, according to the Court, don’t fit that mold. But thereafter the Court’s guid-

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ance screamed to a halt. The Court concluded that “the structuring of the present rule-of-reason antitrust litigation” is best left to the lower courts. Not surprisingly, lower courts have struggled with and differed on this task.<sup>49</sup>

To date, courts have generally adopted one of two overlapping approaches. The first—which has been adopted by most courts—assigns plaintiffs an initial or threshold burden of showing a large and unjustified reverse payment before weighing under the rule of reason analysis alleged anticompetitive effects against alleged procompetitive justifications for the settlement agreement.<sup>50</sup> The district court in *Lidoderm* outlined the underpinnings for such an approach: “Most district courts read *Actavis* to hold that it is the ‘large and unjustified reverse payment’ that creates the anticompetitive concerns, and only after finding such a payment in the settlement may courts engage in the traditional rule of reason analysis.”<sup>51</sup> Two recent courts of appeals decisions apply the first approach. The First Circuit in *Loestrin* noted in the context of the appropriate pleading standard, that “plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis*.”<sup>52</sup> Citing to this language, the Third Circuit in *Lipitor* made clear that “if plaintiffs do so, they may proceed to prove their allegations under the traditional antitrust rule-of-reason analysis.”<sup>53</sup> Thus, arguably a consensus exists in the First and Third Circuit that plaintiffs must establish a “large and unjustified” reverse payment as a precursor to the rule of reason analysis.

As for the second approach, other courts have blended the required showing of a large and unjustified reverse payment into the rule of reason. For instance, one district court decision, *K-Dur*, expressed “concern[]” that requiring a plaintiff to make a preliminary showing establishing a “large” payment amounts to the “quick look” test *Actavis* rejects.<sup>54</sup> As a result, the court adopted the detailed rule of reason framework articulated by the California Supreme Court in *Cipro*.<sup>55</sup>

Mirroring *Cipro*, *K-Dur* baked in the large and unjustified analysis within the following rule of reason analysis: plaintiffs must first prove an agreement limiting the generic's market entry and that the brand compensated the generic, then defendants must produce evidence showing "the value of litigation costs, products, or services the settlement covered," then plaintiffs must prove that the compensation exceeds "the reasonable value of litigation costs, products, and/or services," and finally the defendant may put forth procompetitive justifications to which the plaintiff can rebut.<sup>56</sup> However, because *K-Dur* preceded the Third Circuit's decision in *Lipitor* (discussed above), it's an open question whether the district court's analysis on this point still holds.

Nevertheless, *Solodyn* offers another example of courts blending "large and unjustified" into the rule of reason. There, the court held that "allegations of a large and unjustified payment are required for plaintiffs to satisfy their initial burden of alleging anticompetitive effects under Section 1."<sup>57</sup> That is proper, the court reasoned, because *Actavis* states "a reverse payment, *where large and unjustified*, can bring with it the risk of significant anticompetitive effects."<sup>58</sup> And, because *Actavis* focuses on "whether a reverse payment could have an anti-competitive effect or whether it was reasonable compensation for litigation costs or the value of services," plaintiffs "must bear this initial burden."<sup>59</sup>

### Antitrust Injury

The Supreme Court in *Actavis* did not address the critical element of antitrust injury<sup>60</sup>—an issue which has proven to be central in the post-*Actavis* landscape. To prove antitrust injury in this context, the plaintiff must show that "the harm they say they experienced . . . was caused by the settlement they are complaining about."<sup>61</sup> In the post-*Actavis* case law, this has typically come to mean that private plaintiffs have the burden of proving that but-for the challenged agreement, generic entry would have occurred earlier.<sup>62</sup> This has proved to be a real, if unforeseen, hurdle as plaintiffs have failed to meet this burden in several cases.<sup>63</sup> To be sure, however, in two instances, district courts have found that the plaintiff proffered sufficient evidence regarding the possible invalidity of the brand's patent to withstand summary judgment.<sup>64</sup>

A notable consideration in the antitrust injury analysis in post-*Actavis* cases is the role of the patent. In *Actavis*, the Court opined that "it is normally not necessary to litigate patent validity to answer the antitrust question,"<sup>65</sup> but the post-*Actavis* landscape is not necessarily as the Court may have envisioned. As Chief Justice Roberts correctly predicted in dissent: "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 defendant (patent holder) will want to use the validity of his patent as a defense—in other words, he'll want to say 'I can do this because I have a valid patent that lets me do this.'"<sup>66</sup> In short, the "turducken task" of "deciding a patent case within an antitrust case about the settlement of the patent case"<sup>67</sup> has

worked its way into the application of *Actavis* by the lower courts.<sup>68</sup>

In particular, courts generally concur that patent validity and/or non-infringement is part of the causation analysis necessary to prove antitrust injury,<sup>69</sup> though some courts disagree.<sup>70</sup> This stems from plaintiffs' reliance on two causation theories which directly implicate patent validity and/or non-infringement: (1) that the generic would have prevailed in the underlying patent litigation,<sup>71</sup> and (2) that the generic would have launched at-risk lawfully.<sup>72</sup> A launch "at-risk" takes place before the questions of infringement and validity are resolved, either through litigation or a license.

The relevance of the patent to the first causation theory is self-explanatory. As for the second, most courts agree that to argue that the generic would have launched at risk, the plaintiff must make some evidentiary showing that the generic "would have" or "could have" succeeded in the underlying patent litigation.<sup>73</sup> Put another way, most courts have emphasized that alleging a launch at risk is not enough, it must be a *lawful* launch at risk.<sup>74</sup> *Wellbutrin* underscored this point because it "is beyond fair dispute" that "a regulatory or legislative bar can break the chain of causation in an antitrust case."<sup>75</sup> Moreover, in that decision, the Third Circuit rejected the plaintiff's causation theories "[b]ecause both of the scenarios . . . fail[ed] to show that [the generic] would have been able to launch its 150 mg version of Wellbutrin XL without running afoul of the [the brand's] patent."<sup>76</sup>

Similarly, the First Circuit in *Nexium* found fatal that "the plaintiffs did not present such evidence that the brand-name's patents would have been declared invalid or that an at-risk launch would not have infringed the patents," because "without such evidence, the 'patent served as an independent regulatory bar to [a generic's] launch.'"<sup>77</sup>

Some courts have sought to apply this requirement in earlier stages of the litigation. Two district courts, for example, have held that to survive summary judgment, plaintiffs must come forward with "some evidence" that the generic "could have" prevailed in the patent litigation.<sup>78</sup> On a motion to dismiss, at least one district court has rejected the argument that plaintiffs "must plead that [the brand's] patents would ultimately have been invalidated or found un infringed."<sup>79</sup> This opinion, however, was issued before the circuit court decisions in *Nexium* and *Wellbutrin*.

### Conclusion

Now five years removed from *Actavis*, the questions emanating from the case still outnumber the answers. Despite this murkiness, several takeaways have emerged from the post-*Actavis* landscape. First, whether a payment is "large" depends on the circumstances of the case and will almost always require more than a rote comparison to saved litigation costs. Second, whether a payment is "justified" is a flexible, fact-specific, and open-ended inquiry. Third, courts are likely to require plaintiffs to prove a "large and unjustified" payment, either as a part of the plaintiff's initial burden in the rule of

reason analysis or as a showing prior to engaging in a rule of reason analysis. And, fourth, despite judicial aversion to “turducken tasks,” the patent will likely play a role in the antitrust injury analysis. Beyond that, however, the post-*Actavis* landscape remains the “wild, wild west.” ■

<sup>1</sup> 570 U.S. 136, 141, 158 (2013).

<sup>2</sup> *Id.* at 160, 173.

<sup>3</sup> In 2015, the authors analyzed *Actavis*' progeny in the two years following the Court's decision. That analysis encompassed 15 district court opinions, one appellate opinion, and one jury trial. Lisa Jose Fales & Paul Feinstein, *Two Years and Counting Since Actavis: Developments in the Law*, ANTITRUST, Fall 2015, at 31–36.

<sup>4</sup> This is not to say that these three issues are the only ones inviting attention from the lower courts. Recently, market power—and specifically, whether the relevant market is limited to the brand and generic version of a drug—has been a focus of several decisions. See, e.g., *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co. (Doryx)*, 838 F.3d 421, 437–38 (3d Cir. 2016); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig. (Solodyn)*, No. 14-md-02503, 2018 WL 563144, at \*4–13 (D. Mass. Jan. 25, 2018); *United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA (Lidoderm)*, No. 14-MD-02521-WHO, 2017 WL 5068533, at \*14 (N.D. Cal. Nov. 3, 2017); *In re Aggrenox Antitrust Litig. (Aggrenox)*, 94 F. Supp. 3d 224, 246 (D. Conn. 2015).

<sup>5</sup> *Apotex, Inc. v. Cephalon, Inc. (Modafinil)*, 2:06-cv-02768-MSG, Trial Tr., Day 3, 146 (June 14, 2017).

<sup>6</sup> See *Solodyn*, 2018 WL 734655, at \*4; see also *Modafinil*, 2:06-cv-02768-MSG, ECF #1259, Final Jury Instructions, Instr. 9 (July 6, 2017) (“Whether a payment is large depends on the specific facts and circumstances of this case.”).

<sup>7</sup> *In re Lamictal Direct Purchaser Antitrust Litig. (Lamictal)*, 18 F. Supp. 3d 560, 567–68 (D.N.J. 2014), *vacated and remanded*, King Drug Co. of Florence v. Smithkline Beecham Corp., 791 F.3d 388 (3d Cir. 2015); *In re Loestrin Antitrust Litig. (Loestrin)*, 45 F. Supp. 3d 180, 190–93 (D.R.I. 2014), *vacated and remanded*, 814 F.3d 538 (1st Cir. 2016).

<sup>8</sup> In 2016, the First Circuit spoke twice on the issue. First, in *Loestrin*, the court concluded that “the district court erred in determining that non-monetary reverse payments do not fall under *Actavis*'s scope.” 814 F.3d at 549. And, in *Nexium*, the court reiterated that “improper reverse payments may take the form of ‘non-monetary’ advantages. The language and logic of *Actavis* dictated that outcome.” 842 F.3d 34, 41 (1st Cir. 2016). See also *Lamictal*, 791 F.3d at 403–05. And not only do the First Circuit and Third Circuit agree, the district court decisions outside those circuits have also held *Actavis* applies to non-cash payments. See *In re Actos End Payor Antitrust Litig.*, No. 13-cv-9244(RA), 2015 WL 5610752, at \*13 (S.D.N.Y. Sept. 22, 2015), *rev'd on other grounds*; *Lidoderm*, 74 F. Supp. 3d at 1069–70 (N.D. Cal. 2014) (same). Cf. *In re Opana ER Antitrust Litig. (Opana)*, 162 F. Supp. 3d 704, 717 (N.D. Ill. 2016).

<sup>9</sup> See, e.g., *Lamictal*, 791 F.3d at 411; *Opana*, 162 F.3d at 717. Since we last wrote, the Third Circuit has reversed the District Court for the District of New Jersey in *Effexor*, which had dismissed plaintiffs claim for a No-AG as reverse settlement payment. *In re Lipitor Antitrust Litig. (Lipitor)*, 868 F.3d 231, 274 (3d Cir. 2017). And, on remand from the First Circuit, the District Court for the District of Rhode Island, in *Loestrin*, concluded that because the no-AG exceeded \$40 million dollars to the generic, the plaintiffs “plausibly allege[d] that a no-AG agreement is both very valuable to a generic manufacturer (and thus may induce it to stay out of the market) and amounts to a sacrifice by a brand manufacturer, rendering the potential anti-competitive effect plain.” 261 F. Supp. 3d 307, 333 (D.R.I. 2017).

<sup>10</sup> See, e.g., *Solodyn*, 2018 WL 563144, \*3; *Opana*, 162 F.3d at 716–17; *Modafinil*, 88 F. Supp. 3d at 409.

<sup>11</sup> See, e.g., *Lipitor*, 46 F. Supp. 3d 523, 549 (D.N.J. 2014), *rev'd on other grounds*; *Nexium*, 42 F. Supp. 3d 231, 293 (D. Mass. 2014).

<sup>12</sup> See, e.g., *In re K-Dur Antitrust Litig. (K-Dur)*, No. 01-cv-1652-SRC, 2016 WL 755623, at \*12 (D.N.J. Feb. 25, 2016); *Aggrenox*, 94 F. Supp. 3d at 244; *Modafinil*, 88 F. Supp. 3d at 416–17; *In re Effexor XR Antitrust Litig.*, No. CIV.A. 11-5479 PGS, 2014 WL 4988410, at \*23 (D.N.J. Oct. 6, 2014), *rev'd on other grounds*, *Lipitor*, 868 F.3d 231 (3d Cir. 2017).

<sup>13</sup> *Actavis*, 570 U.S. at 159.

<sup>14</sup> See, e.g., *Aggrenox*, 94 F. Supp. 3d at 243 (“Even if the payments exceed avoided litigation costs, the *Actavis* factors . . . still matter.”); *Modafinil*, 88 F. Supp. 3d at 417 (holding “a reverse payment is sufficiently large (1) if it exceeds saved litigation costs and (2) a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim.”) (emphasis added); *K-Dur*, 2016 WL 755623, at \*12 (implying that largeness requires that, among other things, that consideration “exceeded the estimated cost of litigation and the costs of other services and products.”) (emphasis added).

<sup>15</sup> *Aggrenox*, 94 F. Supp. 3d at 243.

<sup>16</sup> 162 F. Supp. 3d at 718 (emphasis added).

<sup>17</sup> 2016 WL 755623, at \*12. Note that some courts, like the Third Circuit in *Lipitor*, consider litigation costs relevant only to whether a payment is justified. 868 F.3d at 256 (“The alleged reverse payment here was also ‘unjustified.’ As noted earlier, avoiding litigation costs, providing payment for services, or other consideration may justify a large reverse payment.”).

<sup>18</sup> 94 F. Supp. 3d at 243.

<sup>19</sup> In the only other case to go to trial since *Actavis*, the plaintiffs in *Nexium* alleged a payment of up to \$690 million, so the precise meaning of “large” was not extensively argued. *Nexium*, 842 F.3d 34, 50 (1st Cir. 2016). That said, in its instructions to the jury, the court did not narrowly limit the meaning of “large.” As the court explained: “whether a payment is ‘large’ depends upon the specific circumstances of a particular case.” The court did, however, draw a lower bound: “It’s got to be at least more than [the brand’s] reasonably estimated save-litigation costs.” *Nexium*, 12-md-02409-WGY, Jury Charge, Trial Tr. at 35–36 (D. Mass.).

<sup>20</sup> See *In re AndroGel Antitrust Litig. (No. II)*, No. 1:09-MD-2084, 2013 U.S. Dist. LEXIS 174273, at \*10 (N.D. Ga. Oct. 23, 2013) (“As much as I would love some guidance from the Eleventh Circuit on how in the heck a trial judge (and a jury) is supposed to apply the *Actavis* decision to an actual case, I doubt that the Eleventh Circuit is going to jump into that briar patch until it has to.”).

<sup>21</sup> See *Modafinil*, 2:06-cv-02768-MSG, ECF #1259, Final Jury Instructions, Instr. 9 (July 6, 2017).

<sup>22</sup> *Modafinil*, 88 F. Supp. 3d at 417.

<sup>23</sup> 2:06-cv-02768-MSG, ECF #1259, Final Jury Instructions, Instr. 9, Trial Tr. at 31–32 (July 6, 2017).

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

<sup>25</sup> *Actavis*, 570 U.S. 136, 148–49 (emphasis added).

<sup>26</sup> *Id.* at 147.

<sup>27</sup> *Solodyn*, 14-md-02503, Pls. Mot. at 1.

<sup>28</sup> See ECF #1089, Order: “Court’s Rulings on various motions in limine” (Mar. 8, 2018) (quoting *Actavis*, 570 U.S. at 158).

<sup>29</sup> ECF #1089, Order: “Court’s Rulings on various motions in limine” (Mar. 8, 2018). (emphasis added); see also *Barba v. Shire*, 2016 WL 3964606, at \*4–5 (approving defense expert’s analysis comparing the alleged payment to the brand name manufacturer’s monthly income from the drug and explaining that the analysis is “not necessarily linked to a determination of largeness,” but is instead “linked to the overall issue of whether the payment is anticompetitive.” The weight of this case is limited, however, because it settled prior to the district judge’s ruling on the magistrate’s Report and Recommendations.

<sup>30</sup> *Actavis*, 570 U.S. at 156.

<sup>31</sup> *Lipitor*, 868 F.3d at 251.

<sup>32</sup> *Actavis*, 570 U.S. at 160 (Roberts, C.J., dissenting).

<sup>33</sup> *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 162 (3d Cir. 2017).

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 163.

- <sup>36</sup> *Id.* at 163 n.49.
- <sup>37</sup> *Solodyn*, 2018 WL 734655, \*5.
- <sup>38</sup> *Id.* at \*4.
- <sup>39</sup> *Id.*
- <sup>40</sup> *Id.*
- <sup>41</sup> See, e.g., *Nexium*, 42 F. Supp. 3d at 261–62.
- <sup>42</sup> 570 U.S. at 156.
- <sup>43</sup> See *Nexium*, 42 F. Supp. 3d at 263–64 (“The *Actavis* opinion makes it clear that evidence of a fair value exchange can ‘redeem[ ]’ an otherwise suspicious reverse payment.”); see also *K-Dur*, 2016 WL 755623, at \*15.
- <sup>44</sup> See *Modafinil*, 88 F. Supp. 3d at 419 (agreeing with *Nexium* that “establishing fair market value is just one of many possible defenses available to a Defendant seeking to demonstrate procompetitive justifications for a reverse payment.”) (quoting *Nexium*, 42 F. Supp. 3d at 263–64).
- <sup>45</sup> *Solodyn*, 2018 WL 734655, at \*4, \*6.
- <sup>46</sup> *Id.* at \*6.
- <sup>47</sup> See, e.g., *K-Dur*, 2016 WL 755623, at \*15–16; *Modafinil*, 88 F. Supp. 3d at 419–21.
- <sup>48</sup> *Actavis*, 570 U.S. at 159.
- <sup>49</sup> Compare *K-Dur*, 2016 WL 755623, at \*13, with *Lidoderm*, 2015 WL 5458570, at \*7.
- <sup>50</sup> See, e.g., *Lipitor*, 868 F.3d at 253; *Loestrin*, 261 F. Supp. 3d at 338. Relatedly, most courts, in conducting the rule of reason analysis, have maintained that the analysis should focus on the settlement agreement as a whole. See, e.g., *Opana*, 162 F. Supp. 3d at 718.
- <sup>51</sup> *Lidoderm*, 74 F. Supp. 3d at 105.
- <sup>52</sup> *Loestrin*, 814 F.3d at 552 (1st Cir. 2016). See also *Loestrin*, 261 F. Supp. 3d at 338 (“Plaintiffs have satisfied their burden to allege facts that [“the sum total of the Watson Agreement constituted a large and unjustified payment”] [and] have the reasonable expectation of proving their prima facie case under the rule of reason.”).
- <sup>53</sup> *Lipitor*, 868 F.3d 231, 252; see also *Lamictal*, 791 F.3d at 412 (holding that under rule of reason analysis the plaintiff is burdened to show pay for delay—“a payment that prevents the risk of competition”—and, if shown, the defendant must show that “legitimate justifications” accompany the challenged conduct (e.g., a payment no more than saved litigation costs, fair value exchange for services) to which the plaintiff can rebut); *Lipitor*, 868 F.3d at 253 (“Because the complaint in [*Lamictal*] plausibly alleged a large and unjustified reverse payment, the plaintiffs there could proceed to prove their claim through ‘the traditional rule-of-reason approach.’”).
- <sup>54</sup> 2016 WL 755623, at \*12.
- <sup>55</sup> *In re Cipro Cases I & II*, 348 F.3d 845, 863 (2015).
- <sup>56</sup> See *K-Dur*, 2016 WL 755623, at \*13 (adopting *Cipro*). Before *K-Dur* adopted *Cipro*, however, the court recognized that *Actavis* “gave lower courts further guidance on the application of the rule of reason to reverse payment settlement cases.” *K-Dur*, 2016 WL 755623, at \*11. That guidance included the following: “antitrust considerations only arise if a ‘reverse payment’ has occurred, and that the reverse payment in question must be ‘large and unexplained.’” *Id.* (quoting *Actavis*, 570 U.S. at 156–59). Thus, the court’s criticism of threshold burdens seems puzzling if, as it recognizes, antitrust scrutiny under *Actavis* is not triggered absent a large and unexplained reverse payment.
- <sup>57</sup> 2015 WL 5458570, at \*7.
- <sup>58</sup> *Id.* (quoting *Actavis*, 570 U.S. at 158).
- <sup>59</sup> *Solodyn*, 2015 WL 5458570, at \*7. See also *Modafinil*, 88 F. Supp. 3d at 416; *Aggrenox*, 2015 WL 1311352, at \*9.
- <sup>60</sup> Subsequent decisions suggest that this was at least partly due to the fact that the FTC was the plaintiff in *Actavis*, as opposed to a private entity. See, e.g., *Nexium*, 842 F.3d at 60 (“Private plaintiffs and the FTC as government enforcer stand in different shoes . . . . The Supreme Court has consistently held private plaintiffs to this standard of proving both antitrust violation and antitrust injury.”); *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d at 764 (“*Actavis*, however, was brought by the FTC. The FTC faces a different standard of causation in bringing agency antitrust actions such as *Actavis*: the FTC must establish only that the defendant’s action is ‘likely to cause injury.’ Because the FTC Act’s causation requirement is broader and more relaxed than the Clayton Act’s, no showing of proximate cause is required.”) (internal citations omitted).
- <sup>61</sup> *Wellbutrin*, 868 F.3d at 164–65.
- <sup>62</sup> See, e.g., *Wellbutrin*, *id.* at 151–52 (“[T]o establish an antitrust claim for anti-competitive litigation, the Appellants had to show not only that GSK’s litigation was a sham, but also that it caused an antitrust injury by delaying generic competition.”).
- <sup>63</sup> See, e.g., *Nexium*, 842 F.3d at 65 (affirming district court’s grant of summary judgment; and jury verdict in favor of defendants on causation); *Wellbutrin*, 133 F. Supp. 3d at 762 (granting defendants summary judgment).
- <sup>64</sup> *Solodyn*, 2018 WL 563144, at \*18 (“Plaintiffs have provided ‘some evidence’ of the invalidity of [the brand’s] patent, sufficient to raise a genuine dispute of material fact on this causation theory and overcome Defendants’ motion for summary judgment.”); *Lidoderm*, 2017 WL 5068533, at \*5–12 (finding that plaintiffs met “some evidence” standard for two of their causation theories).
- <sup>65</sup> *Actavis*, 570 U.S. at 157.
- <sup>66</sup> *Id.* at 171 (Roberts, C.J., dissenting).
- <sup>67</sup> *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1315 (11th Cir. 2012), *rev’d and remanded*, *Actavis*, 570 U.S. 136 (2013).
- <sup>68</sup> A turducken, a traditional meal in the southern United States but enjoyed everywhere, consists of a deboned duck stuffed in a deboned chicken that is then stuffed in a deboned turkey. See Amanda Hesser, *Turducken*, N.Y. TIMES: COOKING, <https://cooking.nytimes.com/recipes/548-turducken>.
- <sup>69</sup> See, e.g., *Nexium*, 842 F.3d at 63; *Modafinil*, 255 F. Supp. 3d 604, 614 (E.D. Pa. 2017); *Solodyn*, 2018 WL 563144, at \*13 (D. Mass. Jan. 25, 2018); *Lidoderm*, 2017 WL 5068533, at \*2 (N.D. Cal. Nov. 3, 2017).
- <sup>70</sup> For example, the court in *Aggrenox* held that “the salient question is not whether the fully-litigated patent would ultimately be found valid or invalid—that may never be known—but whether the settlement included a large and unjustified reverse payment leading to the inference of profit-sharing to avoid the risk of competition.” 94 F. Supp. 3d at 241. See also *Opana*, 162 F. Supp. 3d at 720.
- <sup>71</sup> See, e.g., *Wellbutrin*, 868 F.3d at 166; *Nexium*, 842 F.3d at 62; *Modafinil*, 255 F. Supp. 3d at 614; *Solodyn*, 2018 WL 563144, at \*13.
- <sup>72</sup> See, e.g., *Nexium*, 842 F.3d at 62; *Lidoderm*, 2017 WL 5068533, at \*4.
- <sup>73</sup> See *Wellbutrin*, 868 F.3d at 165; *Nexium*, 842 F.3d at 62; *Lidoderm*, 2017 WL 5068533, at \*4–5; *Solodyn*, 2018 WL 563144, at \*13.
- <sup>74</sup> See *Wellbutrin*, 868 F.3d at 165 (“It is not enough for the Appellants to show that Anchen wanted to launch its drug; they must also show that the launch would have been legal.”); *Solodyn*, 2018 WL 563144, at \*13 (“To succeed on an at-risk launch theory, Plaintiffs must show that Impax could have launched at-risk lawfully, i.e., without infringing any lawful patent held by Medicis.”).
- <sup>75</sup> *Wellbutrin*, 868 F.3d at 165.
- <sup>76</sup> *Id.*
- <sup>77</sup> 842 F.3d at 63.
- <sup>78</sup> *Solodyn*, 2018 WL 563144, at \*14 (quoting *Lidoderm*, 2017 WL 5068533, at \*4).
- <sup>79</sup> *Opana*, 162 F. Supp. 3d at 720; *id.* (“Plaintiffs need not plead (or prove) the weakness of the Endo patents, because the patent’s ultimate validity is not at issue.”). That court grounded its holding in *Actavis*’ refrain that “it is normally not necessary to litigate patent validity” because “[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival.” *Id.* The court, in *Aggrenox*, similarly held that “the salient question is not whether the fully-litigated patent would ultimately be found valid or invalid—that may never be known—but whether the settlement included a large and unjustified reverse payment leading to the inference of profit-sharing to avoid the risk of competition.” 94 F. Supp. 3d at 241.