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HOW NOT TO APPLY *ACTAVIS*

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I. INTRODUCTION

One of the most pressing issues in patent and antitrust law today involves agreements by which brand-name drug companies pay generic firms to delay entering the market. In June 2013, in *FTC v. Actavis, Inc.*, the U.S. Supreme Court concluded that these "exclusion payment"[1] settlements (in which exclusion comes from the payment rather than the patent) could have "significant anticompetitive effects" and violate the antitrust laws.[2]

In ensuring a robust role for antitrust analysis, the Court handed down one of the most important business cases in the past generation. And it articulated a blueprint for future analysis based on antitrust law's "rule of reason." But the Court did not specify every step in the analysis or consider every type of settlement. Instead, it called on "lower courts . . . [to] structur[e] . . . the present rule-of-reason antitrust litigation."[3]

Along these lines, two recent district court rulings portend ominous signs. In the first case, *In re Lamictal Direct Purchaser Antitrust Litigation*, the District of New Jersey granted a motion to dismiss plaintiffs' challenge to a settlement on a drug treating epilepsy and bipolar disorder.[4] In doing so, the *Lamictal* court used the five factors that the *Actavis* Court had employed to justify *more* aggressive antitrust scrutiny to instead excuse its decision to employ *less* vigorous scrutiny. Just as concerning, it substituted its own armchair analysis for the burdens of proof articulated in *Actavis*.

In the second case, *In re Loestrin 24 FE Antitrust Litigation*, the Rhode Island District Court relied on *Lamictal*'s flawed framework to grant motions to dismiss plaintiffs' challenge to a settlement delaying generic entry of an oral contraceptive.[5] The court agonized over the "close call" presented by the case while failing to recognize that it was its own following of the *Lamictal* court's framework that led it into briar patches of

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[1] Payments from brands to generics are often called "reverse payments" because the payment flows from patentee to alleged infringer (unlike typical settlements in which alleged infringers pay to enter the market). This Essay uses the phrase "exclusion payments," which better captures the exclusion that brands can obtain by paying generics to delay entering the market.

[2] 133 S. Ct. 2223, 2237–38 (2013) [http://perma.cc/W67P-MU74].

[3] *Id.* at 2238.

[4] No. 12–cv–995 (WHW), 2014 WL 282755 (D.N.J. Jan. 24, 2014) [http://perma.cc/A5GN-Q6TE].

[5] MDL No. 13–2472–S–PAS, 2014 WL 4368924 (D.R.I. Sept. 4, 2014) [http://perma.cc/GT72-TGLW].

confusion, uncomfortable policy conclusions, neglect of pleading standards, and encouragement of conduct that it knew would "evade [antitrust] scrutiny."[6]

If the *Lamictal* and *Loestrin* decisions are upheld and adopted by other courts, plaintiffs will face insurmountable hurdles, rendering the landmark *Actavis* decision nothing more than a dead letter. This Essay shows that the *Lamictal* and *Loestrin* courts erred in (1) applying a framework never anticipated in *Actavis*; (2) ignoring crucial holdings from *Actavis*; and (3) amassing unjustified powers for themselves.

By blocking affordable generic prescription drugs, exclusion-payment settlements cost consumers billions of dollars and have profound consequences for public health. But if the trend unleashed by the *Lamictal* and *Loestrin* cases is not quickly reversed, courts will be relegated to the role of traffic cops waving anticompetitive settlements through flashing green lights of judicial "scrutiny."

II. *ACTAVIS*

In *Actavis*, the Supreme Court issued a landmark ruling on the application of antitrust law to exclusion-payment settlements. Most important, it held that the existence of a patent did not immunize such settlements from antitrust scrutiny. The Court found that "it would be incongruous to determine antitrust legality by measuring [a] settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well."[7]

Actavis was a significant ruling. In most of the decade before the Court's decision, nearly all the appellate courts that had examined exclusion-payment settlements concluded that they did not present antitrust concern because they fell within the scope of the patent.[8] As applied by these courts, judges relied on the mere existence of a patent—even one that was invalid or not infringed—to justify any payment.[9] In contrast, in recognizing the anticompetitive effects of a payment for a potential rival to delay entering the market, the Supreme Court offered a more nuanced and appropriate analysis.

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[6] *Id.* at *12–13.

[7] *Actavis*, 133 S. Ct. at 2231.

[8] *See, e.g.*, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1336 (Fed. Cir. 2008) ("The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent.") [http://perma.cc/P7NU-WEK9]; *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213 (2d Cir. 2006) (holding that the settlement did not "unlawfully extend the reach" of the patent) [http://perma.cc/A6X7-NG3J]; Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1072 (11th Cir. 2005) (finding that the exclusion payments were "within the patent's exclusionary power") [http://perma.cc/33PW-R8NW].

[9] The courts only carved out exceptions for fraud before the Patent Office or sham litigation. *See, e.g.*, *Ciprofloxacin*, 544 F.3d at 1337; FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012) [http://perma.cc/4NT-FZB7].

The Court in *Actavis* found that a brand's payment "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."[10] The Court worried that "a party with no claim for damages . . . walks away with money simply so it will stay away from the patentee's market."[11] And it lamented that "payment in return for staying out of the market . . . simply keeps prices at patentee-set levels," which leads to gains for the patentee and challenger but losses for the consumer.[12]

In addition to subjecting exclusion-payment settlements to antitrust scrutiny, the Court made clear that future courts should analyze such agreements under the rule of reason, which considers an agreement's anticompetitive and procompetitive effects. Such a framework "consider[s] traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations."[13] As part of the proposed analysis, the Court allowed plaintiffs to use shortcuts to demonstrate anticompetitive effects and market power.[14] And it anticipated that defendants would bear the burden of demonstrating a payment's justifications.[15]

III. FIVE FACTORS: FRAMEWORK

The *Lamictal* and *Loestrin* courts purported to apply an analysis based on the rule of reason. But they diverged from the Supreme Court in centering their analysis on five factors discussed in *Actavis*. The *Lamictal* court stated that "[t]he *Actavis* opinion lays out 'five considerations' to guide district courts in applying the rule of reason."[16] And the *Loestrin* court agreed that "[o]stensibly to assist the lower courts, *Actavis* set forth five 'considerations' to guide the inquiry as to whether a settlement payment satisfies the rule of reason."[17]

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[10] *Actavis*, 133 S. Ct. at 2234.

[11] *Id.* at 2233.

[12] *Id.* at 2234–35.

[13] *Id.* at 2231. Courts engage in a more comprehensive analysis under the rule of reason than they conduct under the per se review applicable to price-fixing, output-limitation, and market-allocation agreements. *See, e.g.*, Palmer v. BRG of Ga., Inc., 498 U.S. 46 (1990) [http://perma.cc/SR2M-K3X9].

[14] *Actavis*, 133 S. Ct. at 2234, 2236 (explaining that exclusion payments have the "potential for genuine adverse effects on competition" and that the "size of the payment" can serve as "a strong indicator of [market] power").

[15] *Id.* at 2236–37 ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present," such as saved litigation costs or "fair value for services . . . . [O]ne who makes such a payment may be unable to explain and to justify it.").

[16] *In re* Lamictal Direct Purchaser Antitrust Litig., No. 12–cv–995 (WHW), 2014 WL 282755, at *5 (D.N.J. Jan. 24, 2014) (quoting and citing *Actavis*, 133 S. Ct. at 2234–37).

[17] *In re* Loestrin 24 FE Antitrust Litig., MDL No. 13–2472–S–PAS, 2014 WL 4368924, at *8 (D.R.I. Sept. 4, 2014). Other courts have similarly erred in making this assertion though they have not

Actavis did not, however, introduce the five factors as the foundation of a new and unique rule-of-reason analysis. The Court's intended analysis followed the familiar antitrust framework that "consider[s] traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations."[18]

Instead, the Court employed the five factors for a very different reason: to show why the "general legal policy favoring the settlement of disputes" did not displace ordinary antitrust analysis.[19] This was important. For the decade before the *Actavis* decision, most appellate courts that had considered exclusion-payment agreements had immunized them largely based on the policy in favor of settlements, which conserve resources and provide certainty. For example, the Eleventh Circuit in *Schering-Plough Corp. v. FTC* found that "[t]he general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits."[20] Similarly, the Federal Circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* highlighted the "long-standing policy in the law in favor of settlements, [which] extends to patent infringement litigation."[21]

Courts also deferred to settlements so as not to harm incentives for innovation. The *Tamoxifen* court stated that rules "severely restricting" settlements could hamper the patent system's goals by increasing uncertainty and delaying innovation.[22] Similarly, the Eleventh Circuit in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.* concluded that reduced settlement options would raise enforcement costs and "impair . . . incentives for disclosure and innovation."[23] And the *Schering-Plough* court found that "the caustic environment of patent litigation" could reduce innovation by increasing the "uncertainty around the drug manufacturer's ability to research, develop, and market the patented product."[24]

The influence of the pro-settlement policy explains why the Supreme Court tackled this argument head-on. To support its conclusion that the policy did not immunize exclusion-payment settlements, the Court employed five wide-ranging arguments that centered on exclusion

ordered their analysis around the five factors. *See, e.g.*, *In re* Effexor XR Antitrust Litig., Civil Action No. 11-5479 (PGS) (LHG), 2014 U.S. Dist. LEXIS 142206, at *59 (D.N.J. Oct. 6, 2014) ("[T]he Supreme Court specifically raised the following five sets of considerations to guide its rule of reason analysis . . . .") [http://perma.cc/RV23-EFXE]; *In re* Lipitor Antitrust Litig., Civil Action No. 3:12-cv-02389 (PGS), slip op. at 23 (D.N.J. Sept. 12, 2014) (same) [http://perma.cc/A27G-588U].

[18] *Actavis*, 133 S. Ct. at 2231. For a discussion of plaintiffs' ability to use exclusion payments as shortcuts in proving anticompetitive effects and market power, see *supra* note 14.

[19] *Id.* at 2234.

[20] 402 F.3d 1056, 1072 (11th Cir. 2005).

[21] 544 F.3d 1323, 1333 (Fed. Cir. 2008).

[22] *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 203 (2d Cir. 2006).

[23] 344 F.3d 1294, 1308 (11th Cir. 2003) [http://perma.cc/4L4U-5KN3].

[24] *Schering-Plough*, 402 F.3d at 1075.

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.[25]

In case there were any doubt as to the Court's use of the factors, it made clear that "these [five] considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements."[26] Applied to the case, the Court explained that "the FTC should have been given the opportunity to prove its antitrust claim."[27]

In contrast to the Supreme Court's unmistakable use of the factors to open a courthouse door that had been slammed shut by excessive deference to the policy supporting settlements, the *Lamictal* and *Loestrin* courts used the factors to conclude that the plaintiffs should *not* be given an opportunity to prove their antitrust claim. In addition to using the five factors for very different reasons than in *Actavis*, the courts adopted policy conclusions the Supreme Court had specifically rejected. Finally, the *Lamictal* court found room in the factors to engage in armchair speculation, while the *Loestrin* court imposed astronomically high standards that future plaintiffs will almost never be able to satisfy. These problems become painfully apparent through analysis of each of the factors.

IV. FIVE FACTORS: APPLICATION

The framework that the *Lamictal* and *Loestrin* courts used to analyze exclusion-payment settlements was wrong not only in the theory of the Supreme Court's anticipated antitrust analysis, but also in the application of each of the five factors. Each of the factors was marred by analysis based on speculation and the imposition of requirements nowhere found in—and sometimes directly contrary to—*Actavis*.

A. Factor One: Adverse Effects on Competition

For the first factor, the *Lamictal* court assumed that "the settlement does not have the potential for genuine adverse effects on competition."[28] The settlement involved a brand's promise not to introduce its own generic, known as an "authorized generic," during the 180-day period reserved for the first generic to file a "Paragraph IV" certification challenging a brand's patent, claiming that it is invalid or not infringed.[29] Authorized generics are approved by the U.S. Food and Drug Administration (FDA) as brand drugs

[25] FTC v. Actavis, Inc., 133 S. Ct. 2223, 2234–37 (2013).

[26] *Id.* at 2237.

[27] *Id.* at 2234.

[28] *In re* Lamictal Direct Purchaser Antitrust Litig., No. 12–cv–995 (WHW), 2014 WL 282755, at *10 (D.N.J. Jan. 24, 2014).

[29] *Id.* at *2*; see also* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2013) [http://perma.cc/UTW5-DWGB].

but marketed as generics.[30] Even though the 180-day period is designed to encourage generic entry and is uniquely valuable (potentially worth hundreds of millions of dollars)[31] to the first-filing generic, the brand is free to introduce its own generic version during the period.[32]

A Federal Trade Commission study on authorized generics found that the first-filing generic's revenues are approximately twice as high when it enjoys the 180-day period without an authorized generic.[33] In addition, the first filer loses 25% of its market share when it competes with an authorized generic during the 180-day period.[34] Given the value provided by a brand's promise not to introduce an authorized generic, the *Lamictal* court was too hasty to assume the absence of the "potential for genuine adverse effects on competition."[35]

Nor are the reasons the court offered for its conclusion persuasive. The court found solace in the fact that the generic "was allowed six months of early entry," that there were no monetary payments, and that the duration of the agreement was a "relatively brief six months."[36] But "six months of early entry" assumes that the brand was entitled to block entry until the end of the patent term—an assumption that *Actavis* expressly rejected.[37] In addition, the court ignored fundamental economics in viewing money as completely different from a promise worth an equivalent amount of money.[38] Finally, the suggestion that the no-authorized-generic pledge covered a relatively brief six months ignores the well-known economics of the pharmaceutical industry (in which drug prices decrease as the number of generics on the market increases),[39] not to mention *Actavis*'s express acknowledgement that "the vast majority of potential profits for a generic drug manufacturer materialize during the 180–day exclusivity period."[40]

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[30] FTC, AUTHORIZED GENERIC DRUGS, at i (2011) [http://perma.cc/LQ6V-65GP].

[31] *Actavis*, 133 S. Ct. at 2235.

[32] *See* Mylan Pharms., Inc. v. FDA, 454 F.3d 270, 275–76 (4th Cir. 2006) [http://perma.cc/E3QQ-CA3F]; Teva Pharm. Indus. v. Crawford, 410 F.3d 51, 55 (D.C. Cir. 2005) [http://perma.cc/N26G-4JS2].

[33] FTC, *supra* note 30, at 58–59. Even after the exclusivity period, the effects continue, with revenues of the first-filing generic 53% to 62% lower in the 30 months following exclusivity. *Id.* at iii.

[34] *Id.* at 57.

[35] *In re* Lamictal Direct Purchaser Antitrust Litig., No. 12–cv–995 (WHW), 2014 WL 282755, at *10 (D.N.J. Jan. 24, 2014).

[36] *Id.*

[37] *Actavis*, 133 S. Ct. at 2231. Such an argument is a variation on the "scope of the patent" test that the Federal, Second, and Eleventh Circuits had followed in the decade before the Supreme Court decisively rejected it in *Actavis*. *See supra* note 8 and accompanying text.

[38] *See* Michael A. Carrier, *Payment After* Actavis, 100 IOWA L. REV. 7, 35–47 (2014) [http://perma.cc/8ED2-BAVL].

[39] *Generic Competition and Drug Prices*, U.S. FOOD & DRUG ADMIN. (Mar. 1, 2010), http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm [http://perma.cc/GTL7-L5DV].

[40] *Actavis*, 133 S. Ct. at 2229.

While the *Lamictal* court incorrectly assumed a lack of competitive harm, the *Loestrin* court erred by imposing hurdles never envisioned by *Actavis*. This court claimed that *Actavis* suggested that application of the first factor on adverse competitive effects "requires a comparison of the anticipated supracompetitive profits associated with continued monopoly sale of the product, and the sum paid to the generic competitor."[41] The *Loestrin* court even claimed that "it would be all but impossible to assess the 'potential for genuine adverse effects on competition' without the ability to compare the expected monopoly profits to the size of the patentee's payment."[42]

But *Actavis* never required such a comparison. Instead, the Court highlighted the harms from payment and confirmed that the presence of multiple generics would not prevent brands from entering into settlements. It explained that a brand's payment is essentially "a purchase . . . of the exclusive right to sell its product" (which it would lose if it lost the patent litigation) and that "payment in return for staying out of the market [] simply keeps prices at patentee-set levels."[43] Additionally, the Court confirmed that brands would be able to enter into settlements (and that there were not too may challengers to "buy off") because of the unique position possessed by first-filing generics.[44]

To support its requirement for comparing monopoly profits and payment size, the *Loestrin* court quoted a passage from *Actavis* that a payment may "'provide strong evidence that the patentee seeks to induce the generic . . . to abandon its claim with a share of its monopoly profits.'"[45] But this passage only references a brand's ability to use its monopoly profits to induce a generic to drop its claim. It does not even hint at precise calculations of monopoly profits and generic payment, let alone a comparison between the two. As discussed below, such a high bar effectively blocks plaintiffs from court.[46]

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[41] *In re* Loestrin 24 FE Antitrust Litig., MDL No. 13–2472–S–PAS, 2014 WL 4368924, at *8 (D.R.I. Sept. 4, 2014).

[42] *Id.* at *9 (quoting *Actavis*, 133 S. Ct. at 2234).

[43] *Actavis*, 133 S. Ct. at 2234. The Court explained that high prices could produce "the full patent-related . . . monopoly return while dividing that return between the challenged patentee and the patent challenger." *Id.* at 2234–35. But it used the phrase "monopoly return" not to require plaintiffs to show an exact amount but to make clear that the patentee and challenger divide the return, which leads to "[t]he patentee and the challenger gain[ing and] the consumer los[ing]." *Id.* at 2235.

[44] *Id.* at 2235.

[45] *Loestrin*, 2014 WL 4368924, at *8 (quoting *Actavis*, 133 S. Ct. at 2235).

[46] Two recent opinions (authored by the same judge) set a similarly elevated bar in requiring non-monetary payments to be "converted to a reliable estimate of its monetary value so that it may be analyzed against the *Actavis* factors such as whether it is 'large' once the subtraction of legal fees and other services provided by generics occurs." *In re* Lipitor Antitrust Litig., Civil Action No. 3:12-cv-02389 (PGS), slip op. at 32 (D.N.J. Sept. 12, 2014); *see also In re* Effexor XR Antitrust Litig., 2014 U.S. Dist. LEXIS 142206, at *63 (D.N.J. Oct. 6, 2014). The *Lipitor* court even required the plaintiffs to prove the patentee's lost profits through showings of "(1) demand for the product; (2) absence of

B. Factor Two: Unjustified Payments

Turning to the second factor, the *Lamictal* court erred by mystically finding that the payment at issue was justified.[47] It reached this conclusion by speculating that the brand "may . . . have derived some ancillary benefit from [the generic's] licensed sales . . . in terms of distribution and marketing."[48] But such speculation is not appropriate: it is the *defendant's* burden to *prove* procompetitive justifications, not the *court's* function to *assume* them.

Compounding its error, the *Lamictal* court found that "the consideration which the parties exchanged in the settlement is reasonably related to the removal of the uncertainty created by the dispute."[49] But *Actavis* was unambiguous in instructing that eliminating the risk that the patent would be found invalid or not infringed—the risk that competition would break out—is *anticompetitive, not procompetitive*. The payment "likely seeks to prevent the risk of competition," which "constitutes the relevant anticompetitive harm."[50] Finally, the court's admission that the consideration "likely exceeds what the parties would have spent litigating the patent dispute"[51] shows that the settling patent litigants would not have been able to rely on *Actavis*'s justification for payments not exceeding litigation costs.

The *Loestrin* court committed a different error in its analysis of the second factor of unjustified anticompetitive effects. In particular, it raised the bar beyond *Actavis* by requiring the plaintiffs' complaint to plead the "monetary value of the settlement payment."[52] Requiring *plaintiffs* to prove that the defendants' business deal exceeded "fair value" contravenes *Actavis*'s holding that defendants have the burden of proof on this procompetitive justification.[53] And requiring plaintiffs to negate this justification *in their complaint*, when defendants possess the evidence relating to the justifications for and valuations of the payment does not make sense.[54]

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noninfringing substitutes; (3) manufacturing and marketing capability; and (4) the amount of profit." *Lipitor*, slip op. at 35. This sets the bar too high: not only would plaintiffs not be able to make these showings (let alone on a motion to dismiss) but also the *Actavis* Court made clear that it is *defendants* that bear the burden of justifying payments for services. *See infra* Part IV.D.

[47] *In re* Lamictal Direct Purchaser Antitrust Litig., No. 12–cv–995 (WHW), 2014 WL 282755, at *10 (D.N.J. Jan. 24, 2014).

[48] *Id.*

[49] *Id.*

[50] FTC v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013).

[51] *Lamictal*, 2014 WL 282755, at *10.

[52] *In re* Loestrin 24 FE Antitrust Litig., MDL No. 13–2472–S–PAS, 2014 WL 4368924, at *9 (D.R.I. Sept. 4, 2014).

[53] *Actavis*, 133 S. Ct. at 2236*; see also supra* note 15.

[54] *See infra* notes 90–91 and accompanying text.

C. Factor Three: Market Power

For the third factor, the *Lamictal* court could not "conclude whether the brand . . . has the market power needed to bring about anticompetitive harm," but it found that "this would not be dispositive."[55] Rather than requiring courts to engage in detailed analyses of market power, however, *Actavis* explained that a firm without market power is unlikely to pay large sums to keep others out of its market.[56] The *Lamictal* court failed to recognize that a brand's promise not to launch an authorized generic can easily reflect "higher-than-competitive profits—a strong indication of market power."[57]

The *Loestrin* court fumbled the ball here, too. In *Actavis*, the Court used the third factor to show that the pro-settlement policy did not immunize settlements because plaintiffs could rely on certain payments themselves to show market power. To the contrary, the *Loestrin* court stated that courts "must consider whether the size of the reverse payment indicates that the patentee held sufficient market power to 'work unjustified anticompetitive harm.'"[58] And the court worked backwards from that false premise to the conclusion that only cash payments are subject to antitrust scrutiny because it is too difficult for courts to calculate the size of non-cash payments.

But the Supreme Court never stated or implied that the only way for a plaintiff to plead or prove market power was through the size of the payment. And in addition to the payment, the *Loestrin* plaintiffs pled that "[a]t all relevant times, [the brand's] price for Loestrin 24 has been at least 60% above its marginal cost of production, and at least 40% above its marginal cost including marketing costs."[59] The plaintiffs also alleged that the brand "has never lowered the price of Loestrin 24 in response to the pricing of other branded oral contraceptives (or the generic versions of those other branded oral contraceptives)."[60]

D. Factor Four: Feasibility

Fourth, *Actavis* held that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness," obviating the need for courts to try a patent case within an antitrust case.[61] The *Lamictal* court, however, turned this around, concluding that "the sweep of the

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[55] *Lamictal*, 2014 WL 282755, at *10.

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

[57] *Id.*

[58] *In re* Loestrin 24 FE Antitrust Litig., MDL No. 13–2472–S–PAS, 2014 WL 4368924, at *8 (D.R.I. Sept. 4, 2014) (quoting *Actavis*, 133 S. Ct. at 2236).

[59] Consolidated Class Action Complaint at ¶ 144, *In re* Loestrin 24 FE Antitrust Litig., MDL No. 13–2472–S–PAS, 2014 WL 4368924 (D.R.I. Sept. 4, 2014) [http://perma.cc/D9L2-C2HS].

[60] *Id.*

[61] *Actavis*, 133 S. Ct. at 2236–37.

settlement [did] not suggest that it [was] intended to maintain supracompetitive prices and serve as a 'workable surrogate for a patent's weakness.'"[62]

This was completely backward. *Actavis* did not add an intent requirement into rule-of-reason analysis. The Supreme Court was referring to courts using the payment as a "surrogate" for patent weakness (analyzing the payment rather than re-litigating the patent merits), not to parties having an intent to use the payment to mask patent weakness. In addition, it would seem presumptuous to assume that the parties did not intend an anticompetitive effect when they paid and received the payment *immediately after a court had ruled that a claim of the patent covering the drug's active ingredient was invalid*.[63]

The *Loestrin* court similarly failed to recognize that *Actavis* employed the fourth factor to show the feasibility of antitrust actions on the grounds that "it is normally not necessary to litigate patent validity to answer the antitrust question," and in fact, "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival."[64] But again, the *Loestrin* court put the burden on the plaintiff to divine a precise value of the payment as a surrogate for a patent's weakness.[65] In other words, if the plaintiff could not provide an exact value, it would not be able to use the payment to demonstrate that the patent likely was invalid or not infringed. Both courts thus took a factor from *Actavis* that allowed plaintiffs to show patent *weakness* and twisted it into an intent defense that courts could invoke to *justify* settlement.

E. Factor Five: Other Settlements

Fifth, the *Lamictal* court stated that "the parties settled in a way that did not involve monetary reverse payments."[66] Referring again to "early" entry and a "limited" six-month period of no authorized-generic entry, the court ensured that the settling parties had the "latitude to settle without triggering the antitrust scrutiny that large, unjustified reverse payments bring."[67] But again, *Actavis* taught the exact opposite lesson in its reminder that litigating parties had ways to settle that did not involve payment.[68] Far

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[62] *In re* Lamictal Direct Purchaser Antitrust Litig., No. 12–cv–995 (WHW), 2014 WL 282755, at *10 (D.N.J. Jan. 24, 2014) (quoting Actavis, 133 S. Ct. at 2236–37).

[63] Consolidated Amended Class Action Complaint at ¶ 18, *In re* Lamictal Direct Purchaser Antitrust Litig., No. 12–cv–995 (WHW), 2014 WL 282755 (D.N.J. Jan. 24, 2014) (noting that the generic "had already succeeded in invalidating Claim 1 of the '017 patent covering the active ingredient of Lamictal" and alleging that "the remaining claims of the patent at issue were extremely weak and highly likely to be held invalid") [http://perma.cc/56PS-Q5X7].

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

[65] *Loestrin*, 2014 WL 4368924, at *9.

[66] *Lamictal*, 2014 WL 282755, at *10.

[67] *Id.*

[68] *Actavis*, 133 S. Ct. at 2237 (noting that litigating parties may "settle in other ways, for example,

from revealing an intent to give patent litigants the leeway to settle with payment, the Supreme Court made clear that the antitrust laws are likely to forbid arrangements by which the settling parties "maintain and . . . share patent-generated monopoly profits."[69]

The *Loestrin* court ventured even further afield in asserting that courts should "assess the payment in light of the reasons given for its having been made."[70] In *Actavis*, the Court highlighted the need for antitrust liability when the parties seek to maintain and share patent-generated monopoly profits. But the Court did not anticipate an open-ended assessment of the reasons for the payment. Nor did it expect plaintiffs to be required to demonstrate a precise settlement value and compare it to monopoly profits to discern the "basic reason" for the settlement.[71]

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In short, the *Lamictal* and *Loestrin* courts applied an antitrust analysis that used the five factors in a manner directly contrary to the Supreme Court's opinion in *Actavis*. The Court applied the factors to show that the pro-settlement policy should not immunize exclusion-payment settlements and allow the FTC to prove its case. In contrast, the *Lamictal* and *Loestrin* courts used the factors to block plaintiffs from proving their cases. The *Lamictal* court assumed that there were no anticompetitive effects, that payments were justified, and that there was no intent to maintain monopoly prices.[72] The *Loestrin* court supplemented this speculation by imposing the hurdle of calculating a "true value" and by punishing plaintiffs that were not able to make such a determination, finding that they would not be able to show anticompetitive effects, unjustified payments, market power, patent weakness, or the "basic reason" for settlement.[73]

V. UNHEEDED HOLDINGS

The *Lamictal* and *Loestrin* courts also erred in disregarding four essential holdings from *Actavis*, which addressed (1) the public policy in favor of settlement; (2) parties' inability to settle cases without exclusion payments; (3) the elimination of risk as a justification; and (4) the burdens imposed on plaintiffs.

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by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point").

[69] *Id.*

[70] *Loestrin*, 2014 WL 4368924, at *9.

[71] *See Actavis*, 133 S. Ct. at 2237.

[72] *In re* Lamictal Direct Purchaser Antitrust Litig., No. 12–cv–995 (WHW), 2014 WL 282755, at *10 (D.N.J. Jan. 24, 2014).

[73] *Loestrin*, 2014 WL 4368924, at *9, *12 (asserting that "each of the five *Actavis* factors plainly requires" the comparing of brand revenues to the payment).

A. Settlement Policy

The first unheeded holding involved an excessive deference to the public policy reasons in support of settlement. As discussed above, this policy played a role in appellate courts' insufficient scrutiny of settlements in the decade before *Actavis*.[74] The *Loestrin* court asserted that "the fact that the majority and the dissent recognize and promote the public policy value of patent settlements[] suggests that *Actavis* should be read to apply solely to the cash settlements that it describes, and to exclude non-cash settlements, preserving for litigants a viable path to resolve their disputes."[75]

In contrast to the *Loestrin* court's assertion, the *Actavis* Court exhaustively detailed why the policy in favor of settlement was not commanding enough to outweigh the other policy considerations favoring antitrust scrutiny of exclusion-payment settlements. The *Loestrin* court's disregard of this holding was particularly ironic given *Actavis*'s invocation of five factors to rebut the policy and the *Loestrin* court's own application of the five factors (albeit for a contrary objective). Along similar lines, the *Loestrin* court's statement that the *Actavis* majority "recognize[d] and promote[d] the public policy value of patent settlements" is brazen in its disregard of the Supreme Court's holding.[76]

B. Need for Exclusion Payments

Second, the *Lamictal* and *Loestrin* courts worried that applying antitrust scrutiny to non-cash settlements would reduce patent litigants' ability to settle. The *Lamictal* court stated that *Actavis* "made clear its intent to give patent litigants latitude to settle without triggering the antitrust scrutiny that large, unjustified reverse payments bring."[77] In addition, the court found that denying a safe harbor for anything other than entry-date settlements (without payment) would "far too greatly constrict parties' power to settle, a power the *Actavis* court clearly meant to keep intact."[78]

The *Loestrin* court went even further, avowing that "there can be no dispute that the holding in *Actavis* and the abandonment of the scope-of-the-patent test will make it more difficult for patent litigants to settle."[79] But this court oddly relied on an article written by a lawyer who has represented defendants in exclusion-payment settlement cases rather than the Supreme Court, which directly addressed the issue.[80] Nor was the *Loestrin* court

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[74] *See supra* notes 20-24 and accompanying text.

[75] *Loestrin*, 2014 WL 4368924, at *11.

[76] *Id.*

[77] *Lamictal*, 2014 WL 282755, at *10.

[78] *Id.* at *7 n.4.

[79] *Loestrin*, 2014 WL 4368924, at *11.

[80] *See id.* (citing Kevin D. McDonald, *Because I Said So: On the Competitive Rationale of* FTC v. Actavis, ANTITRUST, Fall 2013, at 36, 42 (noting representation of "defendants in all of the *Ciprofloxacin* cases" and in the *Nexium* case) [http://perma.cc/B69D-DY3J]).

correct that the Supreme Court rendered non-cash settlements immune from antitrust scrutiny to "preserv[e] for litigants a viable path to resolve their disputes."[81]

In *Actavis*, the Justices made clear that the risk of antitrust liability from payment "does not prevent litigating parties from settling their lawsuit."[82] The Court pointed out that parties could pursue alternative forms of settlement, such as "allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point."[83]

These agreements, by which brands and generics divide the patent term by selecting a time for generic entry, tend to reflect the odds of success in patent litigation (and thus do not present similar antitrust concern).[84] And the settlements are more than possible—in fact, they are typical, as shown by a recent FTC report that more than 70% of settlements do not involve payment or delayed generic entry.[85]

C. Risk as Justification

The *Lamictal* court also erred in accepting the elimination of patent risk as a justification the defendants could offer to excuse their settlement. The court found that "the consideration which the parties exchanged in the settlement is reasonably related to the removal of the uncertainty created by the dispute."[86] But, as discussed above, *Actavis* clearly explained that eliminating the risk that a patent would be found invalid or not infringed is anticompetitive. The payment "likely seeks to prevent the risk of competition," which "constitutes the relevant anticompetitive harm."[87] The *Lamictal* court should not be able to resurrect a justification that the Supreme Court specifically considered *and rejected*.

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[81] *Id.*

[82] FTC v. Actavis, 133 S. Ct. 2223, 2237 (2013).

[83] *Id.*

[84] HERBERT HOVENKAMP ET AL., 1 IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 15.3, at 15–45 (2d ed. Supp. 2012); Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 660 (2004) [http://perma.cc/T23W-LLP8].

[85] *See* FTC BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2012, at 1–2 (2013) [http://perma.cc/4SME-J665]. Evidence from Europe is consistent, with the most recent monitoring report concluding that 93% of settlements between brands and generics "f[e]ll into categories that *prima facie* raise no need for competition law scrutiny." European Commission, *4th Report on the Monitoring of Patent Settlements*, ¶ 51 (Dec. 9, 2013) [http://perma.cc/5N77-CY4N].

[86] *In re* Lamictal Direct Purchaser Antitrust Litig., No. 12–cv–995 (WHW), 2014 WL 282755, at *10 (D.N.J. Jan. 24, 2014).

[87] *Actavis*, 133 S. Ct. at 2236 (emphasis omitted).

D. Burdens on Plaintiffs

Both the *Lamictal* and *Loestrin* courts inappropriately shifted several burdens to the plaintiffs. The *Lamictal* court provided an irrebuttable presumption that the settlement at issue was procompetitive based on its bare assertions that it did not "have the potential for genuine adverse effects on competition," that the payment was justified, and that "the sweep of the settlement does not suggest that it is intended to maintain supracompetitive prices and serve as a 'workable surrogate for a patent's weakness.'"[88]

The *Loestrin* court allowed plaintiffs to try to make these showings. But it imposed the entire burden on plaintiffs, asserting that "[c]ritically, each of the[] five factors requires, on the part of the plaintiff . . . an ability to assess or calculate the true value of the payment."[89] Additionally, if the plaintiff could not definitively prove the monetary value of the payment, it would be unable to demonstrate that the payment was unjustified.[90]

The *Actavis* Court, however, never envisioned plaintiffs being forced to prove each of the factors. The Court explained that "[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present" and that in some cases the defendant might be "unable to explain and to justify [its payment]."[91] Putting the burden on defendants is consistent with their ability to justify a payment by showing that it reflects saved litigation costs or "fair value for services."[92]

In addition to shifting inappropriate burdens to plaintiffs, the *Loestrin* court raised the burdens to extremely high levels, requiring plaintiffs to show a payment's "true value" and asserting that the failure to make such a precise calculation would prevent them from showing each of the factors it expected plaintiffs to prove: anticompetitive effect, unjustified payment, market power, patent weakness, and the reasons for settlement.[93]

The *Loestrin* court recognized that this imposed insurmountable burdens on plaintiffs. The court admitted that the pleading standard articulated in *Bell Atlantic Corp. v. Twombly*[94] requires only "plausible grounds to infer an agreement" and "does not impose a probability

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[88] *Lamictal*, 2014 WL 282755, at *10.

[89] *In re* Loestrin 24 FE Antitrust Litig., MDL No. 13–2472–S–PAS, 2014 WL 4368924, at *9 (D.R.I. Sept. 4, 2014).

[90] *Id.* (citing *Actavis*, 133 S. Ct. at 2236).

[91] *Actavis*, 133 S. Ct. at 2236–37.

[92] *Id.* at 2236; *see also* Aaron Edlin et al., *Activating* Actavis, ANTITRUST, Fall 2013, at 18 (noting that "defendants are in possession of the relevant evidence about their side deals," that "complexity is the result of the defendants' own actions," and that "[t]he parties to a payment for delay have ample reason to pack complexities into the deal (such as relatively unimportant services) to conceal its genuine nature") [http://perma.cc/59QW-6YKA].

[93] *Loestrin*, 2014 WL 4368924, at *9. The court even created the rule that "in reverse payment contexts where rule of reason scrutiny is not applicable, dismissal is required." *Id.* at *12.

[94] 550 U.S. 544 (2007) [http://perma.cc/BPB9-9WRP].

requirement."[95] In fact, the *Loestrin* court confessed that the plaintiffs had submitted "two robust complaints" containing "facts demonstrating illegal contracts or combinations in restraint of trade."[96]

In contravention of its exhortations to show a payment's "true value," however, the court conceded that the plaintiffs "(understandably) struggle[d] to affix a precise dollar value" to the brand's non-cash payment for delay, and that "[t]his should come as no surprise because pleading facts sufficient to glean the monetary value of non-cash settlements is a tall task, one that would typically require considerable discovery to achieve."[97]

Further arguing against itself, the court explained that this was "particularly true" when a "settlement involves licenses and co-promotion arrangements for other drugs and a 'no authorized generic' agreement," as these arrangements make "even a ballpark estimate . . . difficult to conjure."[98] In short, the *Loestrin* court recognized that plaintiffs would not be able to demonstrate a precise value for payment and that its ruling was not consistent with the Supreme Court's opinion in *Twombly*. Despite these legitimate concerns, the court nonetheless forged ahead by manufacturing out of whole cloth precision requirements from *Actavis*. And it applied these creations to dismiss plaintiffs' claims even though it conceded that "the [p]laintiffs have adequately pled the existence of a Sherman Act § 1 violation."[99]

VI. JUDICIAL BLAME-SHIFTING

In addition to misapplying the rule-of-reason framework and neglecting four crucial *Actavis* holdings, the *Loestrin* court placed the blame for its opinion squarely on the Supreme Court. The court lamented that if the Supreme Court had "intended for rule of reason scrutiny to apply to non-cash settlements, it could simply have said so."[100] But this unsuccessful attempt at judicial blame-shifting merely highlights problems with the *Loestrin* court's own reasoning.

The *Loestrin* court concluded that *Actavis* permits antitrust scrutiny of only cash payments because calculating the value of an above-market-value business deal is too difficult and therefore does not satisfy the five factors.

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[95] *Loestrin*, 2014 WL 4368924, at *11 (quoting *Twombly*, 550 U.S. at 556).

[96] *Id.*

[97] *Id.*

[98] *Id.*

[99] *Id.* at *12. Heightened burdens on plaintiffs also result from the three-part test that the *Lamictal* court created (and *Loestrin* court followed), which asks (1) if there is a reverse payment and (2) if such a payment is large and unjustified, followed by (3) the rule of reason. *Id.* at *7; *In re* Lamictal Direct Purchaser Antitrust Litig., No. 12–cv–995 (WHW), 2014 WL 282755, at *5 (D.N.J. Jan. 24, 2014). Such a framework imposes burdens on plaintiffs (who, for example, are required to show that the payment is unjustified) and can put undue emphasis on cash payments.

[100] *Loestrin*, 2014 WL 4368924, at *11.

But *Loestrin* lost track of the obvious fact that *Actavis itself involved not a cash payment, but an above-market-value business deal*. As the Supreme Court explained: "[t]he companies described these payments as compensation for other services the generics promised to perform, but the FTC contends the other services had little value."[101] The *Loestrin* court thus was not correct in asserting that *Actavis*'s analysis precludes scrutiny of a payment in the *very form* that the Supreme Court held is subject to scrutiny and as to which it reversed the complaint's dismissal.[102] To state it gently, this is a good indicator that *Loestrin*'s reading of *Actavis* is wrong.

Pointing to an additional form of payment—the no-authorized-generic clause—*Loestrin* lamented that *Actavis* did not address *all* of the non-cash forms that an unlawful payment might take. But it is not realistic to expect the Court to address every issue that could conceivably arise in any future case, including the form that every such agreement could take. The Court decided numerous contested issues for the first time in *Actavis*, including (1) the role of antitrust law in reviewing exclusion-payment settlements, (2) the effect of the "scope of the patent" test, (3) the effect of the policy favoring settlements, (4) whether brands could pay off all the relevant generics, (5) which justifications the Court would allow the settling parties to offer, (6) the feasibility of antitrust analysis of exclusion-payment settlements, (7) whether the payment provides any information about the patent merits, (8) the ability of the parties to settle without exclusion payments, and (9) the type of analysis that future courts should apply.[103] Is it any surprise that the Court (additionally justifying its ruling against three dissenting Justices) did not address every possible permutation of settlement and conveyance of non-cash consideration?

The *Loestrin* court soberly considered its role as a loyal foot soldier in the process of developing the common law, which is marked by "stability" and undergoes an "evolution [that] takes place gradually and incrementally and usually in a direction that can be predicted."[104] But it recognized that the *Actavis* decision would "only serve as the solution to anticompetitive pay for delay arrangements insofar as it encompasses both cash and these increasingly prevalent non-cash settlements."[105] In fact, the court recognized that patent settlements were increasingly taking non-cash forms.[106]

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[101] FTC v. Actavis, 133 S. Ct. 2223, 2229 (2013).

[102] *Compare id.* (describing payments for "other services the generics promised to perform") *with Loestrin*, 2014 WL 4368924, at *4 (describing payments for generic's co-promotion of unrelated drug).

[103] *Actavis*, 133 S. Ct. at 2230–38.

[104] *Loestrin*, 2014 WL 4368924, at *10.

[105] *Id*. at *12.

[106] *Id*. The *Loestrin* court's error in failing to acknowledge that *Actavis* itself involved an above-market-value business deal infiltrated its analysis of the no-authorized-generic provision. The complaint in *Actavis* alleged that through the side agreement, "*in substance*, the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market." *Actavis*, 133 S. Ct. at 2231 (emphasis added). The *Loestrin* court failed to recognize its duty to determine whether the no-authorized-generic

Ironically, the *Loestrin* court understood that "it is of relatively little import whether a payment for delay is made in the form of cash or some other form of consideration."[107] The reason is that "[w]hen a patent holder pays a would-be generic competitor to stay out of the market—regardless of the form of the payment—value is exchanged and the brand manufacturer is able to continue on with fewer competitors."[108]

In other words, the court recognized that its "cautious" approach would lead to insufficient scrutiny.[109] In fact, the court admitted that its ruling would result in "pharmaceutical companies tak[ing] the obvious cue to structure their settlements in ways that avoid cash payments," which would lead to the agreements "evad[ing] Sherman Act scrutiny."[110] It is hard to see how a ruling that throws open the barnyard doors to any and all anticompetitive settlements, even in a case that the court conceded met *Twombly*'s pleading requirements, charts a defensible course to the analysis of conduct that "tend[s] to have significant adverse effects on competition."[111]

CONCLUSION

In *Actavis*, the Supreme Court emphasized the dire harms that result when brands pay generics to delay entering the market. And it made clear that future courts would apply the rule of reason to this conduct, bestowing on plaintiffs potential shortcuts to show anticompetitive harm and market power, and imposing burdens on defendants to show justifications based on litigation costs or unrelated services.

The *Lamictal* and *Loestrin* courts turned this framework on its head. They took the five factors that *Actavis* employed to show why the pro-defendant policy in favor of settlement was not dispositive and used it, combined with armchair speculation and astronomical hurdles, to block plaintiffs from the courthouse steps. They did this even at the motion-to-dismiss stage in contravention of *Twombly* and in recognition of the fact that the requisite evidence was not available until after discovery.

The two courts got it exactly backwards. The *Lamictal* court assumed the defendants' case to be true. And the *Loestrin* court forced plaintiffs to bear the burden of proving a precise payment instead of merely recognizing the existence of a payment for delayed generic entry. If these decisions are allowed to stand and are adopted by other courts, there will be no scrutiny of these agreements. The patent litigants will gladly accept the roadmap the

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pledge (and above-market-value side deals) *in substance* alleged the same.

[107] *Loestrin*, 2014 WL 4368924, at *12.

[108] *Id.*

[109] *Id.* at *10.

[110] *Id.* at *12.

[111] *Actavis*, 133 S. Ct. at 2231.

Loestrin court graciously provided, which will lead them to (as *Loestrin* warned) "evade Sherman Act scrutiny."[112]

Such treatments of *Actavis* are not consistent with the Court's framework and in fact gut the Court's decision. Lower courts should not be able to read Supreme Court opinions out of existence by adopting frameworks antithetical to the opinion, ignoring the Court's policy conclusions, and amassing powers for themselves that the Court never anticipated.

Not only would such a course have catastrophic consequences for our judicial system, but it also would return us to the days between 2005 and 2012, when the courts, applying the scope-of-the-patent test, immunized nearly all exclusion-payment settlements. For agreements that cost consumers billions of dollars and have dramatic consequences for public health, the results would be catastrophic.

[112] *Loestrin*, 2014 WL 4368924, at *12.