Two Years and Counting Since *Actavis*: Developments in the Law

BY LISA JOSE FALES AND PAUL FEINSTEIN

ON JUNE 17, 2013, THE SUPREME Court issued its landmark decision in *FTC v. Actavis*,[1] forever altering the framework by which pharmaceutical patent litigation settlements are analyzed under antitrust law. In the nearly two-and-a-half years since, lower courts have grappled with what the decision means and how to apply it.

The decision has been interpreted in more than 15 district court opinions, one appellate court opinion, and one jury trial. Though no set of facts is the same, courts have generally focused on four issues under *Actavis*: the meaning of the term "large and unjustified" reverse payment, the structure and analysis of the rule of reason standard, the role of the patent in the antitrust inquiry, and how to handle antitrust causation.[2] To put the analysis of the lower courts in context, a brief discussion of *Actavis* is instructive.

FTC v. Actavis

In the pharmaceutical context, a "reverse payment" settlement is a settlement of patent litigation regarding a brand manufacturer's patent (or patents) in which a generic manufacturer receives a licensed entry date under the brand's patent (or patents) that is prior to patent expiry, and consideration of some form allegedly flows from the brand to the generic.[3] Prior to the Supreme Court's decision in *Actavis*, most courts adhered to the "scope of the patent test," pursuant to which reverse payment settlements were generally immune from antitrust liability so long as the settlement allowed for generic entry prior to the expiration of the brand's patent (and absent sham litigation or fraud in obtaining the patent).[4] In contrast, the Third Circuit implemented a "quick look" approach whereby the mere presence of a reverse payment was considered prima facie evidence of an unreasonable restraint of trade.[5]

In *Actavis*, the Court declined to adopt the "scope of the patent test" or a "quick look" approach, and instead instructed courts to employ the rule of reason to strike a balance "between the lawful restraint of trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act."[6] The Court articulated "five sets of considerations" to support its conclusion that the rule of reason should apply: (1) a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; (2) one who makes such a payment may be unable to explain and to justify it; (3) such a firm or individual may well possess market power derived from the patent; (4) a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and (5) parties may well find ways to settle patent disputes without the use of reverse payments.[7]

The Court further concluded that "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payer's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."[8] Taking all of this into account, the Court left it to the lower courts to structure and apply the rule of reason analysis in the reverse payment context.[9] Courts have been struggling to do just that ever since.

What Is a Large and Unjustified Payment?

Given that *Actavis* requires a "large and unjustified" reverse payment, determining what constitutes a "large and unjustified" reverse payment has been a common point of emphasis among the lower courts. More specifically, courts have focused on what qualifies as a "payment" and what makes such a payment "large."

Cash Payments Only? An initial question considered by the lower courts is whether *Actavis* is limited to cash payments. That is, in order for antitrust scrutiny under *Actavis* to apply, must the alleged reverse payment be in cash or can it be a non-monetary term like a No-AG provision (i.e., an agreement by the brand not to launch an authorized generic version of the drug during the generic's 180-day exclusiv-

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Beyond determining whether certain types of non-monetary terms might qualify as a reverse payment, courts have also begun to opine on what makes such a payment "large."

ity period)? Relying primarily on the fact that the Court in *Actavis* was only analyzing a cash payment and the "cash-focused guidance [provided by the Court] for applying the rule of reason," two district courts held that *Actavis* only applies to reverse payments of money, and thus does not apply to No-AG provisions or other non-monetary terms like a co-promotion agreement.[10] Other courts concluded that *Actavis* was not so limited.[11]

In June 2015, the first of these decisions reached the court of appeals. In *Lamictal*, the Third Circuit overturned the district court and held that the *Actavis* rule of reason framework is not limited to settlements involving cash payments.[12] The Third Circuit found that a No-AG provision can be subject to antitrust scrutiny under *Actavis* because "it may represent an unusual, unexplained reverse transfer of considerable value . . . and may therefore give rise to the inference that it is a payment to eliminate the risk of competition."[13]

No-AG Provisions. Other than *Loestrin* and *Lamictal*, one other court has dismissed a claim based on a No-AG provision. In *Effexor*, the court dismissed the plaintiffs' claim because the plaintiffs failed to allege sufficient facts to "demonstrate a reliable foundation showing a reliable cash value" of the No-AG provision.[14] Without a "reliable estimate of its monetary value," the court reasoned, the No-AG provision could not be "analyzed against the *Actavis* factors."[15] Another court took a somewhat different approach in denying a motion to dismiss a claim based on a No-AG provision. In *Aggrenox*, the court denied a motion to dismiss despite the fact that the plaintiffs did not "attempt[] to assign dollar values [for the No-AG provision] with significant precision or very obvious methodological justification."[16] The court found that the lack of "precise figures" was not fatal to the plaintiffs' claims.[17]

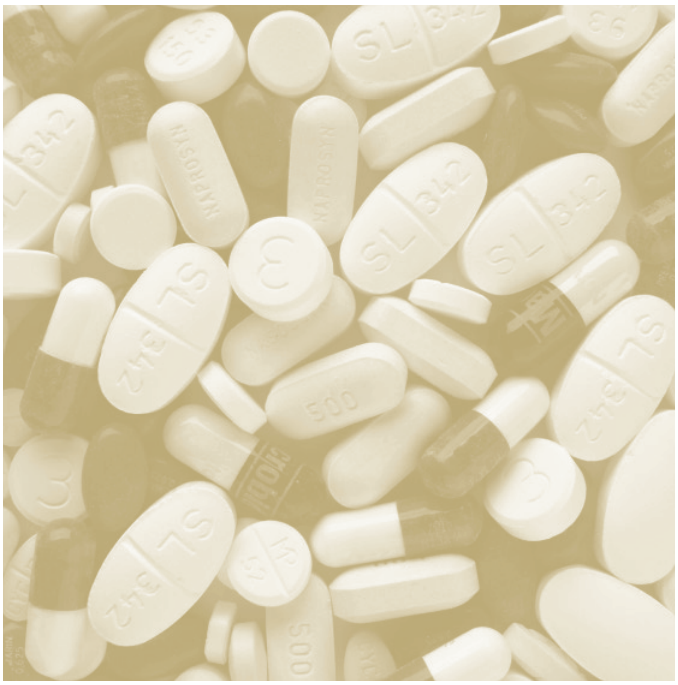
Other Business Arrangements. Courts have also considered whether a variety of business transactions entered into simultaneously with patent litigation settlements might constitute reverse payments. So far, such business transactions have included distribution agreements, co-promotion agreements, supply agreements, joint development agreements, manufacturing agreements, asset purchase agreements, and intellectual property licenses where the generic is licensing intellectual property to the brand. In these instances, plaintiffs have generally alleged that such deals are pretextual and favorable to the generic such that they constitute a payment.[18]

Three district courts have allowed claims based on co-promotion agreements, joint development agreements, asset purchase agreements and/or manufacturing agreements to survive motions to dismiss,[19] and two district courts have allowed supply agreements, intellectual property licenses, and/or distribution agreements to survive summary judgment.[20] In contrast, the U.S. District Court for the Eastern District of Pennsylvania dismissed an *Actavis* claim based on a distribution agreement that enabled the generic to distribute an authorized generic version of another product in competition with the brand.[21] The court reasoned that the distribution agreement did not fall under *Actavis* because the brand was not making any payments to the generic and the distribution agreement itself was procompetitive because it allowed the generic to enter a different market with a generic product to compete with the brand's product.[22]

Settlements of Other Litigation. Another form of alleged payment that courts have considered is the settlement of unrelated patent litigation. The plaintiffs' theory in these cases is that the terms of a simultaneous settlement of unrelated patent litigation are discounted or unduly favorable to the generic and thus constitute a payment. Since *Actavis*, two district courts have assessed this theory. In the first, *Lipitor*, the District Court for the District of New Jersey dismissed the plaintiffs' claim because, like *Effexor*, the plaintiffs failed to provide a "reliable estimate of [the allegedly discounted settlement's] monetary value."[23] According to the court: "Where [p]laintiffs rely on a non-monetary reverse payment of an inchoate claim, they must plead plausible facts including an estimate of the monetary value of same so the *Actavis* rationale can be applied. The [p]laintiffs have failed to delineate any type of methodology to connect the claim to its monetary value."[24]

In *Nexium*, the court allowed a claim against one generic based on an allegedly discounted settlement of unrelated litigation to survive summary judgment and rejected a similar claim against another generic. In the claim that survived, the settlement of unrelated patent litigation involved the generic "agree[ing] to the amount of damages it owed [the brand] in a case [the generic] lost."[25] In contrast, the rejected claim involved the settlement of unrelated patent litigation in which the generic had "agreed to the dismissal of an appeal in a case it [had] won [against the brand]."[26] In the court's estimation, this second claim "hardly seem[ed] to qualify as a large and unjustified payment as imagined by the *Actavis* court."[27]

What Is "Large"? Beyond determining whether certain types of non-monetary terms might qualify as a reverse payment, courts have also begun to opine on what makes such a payment "large." *Actavis* itself provides little express guidance on this issue. The courts are generally in agreement that a reverse payment must exceed the brand's avoided litigation costs,[28] but otherwise no consensus has emerged. As articulated by the court in *Aggrenox*, "Payments exceeding avoided litigation costs are not automatically deemed unlawful



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for that reason alone."[29] As such, the courts have pointed to other factors to consider. Specifically, courts have referenced the size of the reverse payment in relation to the anticipated value of the patent,[30] the size compared to the amount of annual sales by the brand,[31] and a comparison to what the generic would gain in profits if it won the patent litigation and entered the market.[32] One court held that, to be "large," a payment must also have been "significant enough to induce a generic challenger to abandon its patent claim."[33] According to the court, evidence that the reverse payment "comes close to or exceeds the expected profits to be earned by prevailing in the patent litigation" could be sufficient.[34]

The Rule of Reason

Pursuant to the Court's directive in *Actavis*, the lower courts have begun "structuring" the rule of reason analysis that applies to alleged reverse payment settlements.[35] As with the question of what constitutes a "large and unjustified" reverse payment, the lower courts have not reached a consensus as to what exactly the rule of reason analysis means in this context or how to structure it.

In *Lamictal*, the only circuit court to consider the issue (the Third Circuit) held that the "five sets of considerations" that persuaded the Court in *Actavis* to conclude that the rule of reason applies are not a "redefinition" of the rule of reason itself.[36] The Third Circuit described the rule of reason in three steps. First, "to prove anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, payment to prevent risk of competition."[37] The court quoted directly from *Actavis* that the likelihood of anticompetitive effects depends upon a reverse payment's "size, its scale in relation to the payer's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."[38] Second, if the plaintiff proves anticompetitive effects, "the burden then shifts to the defendant to show 'that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.'"[39] The court again cited directly to *Actavis* for examples of justifications: the reverse payment "may amount to no more than a rough approximation of the litigation expenses saved" or "compensation for other services that the generic has promised to perform," or "there may be other justifications."[40] The court expressly declined to decide what those "other justifications" might be or impose any limitations on what they may be.[41] Finally, if the defendants show legitimate justifications, "the plaintiff will have the opportunity to rebut the defendant's explanation."[42]

Among the district courts, there have been divergent views as to whether proving a "large and unjustified" reverse payment is a threshold burden that must be met before reaching the rule of reason, as well as where the justifications (or lack thereof) for a payment fit into the analysis. For example, the court in *Loestrin* has effectively interpreted *Actavis* as imposing a three-part inquiry: whether there is a reverse payment; whether the reverse payment is large and unjustified; and the rule of reason.[43] In contrast, the court in *Provigil* rejected the defendants' argument that *Actavis* imposes a "threshold burden," and instead held that plaintiffs "must present evidence of a large reverse payment as part of their initial burden of demonstrating anticompetitive effects under the rule of reason."[44] From there, if plaintiffs meet their burden, "the burden shifts to the [d]efendants to justify the reverse payment as procompetitive," and if that occurs, the plaintiffs must then "present sufficient evidence so as to raise a genuine dispute of material fact as to whether the reverse payment is unjustified or unexplained."[45]

Other courts have articulated somewhat of a middle ground. In *Nexium*, for example, the court found that the "initial burden of proof lies with the [p]laintiffs who must present evidence . . . to show that the accused brand manufacturer made a payment to a generic manufacturer that exceeded anticipated future litigation costs, exceeded the costs of other services, and lacked 'any other convincing justification.'"[46] From there, the burden then shifts to the defendants "to show that a challenged payment was justified by some procompetitive objective," and if the defendants can do so, "the burden shifts back to the [p]laintiffs to establish, under the rule of reason, that the settlement is nevertheless anticompetitive on balance."[47] Similarly, in *Solodyn*, the court concluded that "allegations of a large and unjustified payment are required for plaintiffs to satisfy their initial burden of alleging anticompetitive effects under Section 1, but once plaintiffs do so, the burden shifts to defendants to show that the challenged conduct promotes a sufficiently procompetitive objective."[48]

Perhaps the most detailed discussion of the structure of the rule of reason under *Actavis* has come from the California Supreme Court. In finding that the Court's analysis in *Actavis* applied to California state law (specifically, the Cartwright Act), the court laid out a "structured" rule of reason in which the plaintiff has the initial burden to prove that (1) the settlement includes a limit on the settling generic challenger's entry into the market; (2) the settlement includes cash (or equivalent financial consideration) flowing from the brand to the generic; and (3) the consideration exceeds the value of goods and services other than delay in market entry provided by the generic to the brand plus the brand's expected remaining litigation costs absent the settlement.[49]

According to the court, once a plaintiff has shown the first two elements (reverse payment and delay), "the defendants have the burden of coming forward with evidence of litigation costs and the value of collateral products and services," and if defendants do so, "the plaintiff must carry the ultimate burden of persuasion that any reverse payment exceeds litigation costs and the value of collateral products or services."[50] If the plaintiff's prima facie case has been made, "the burden shifts to the defendants to offer legitimate justifications and come forward with evidence that the challenged settlement is in fact procompetitive," and if defendants do so, the plaintiff must "show that any procompetitive justifications proffered by the defendants are unsupportable."[51]

Role of the Patent

Although not emphasized in many of the decisions interpreting *Actavis*, a question present in every *Actavis* case is what role, if any, the patent (or patents) at issue in the underlying patent litigation should play in the antitrust analysis. In *Actavis*, the Court reasoned that "it is normally not necessary to litigate patent validity to answer the antitrust question."[52] In the Court's estimation, "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."[53] Aside from not necessarily having to engage in "a detailed exploration of the validity of the patent," the Court provided little guidance as to the precise role of the patent. In the more than two years since *Actavis*, some lower courts have attempted to fill in the gaps.

At the pleading stage, one issue that has arisen is whether and to what extent the plaintiff must plead facts to show that the patent at issue was "weak" and/or likely to be invalidated but for the settlement. Not surprisingly, there is no consensus among the courts. At least one district court has held that plaintiffs "need not plead (or prove) the weakness of the [relevant patent], because the patent's ultimate validity is not at issue."[54] In another case, *Niaspan*, the defendants moved for dismissal (in part) on grounds that the plaintiffs had failed to allege facts to support the conclusion that the generic would have prevailed in the underlying patent litigation. The court was not convinced that the pleading standard was as high as the defendants contended—reasoning that "probabilistic harm" may be enough—but, in any event, found that the plaintiffs had plausibly alleged that the generic would have prevailed.[55] The Third Circuit's *Lamictal* opinion is silent as to whether such allegations are necessary, but the allegation that the patent was "likely to be invalidated" was among the plaintiffs' allegations that the court cited as sufficient to survive a motion to dismiss.[56] That said, the court expressly stated that it was not addressing or deciding whether the plaintiff had pled antitrust injury (see Causation Section below), so this finding is of limited import moving forward.[57]

The role of the patent has also come up in the context of assessing procompetitive justifications and/or anticompetitive effects. In *Provigil*, the patent at issue in the underlying patent litigation was found invalid several years after the generic defendants settled with the brand. In an opinion deciding how the patent ruling would impact the antitrust trial, the District Court for the Eastern District of Pennsylvania held that "the fact that the patent was found invalid . . . should have no bearing on the proofs necessary to hold the [generic defendants] liable for antitrust violations."[58] Later, at summary judgment, the court cited evidence "suggesting [the brand] had knowledge of the [] patent's weakness" and evidence that "the arguments raised by the Generic Defendants in the [patent litigation] largely mirrored the facts that were eventually used to invalidate and render unenforceable the [patent at issue]" as evidence, in part, to "rebut [the defendants'] procompetitive justifications and raise a genuine factual dispute as to whether the payments were reasonably necessary to achieve the procompetitive benefits."[59]

The California Supreme Court has also considered the patent's role in assessing procompetitive or anticompetitive effects. In *Cipro*, similar to *Provigil*, the court found that whether an agreement is procompetitive will not turn on whether the patent would ultimately have been proved valid or invalid: "Just as later invalidation of a patent does not prove an agreement when made was anticompetitive, later evidence of validity will not automatically demonstrate an agreement was procompetitive."[60]

One court has considered an allegation by the Federal Trade Commission that a brand and generic might be liable under Section 1 for an alleged reverse payment settlement where it is alleged that the generic "settled with the knowledge that the [patent] litigation was groundless."[61] In *AbbVie*, in support of this allegation, "the FTC reli[ed] on [the generic's] counterclaim [in the patent litigation] stating that the [brand] had filed sham litigation against it."[62] The District Court for the Eastern District of Pennsylvania dismissed the FTC's claim, reasoning in part that the generic's "allegations in its counterclaim had simply not been ruled upon by the court, and [the generic] did not and could not plausibly know until then whether the lawsuit was a sham."[63] In reaching this conclusion, the court expressed concern that accepting the FTC's "line of reasoning" would mean that a generic "would risk

antitrust liability by claiming the underlying action brought against it is baseless and thereafter agreeing to settle."[64] According to the court, "Such a result would undermine the salutary public policy favoring settlement far beyond the holding of *Actavis*."[65]

Causation

Another issue that has loomed large in post-*Actavis* case law is antitrust causation. In a private antitrust case, a plaintiff "must prove that he or she suffered damages from an antitrust violation and that there is a causal connection between the illegal practice and the injury."[66] In the context of a reverse payment case, this means a plaintiff must establish that the alleged reverse payment settlement actually caused a delay in generic entry.[67] The Court did not address this issue in *Actavis* because the plaintiff was the FTC, which does not have to prove antitrust injury.[68] That said, as private plaintiffs have brought claims under *Actavis*, causation has been at issue in nearly every case, and was front and center in the first and only jury trial since *Actavis*.

At the pleading stage, two courts have granted motions to dismiss based on causation.[69] In *Solodyn*, the District Court for the District of Massachusetts dismissed one of the plaintiffs' claims because the plaintiffs failed to "plausibly allege[] any delay." According to the court, the generic defendant "did not receive the FDA approval necessary for the launch of [its product]" until after the licensed entry date in its agreement with the brand. As such, the court reasoned that "the FDA's approval, not [the settlement agreement], was the limiting factor in [the generic's] ability to bring [its generic product] to market." Accordingly, the settlement was not the "substantial cause" of the plaintiffs' alleged injury, and the plaintiffs thus failed to allege cognizable antitrust injury.[70]

In *Actos*, the District Court for the Southern District of New York found that the plaintiffs' "general theory of causation [was] too speculative to state an antitrust injury resulting from the settlement agreements," and that this provided a basis for dismissal.[71] More specifically, the court found that each of the plaintiffs' causation theories required the court "to assume that [the brand's] patent claims were invalid and the infringement actions against the [generic defendants] would have failed."[72] According to the court, "Such assumptions regarding success at trial are generally rejected as unduly speculative unless the facts alleged establish a basis for concluding otherwise."[73] Given that the plaintiffs had failed to allege such facts, their claims were dismissed.[74]

Other courts have been more favorable to plaintiffs as to what they need to allege to plead causation. For example, in *Aggrenox*, the court found that the "sparsity" of the plaintiffs' allegations regarding the patent's vulnerability and the hypothetical earlier entry of a generic if not for the settlement agreement did not fatally undermine their claims of antitrust injury under *Actavis*.[75] Elsewhere, the court in *Lidoderm* found plausible the plaintiffs' allegation that the generic was able and willing to launch "at risk"[76] based on detailed allegations that the generic was expanding its facilities, preparing for an imminent launch, and stating that it was confident about its chances of success in the patent litigation.[77] The court also found plausible the plaintiffs' assertion that the generic would have been able to enter the market on a specific date after it received FDA approval.[78]

In another case denying a motion to dismiss, *Niaspan*, the defendants argued that the plaintiffs had failed to allege antitrust injury because the complaint lacked factual allegations supporting the conclusion that the generic would have prevailed in the patent litigation. In rejecting the defendants' argument, the court questioned the standard articulated by the defendants but found that the plaintiff had plausibly alleged that the generic would have prevailed based on detailed allegations that: there was a large reverse payment; the brand conducted "extensive research analysis" and "legal due diligence" and "knew there was a substantial risk it would lose"; and the generic was planning to launch "at risk."[79]

Causation has also featured prominently in the three summary judgment opinions since *Actavis*. In *Provigil*, one defendant argued for summary judgment on causation because the generic would not have launched "at risk," which was the plaintiffs' only theory of causation. The court denied summary judgment, finding that there was a genuine dispute of material fact as to whether the generic would launch "at risk" given references in some of the generic companies' documents to a "likely launch date" and concluded that certain documents supported a reasonable inference of "indicat[ions] that [the generic] was planning to place an order for a 'launch quantity' of [active pharmaceutical ingredient]."[80]

In *Nexium*, the defendants had more success with their causation arguments. The court articulated part of the causation issue as "whether [the FDA] would have approved a product earlier in time" but for the alleged reverse payment settlement. With regard to one of the generic defendants, the court found that there was insufficient evidence that the generic could have received FDA approval earlier than the licensed entry date in its settlement agreement and granted summary judgment in favor of the defendants on that issue.[81] One of the plaintiffs' other causation theories, however, survived to trial, where it played a pivotal role.[82] Ultimately, four of the seven questions on the jury verdict form dealt directly with causation, one of which ended up being the decisive issue in the case. Specifically, the jury found that the brand and generic would not have agreed to an earlier entry date but for the alleged reverse payment.[83] Accordingly, there was no delay caused by the settlement, and the jury found in favor of the defendants. In the presiding judge's estimation, this sent a clear message: "[T]he plaintiffs' bar will need far more detailed evidence of events in the 'but-for' world before a jury will find actual antitrust damages."[84]

More recently, in *Wellbutrin*, the District Court for the Eastern District of Pennsylvania also held for the defendants on the issue of causation. Specifically, the court granted the defendants' motion for summary judgment, in part, on

grounds that the plaintiffs could not "prove that they [had] suffered antitrust injury or that the [settlement at issue] was the proximate cause of any injury suffered because they [had] not presented evidence that the [settlement], as opposed to an independent patent, prevented market entry of Wellbutrin XL."[85]

Looking Ahead

If the nearly two-and-a-half years since *Actavis* have made anything clear, it is that *Actavis* has raised at least as many questions as it has answered. This article highlights several major areas of analysis thus far, but, of course, there are many other equally important issue the courts are grappling with.[86] Opinions are coming at a steady rate and will continue to do so as the many ongoing cases move through discovery and summary judgment and on to trial and appeal. One appellate court has already spoken, and, as of this writing, three other cases are currently on appeal in the First and Third Circuits. Chief Justice Roberts was truly clairvoyant when he wished "good luck to the district courts" in dealing with *Actavis*.[87] If the past few years are any indication of what is to come, *Actavis* may not be the Supreme Court's final word on reverse payment settlements. ■

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

2 Although this article focuses on these four issues, they are by no means all the issues that courts have considered under *Actavis*. *See infra* note 86.

3 *Actavis*, 133 S. Ct. at 2228.

4 *See, e.g.*, FTC v. Watson Pharms., Inc., 677 F.3d 1298 (11th Cir. 2012); *In re* Ciprofloxacin Hydrocholoride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006).

5 *In re* K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012); *see also In re* Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003) (interim patent settlement in which the brand paid the generic to delay entry pending resolution of the lawsuit was deemed per se illegal).

6 *Actavis*, 133 S. Ct. at 2231.

7 *Id.* at 2235–37.

8 *Id.* at 2237.

9 *Id.* at 2238.

10 *In re* Lamictal Direct Purchaser 24 FE Antitrust Litig., 18 F. Supp. 3d 560, 567–68 (D.N.J. 2014); *In re* Loestrin 24 FE Antitrust Litig., 45 F. Supp. 3d 180, 190–93 (D.R.I. 2014).

11 *In re* Actos End Payer Antitrust Litig., No. 13-9244, 2015 WL 5610752, at *13 (S.D.N.Y. Sept. 22, 2015); *In re* Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 242–43 (D. Conn. 2015); *In re* United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma. USA, Inc., 74 F. Supp. 3d 1052, 1069–70 (N.D. Cal. 2014) (*Lidoderm*); *In re* Lipitor Antitrust Litig., 46 F. Supp. 3d 523, 550 (D.N.J. 2014); *In re* Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 750–51 (E.D. Pa. 2014); *In re* Nexium Antitrust Litig., 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

12 King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 403–05 (3d Cir. 2015) (*Lamictal*). The other district court decision, *Loestrin*, is currently on appeal at the First Circuit. *See In re* Loestrin Antitrust Litig., Nos. 14-2071, 15-1250 (1st Cir.).

13 *Lamictal*, 791 F.3d at 394.

14 *In re* Effexor XR Antitrust Litig., No. 11:5479, 2014 WL 4988410, at *21 (D.N.J. Oct. 6, 2014). The *Effexor* decision is currently on appeal at the Third Circuit. *In re* Effexor XR Antirust Litig., No. 15-1184 (3d Cir. 2015).

15 *In re Effexor XR*, 2014 WL 4988410, at *21; *see also In re Actos*, 2015 WL 5610752, at *13 (holding that "not all non-cash settlement terms fall within the purview of *Actavis*; rather, in order for the Court to find an unlawful reverse payment, it must be able to estimate the value of the term").

16 *In re Aggrenox*, 94 F. Supp. 3d at 244–45. *See also Lamictal*, 791 F.3d at 409–10; *In re Lidoderm*, 74 F. Supp. 3d at 1071 (finding the plaintiffs' estimated value of a No-AG provision to be plausible).

17 *In re Aggrenox*, 94 F. Supp. 3d at 244–45.

18 *See, e.g.*, FTC v. AbbVie Inc., No. 14-5151, 2015 WL 2114380 (E.D. Pa. May 6, 2015); King Drug Co. of Florence, Inc. v. Cephalon, Inc., 88 F. Supp. 3d 402 (E.D. Pa. 2015) (*Provigil*).

19 *In re* Solodyn Antitrust Litig., No. 14-md-02503-DJC, 2015 WL 5458570, at *16–17, *19–22 (D. Mass, Sept. 16, 2015); *In re Aggrenox*, 94 F. Supp 3d 224; *In re Niaspan*, 42 F. Supp. 3d 735.

20 *Provigil*, 88 F. Supp. 3d 402; *In re* Nexium Antitrust Litig., 42 F. Supp. 3d 231 (D. Mass. 2014).

21 *AbbVie*, 2015 WL 2114380, at *7.

22 *Id.*

23 *See In re Lipitor*, 46 F. Supp. 3d at 550. The *Lipitor* decision is currently on appeal to the Third Circuit. *In re* Lipitor Antitrust Litig., No. 14-4202 (3d Cir.).

24 *In re Lipitor*, 46 F. Supp. 3d at 550.

25 *In re Nexium*, 42 F. Supp. 3d at 293.

26 *Id.*

27 *Id.*

28 *See, e.g.*, *In re Solodyn*, 2015 WL 5458570, at *16, *20; *In re Provigil*, 88 F. Supp. 3d at 416–17; *In re Aggrenox*, 94 F. Supp. 3d at 243; *In re Effexor XR*, 2014 WL 4988410, at *24.

29 *In re Aggrenox*, 94 F. Supp. 3d at 243. *But see In re Solodyn*, 2015 WL 545857, at *16, *20 (finding that the plaintiffs had satisfied their burden to allege a large payment by pleading that the reverse payments "substantially exceed[ed]" or were "significantly larger than" the brand manufacturer's estimated saved litigation costs).

30 *In re Aggrenox*, 94 F. Supp. 3d at 243.

31 *In re Effexor XR*, 2014 WL 4988410, at *23.

32 *In re Lipitor*, 46 F. Supp. 3d at 523, 547; *Provigil*, 88 F. Supp. 3d at 416–18.

33 *Provigil*, 88 F. Supp. 3d at 416–17.

34 *Id.* (denying defendants' motions for summary judgment).

35 *Actavis*, 133 S. Ct. at 2238.

36 *Lamictal*, 791 F.3d at 411.

37 *Id.* at 412.

38 *Id.* (quoting *Actavis*, 133 S. Ct. at 2237).

39 *Id.* (quoting *Actavis*, 133 S. Ct. at 2235–36).

40 *Id.* (quoting *Actavis*, 133 S. Ct. at 2236).

41 *Id.*

42 *Id.*

43 *In re Loestrin 24 FE*, 45 F. Supp. 3d at 189. This opinion is currently on appeal at the First Circuit. *See also Lidoderm*, 74 F. Supp. 3d at 1066 (finding that "[m]ost district courts read *Actavis* to hold that . . . only after finding [a large and unjustified reverse payment] in the settlement may courts engage in the traditional rule of reason analysis"); *In re Lipitor*, 46 F. Supp. 3d at 546–47 (the term was not a large and unjustified reverse payment, so the court did not apply the rule of reason); *In re Effexor XR*, 2014 WL 4988410, at *18–19 (same).

44 *Provigil*, 88 F. Supp. 3d at 405.

45 *Id.*

46 *In re Nexium*, 42 F. Supp. 3d at 262 (quoting *Actavis*, 133 S. Ct. at 2237).

47 *Id.*

48 *In re Solodyn*, 2015 WL 5458570, at *15; *see also In re Aggrenox*, 94 F. Supp. 3d at 240 (holding that, for claims to survive after *Actavis*, plaintiffs must "plead facts sufficient to infer (and they must ultimately prove, with-

in the rule-of-reason framework) that a large and otherwise unjustified reverse payment was made as part of the settlement in order to shore up some perceived risk of the . . . patent's invalidity").

[49] *In re Cipro Cases I & II*, 61 Cal. 4th 116, 156 (Cal. 2015).

[50] *Id.* at 153–54.

[51] *Id.* at 157–59.

[52] *Actavis*, 133 S. Ct. at 2236.

[53] *Id.* at 2237.

[54] *In re Aggrenox*, 94 F. Supp. 3d at 240–41.

[55] *In re Niaspan*, 42 F. Supp. 3d at 754–55.

[56] *Lamictal*, 791 F.3d at 409–10.

[57] *Id.* at nn.3 & 35.

[58] King Drug Co. of Florence, Inc. v. Cephalon, Inc. No. 2:06-cv-1787, 2014 WL 982848, at *13 (E.D. Pa. Mar. 13, 2014).

[59] *Provigil*, 88 F. Supp. 3d at 419.

[60] *In re Cipro Cases I & II*, 61 Cal. 4th at 158.

[61] *AbbVie*, 2015 WL 2114380, at *8.

[62] *Id.*

[63] *Id.* at *8–9.

[64] *Id.* at *8.

[65] *Id.*

[66] Sullivan v. Nat'l Football League, 34 F.3d 1091, 1103 (1st Cir. 1994).

[67] *See, e.g.*, *In re Nexium*, 42 F. Supp. 3d at 266.

[68] *See In re* Nexium Antitrust Litig., 309 F.R.D. 107, 141 (D. Mass. 2015) ("[C]ase law on causation . . . is very clear that private plaintiffs bear the burden of establishing causation . . . . This is to be distinguished from actions filed by the Federal Trade Commission under the FTC Act, which requires only that the government prove that a defendant's action is likely to cause injury") (internal citations and emphasis omitted).

[69] As discussed above, several courts have dismissed claims on other grounds and thus have not reached the causation question.

[70] *In re Solodyn*, 2015 WL 5458570, at *21.

[71] *In re Actos*, 2015 WL 5601752, at *26.

[72] *Id.* at *27.

[73] *Id.*

[74] *Id.*

[75] *In re Aggrenox*, 94 F. Supp. 3d at 241.

[76] In the pharmaceutical industry, an "at risk" launch is when a generic manufacturer launches a generic product at risk of the brand manufacturer's patent(s)—that is, prior to the final resolution of any patent litigation, including all appeals. The plaintiffs' theory of causation involving an at-risk launch is that but for the settlement agreement, the generic would have launched its competing generic product at risk, meaning at risk of violating the patent or patents.

[77] *Lidoderm*, 74 F. Supp. 3d at 1073–74.

[78] *Id.* at 1073.

[79] *In re Niaspan*, 42 F. Supp. 3d at 754–57.

[80] *Provigil*, 88 F. Supp. 3d at 421–22.

[81] *In re Nexium*, 42 F. Supp. 3d at 269–75.

[82] According to the court, "In order to prove antitrust damages, [the plaintiffs] would have to prove that, had it not been for the [alleged reverse payment] settlement agreement [], [the generic defendant] would have teamed with [another generic] to launch a generic version of Nexium." *In re Nexium*, 309 F.R.D. at 120.

[83] Jury Verdict at 1, *In re* Nexium Antitrust Litig., MDL No. 2409 (D. Mass. Dec. 5, 2014) (Dkt. No. 1383).

[84] *In re Nexium*, 309 F.R.D. at 145.

[85] *In re* Wellbutrin XL Antitrust Litig., No. 08-02431, 2015 WL 5582289, at *2, *23–30 (E.D. Pa. Sept. 23, 2015).

[86] For example, several courts have considered the application of the *Noerr-Pennington* doctrine in reverse payment cases. Two courts have expressly rejected its application, while another court (though not directly addressing *Noerr-Pennington*) reasoned that any alleged antitrust intent was negated by the fact that the settlement at issue had been forwarded to the Federal Trade Commission for review prior to it becoming effective. *See In re Effexor XR*, 2014 WL 4988410, at *24 ("Any alleged antitrust intent held by the parties is negated by the fact that the settlement and license agreements were forwarded to the FTC evidencing the parties' willingness to submit those agreements for review prior to the settlement becoming effective"); *In re* Androgel Antitrust Litig., No. 09-2084, 2014 WL 1600331, at *6–8 (N.D. Ga. Apr. 21, 2014) (holding that defendants were not entitled to *Noerr-Pennington* immunity); *In re Nexium*, 968 F. Supp. 2d at 394–98. Courts have also addressed plaintiffs' overarching conspiracy claims which allege that a brand and multiple generics have conspired to delay generic entry. *In re Actos*, 2015 WL 5610752, at *23–26 (granting defendants' motion to dismiss overarching conspiracy claim); King Drug Co. of Florence, Inc. v Cephalon, Inc., No. 2:06-cv-1797, 2014 WL 2813312 (E.D. Pa. June 23, 2014) (granting defendants summary judgment on overarching conspiracy claims); *In re Nexium*, 42 F. Supp. 3d at 248–58 (denying defendants' motion for summary judgment on overarching conspiracy); *but see* Electronic Clerk's Notes, *In re* Nexium Antitrust Litig., MDL No. 2409 (D. Mass. Nov. 21, 2014) (Dkt. No. 1319) and 11/21/14 Trial Tr. at 4:14-24, *In re* Nexium Antitrust Litig., MDL No. 2409 (D. Mass. Nov. 21, 2014) (granting defendants' motion for a directed verdict on overarching conspiracy).

[87] *Actavis*, 133 S. Ct. at 2245 (Roberts, C.J., dissenting).