Nos. 24-1585 (lead), 24-1601, 24-1636, 24-1639, 24-1659, 24-1662, 24-1671, 24-1697, 24-1704, 24-1708, 24-1763, 24-1764, 24-1766, 24-1831, 24-1832, 24-1833, and 24-1849 (consolidated)

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED HEALTHCARE SERVICES, INC.,
Plaintiff-Appellant,

v.

GILEAD SCIENCES, INC., *et al.*,
Defendants-Appellees.
Case No. 24-1585

On Appeal from the United States District Court
for the Norther District of California,
No. 3:19-cv-02573 (Hon. Edward M. Chen)

BRIEF FOR THE FEDERAL TRADE COMMISSION AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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(*caption, cont'd*)

BLUE CROSS AND BLUE SHIELD OF FLORIDA, INC., *et al.*,
Plaintiffs-Appellants,

v.

GILEAD SCIENCES, INC., *et al.*,
Defendants-Appellees.
Case No. 24-1601

FRATERNAL ORDER OF POLICE, MIAMI LODGE 20 INSURANCE TRUST FUND, *et al.*,
Plaintiffs-Appellants,

v.

GILEAD SCIENCES, INC., *et al.*,
Defendants-Appellees.
Case No. 24-1636

UNITED HEALTHCARE SERVICES, INC.,
Plaintiff-Appellant,

v.

GILEAD SCIENCES, INC., *et al.*,
Defendants-Appellees.
Case No. 24-1639

HUMANA INC.
Plaintiff-Appellant,

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Appellee.
Case No. 24-1659

(*caption, cont'd*)

HUMANA INC.
Plaintiff-Appellant,

v.

GILEAD SCIENCES, INC., *et al.*,
Defendants-Appellees.
Case No. 24-1662

BLUE CROSS AND BLUE SHIELD OF FLORIDA, INC., *et al.*,
Plaintiffs-Appellants,

v.

GILEAD SCIENCES, INC., *et al.*,
Defendants-Appellees.
Case No. 24-1671

BLUE CROSS AND BLUE SHIELD OF FLORIDA, INC., *et al.*,
Plaintiffs-Appellants,

v.

TEVA PHARMACEUTICALS USA, INC.
Defendant-Appellee.
Case No. 24-1697

CENTENE CORPORATION,
Plaintiff-Appellant,

v.

GILEAD SCIENCES, INC., *et al.*,
Defendants-Appellees.
Case No. 24-1704

(*caption, cont'd*)

TRIPLE-S SALUD, INC.,
Plaintiff-Appellant,

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Appellee.
Case No. 24-1708

HEALTH CARE SERVICE CORPORATION,
Plaintiff-Appellant,

v.

GILEAD SCIENCES, INC., *et al.*,
Defendants-Appellees.
Case No. 24-1763

TRIPLE-S SALUD, INC.
Plaintiff-Appellant,

v.

GILEAD SCIENCES, INC., *et al.*,
Defendants-Appellees.
Case No. 24-1764

CENTENE CORPORATION,
Plaintiff-Appellant,

v.

TEVA PHARMACEUTICALS USA, INC.
Defendant-Appellee.
Case No. 24-1766

(*caption, cont'd*)

KAISER FOUNDATION HEALTH PLAN, INC.,
Plaintiff-Appellant,

v.

GILEAD SCIENCES, INC., *et al.*,
Defendants-Appellees.
Case No. 24-1831

BLUE CROSS AND BLUE SHIELD OF KANSAS CITY,
Plaintiff-Appellant,

v.

GILEAD SCIENCES, INC., *et al.*,
Defendants-Appellees.
Case No. 24-1832

KAISER FOUNDATION HEALTH PLAN, INC.,
Plaintiff-Appellant,

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Appellee.
Case No. 24-1833

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Defendant-Appellee.
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INTRODUCTION AND INTERESTS OF *AMICUS CURIAE*

In *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), the Supreme Court held that "reverse-payment" agreements may violate the antitrust laws. In a reverse-payment agreement, a patentholder (usually a brand pharmaceutical company) compensates an alleged infringer (usually a generic competitor) in exchange for the latter's agreement to drop its litigation challenges to the patent. In effect, the patentholder shares some of its monopoly profits with its potential competitor to eliminate the possibility of price-lowering competition. Although several other circuits have addressed the *Actavis* framework, this is the first case in which this Court has been called upon to assess the legality of an alleged reverse-payment agreement. The Federal Trade Commission submits this brief both to set forth the legal standards that govern reverse-payment claims under *Actavis* and to address several errors committed by the district court in applying those standards.

As an independent agency of the United States charged with preventing unfair methods of competition, *see* 15 U.S.C. § 45(a), the Commission has a strong interest in the correct application of the law relating to reverse-payment agreements. The Commission has long used

its law enforcement authority to address anticompetitive pharmaceutical patent settlements through administrative proceedings and federal court suits, including the *Actavis* litigation.[1] The Commission also regularly files *amicus curiae* briefs in pharmaceutical antitrust cases, including during the district court proceedings of one of the cases now on appeal.

Congress has recognized that pharmaceutical settlements implicate the Commission's competition mission and expertise. Since 2003, Congress has required certain agreements between drugmakers to be filed with the Commission, including agreements to settle patent litigation, so that the Commission can evaluate whether those agreements may violate the antitrust laws. See Pub. L. No. 108-173, §§ 1111-1118 (codified at 21 U.S.C. § 355 note). The Commission reviews and publishes data regarding these agreements. More generally, the Commission has issued several empirical studies addressing the competitive effects of generic substitution for brand-

[1] *See, e.g.*, *Impax Labs., Inc. v. FTC,* 994 F.3d 484 (5th Cir. 2021); *FTC v. AbbVie, Inc.*, 976 F.3d 327, 351-59 (3d Cir. 2020); *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402 (E.D. Pa. 2015).

name drugs.[2] The Supreme Court and other federal courts have relied on those studies.[3]

In this case, Appellants allege that Gilead Pharmaceuticals and Teva Pharmaceuticals entered into unlawful reverse-payment agreements relating to two HIV drugs. A jury returned a special verdict for the defendants, finding that Appellants failed to prove either (1) that Gilead had sufficient market power or (2) that the settlements included large and unjustified reverse payments. The Commission takes no position on market power; it writes to explain that the district court committed two significant legal errors when analyzing the reverse-payment issue. First, the district court wrongly held that defendants could argue that the payment in question was not "large" in comparison to Gilead's monopoly profits. In fact, the proper benchmark is the litigation expense the brand avoided by settling. Second, the district court incorrectly held that the strength of Gilead's patent could justify a

[2] *E.g.*, FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011); FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010).

[3] *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012); *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 404 n.21 (3d Cir. 2015).

reverse payment. Under *Actavis,* patent strength is legally irrelevant to whether an antitrust violation occurred. These errors, if adopted by other courts, could significantly harm efforts by government and private parties to redress reverse-payment agreements. Thus, if the Court reaches the reverse-payment issues, it should correct these errors to ensure proper application of the law in future reverse-payment cases.

STATEMENT

A. Regulation of Brand and Generic Drugs Under the Hatch-Waxman Act

Reverse-payment agreements may occur in patent litigation arising from the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch Waxman Act. Under that scheme, the manufacturer of a new drug (*i.e.*, the "brand" company) must file a New Drug Application ("NDA") with the Food and Drug Administration, demonstrating that the drug is safe and effective. 21 U.S.C. § 355(b). The brand company must list certain patents relating to that drug, along with their expiration dates, in an FDA publication known as the Orange Book. The NDA must be approved before the brand can market the drug.

After an NDA for a drug is approved, another company may file an Abbreviated New Drug Application ("ANDA"), seeking to market a generic version of the drug. *Id.* § 355(j). An ANDA is a streamlined process that does not require proof of safety or efficacy. Instead, the ANDA applicant must show that the generic drug is "bioequivalent" to the brand, *i.e.*, that it contains the same active ingredient in the same amounts and works in the body the same way. *Id.* § 355(j)(2)(A). Generic drugs are as safe and effective as their brand name counterparts but are usually much less expensive Accordingly, third party payors (*e.g.*, health insurers) encourage pharmacists to substitute generics for brand-name drugs, and all states permit such substitution. In theory, once generics enter the market, they should typically capture the vast majority of the brand's sales, with consumers then getting the same medication at much lower prices.

If an ANDA applicant seeks to market a generic drug before expiration of a patent listed in the Orange Book for the brand-name reference drug, it must include a "Paragraph IV" certification in its ANDA asserting that the patent is invalid or that the generic product will not infringe *Id.* § 355(j)(2)(A)(vii)(IV). Such a certification is deemed

a technical act of infringement, which enables the brand company to file suit.

As an incentive to encourage generic development, the first company to file an ANDA containing a Paragraph IV certification for a drug receives a 180-day period of generic exclusivity; the FDA will not approve other generics until 180 days after the first ANDA filer begins commercial marketing of its generic. *Id.* § 355(j)(5)(B)(iv). This right can be extraordinarily valuable—sometimes worth as much as "several hundred million dollars." *Actavis*, 570 U.S. at 155.

B. Reverse Payments Can Be Antitrust Violations

In patent litigation between a brand and a generic company under the Hatch-Waxman scheme, the profits the generic company stands to earn if it wins the infringement suit and launches its product are normally much less than those the brand stands to lose from generic entry. *See, e.g.*, *Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187, 209 (2d Cir. 2006). Thus, both the brand and generic manufacturers may benefit, at the expense of consumers, if the parties settle the lawsuit with the brand company paying compensation to the generic in exchange for the generic's agreement to

stop contesting the patent and stay out of the market. Such an arrangement is called a "reverse payment" because it involves the plaintiff (the brand) paying the defendant (the generic), rather than the other way around. In effect, the brand company preserves its monopoly by sharing monopoly profits with the generic.

In *Actavis*, the Supreme Court held that a "large and unjustified" reverse payment "can bring with it the risk of significant anticompetitive effects." *Actavis*, 570 U.S. at 158. Accordingly, reverse-payment agreements may violate the Sherman Act's prohibition on restraints of trade. *See* 15 U.S.C. § 1. The anticompetitive concern with a reverse payment is that it may "seek[] to prevent the risk of competition." *Actavis*, 570 U.S. at 158. The disputed patent "may or may not be valid, and may or may not be infringed." *Id.* at 147. But a reverse payment can avoid a judicial decision on those questions and instead "maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." *Id.* at 157. The result is that "[t]he patentee and the challenger gain; the consumer loses." *Id.* at 154.

Courts applying the *Actavis* framework have recognized that a reverse payment need not take the form of a straight transfer of money. Any arrangement that conveys monetary value to a generic can be a reverse payment. *Rochester Drug. Co-Op., Inc. v. Warner Chilcott Co. (In re Loestrin 24 Fe Antitrust Litig.)*, 814 F.3d 538, 549-51 (1st Cir. 2016) (concluding that "*Actavis* should reach non-monetary reverse payments" and citing numerous cases); *King Drug of Florence, Inc. v. SmithKline Beechham Corp.*, 791 F.3d 388, 403 (3d Cir. 2015) ("We do not believe *Actavis*'s holding can be limited to reverse payments of cash."). For example, an agreement by a brand company not to launch its own authorized generic to compete with the generic company's product may be of "great monetary value" and is "likely to present the same types of problems as reverse payments of cash." *Id.*

Actavis held that the legality of reverse-payment agreements should be evaluated under antitrust law's "rule of reason." *Actavis*, 570 U.S. at 158-60. To determine whether a challenged restraint violates the rule of reason, courts apply a three-step burden-shifting framework. *Ohio v. Am. Express Co.*, 585 U.S. 529, 541 (2018). At the first step, the plaintiff must show that the agreement has substantial anticompetitive

effect. *Id.* For a reverse-payment agreement, this requires proof that (1) the brand company has market power (*i.e.*, the ability to raise prices above those that would be charged in a competitive market), and (2) the agreement involved a payment from the brand to the generic that was "large and unjustified." *Impax Labs, Inc. v. FTC*, 994 F.3d 484, 492-94 (5th Cir. 2021); *see also King Drug*, 791 F.3d at 412. If the plaintiff makes this showing, the burden shifts to the defendant to show that the restraint produces procompetitive benefits. If that showing is made, the burden shifts to the plaintiff to show that any procompetitive effects could be obtained by less restrictive means. *Ohio*, 585 U.S. at 541-42; *Impax*, 994 F.3d at 492; *King Drug,* 791 F.3d at 412. Where the plaintiff fails to show a less restrictive alternative, "the court must balance the anticompetitive and procompetitive effects of the restraint," and "[i]f the anticompetitive harms outweigh the procompetitive benefits, then the agreement is illegal." *Impax*, 994 F.3d at 492.

Private antitrust plaintiffs must clear an additional hurdle to prevail in a reverse-payment suit. In addition to showing that the reverse payment violated the antitrust laws, private plaintiffs must show that the reverse payment caused them an antitrust injury—*i.e.*,

an injury of the type the antitrust laws were intended to prevent that flows from the violation. *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 163-65 (3d Cir. 2017); *Am. Sales Co., LLC v. AstraZeneca LP (In re Nexium (Esomeprazole) Antitrust Litig.)*, 842 F.3d 34, 60 (1st Cir. 2016); *see generally Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 486, 489 (1977). Although this requirement is referred to "antitrust standing," it is an element of the antitrust merits rather than a jurisdictional consideration related to Article III standing. *Wellbutrin*, 868 F.3d at 163-64. In the context of a reverse-payment claim brought by drug purchasers, the antitrust standing inquiry usually turns on whether the generic would have launched its drug at an earlier date but for the reverse payment, thus lowering prices and saving the purchasers money. *See Nexium*, 842 F.3d at 60 (plaintiff seeking damages "must show actual, quantifiable damages by reason of the antitrust violation").

Government enforcers like the FTC, by contrast, "stand in different shoes." *Id.* The government "is empowered to directly enforce the substantive antitrust laws" and its interest is "to 'prevent and restrain' violations of the antitrust laws along with the attendant social

costs such violations can cause." *Id.* Thus the government, unlike a private plaintiff, need not show that a reverse payment caused a specific quantifiable injury.

C. Proceedings in This Case

Appellants in this case are classes of direct and indirect drug purchasers who allege that Gilead and Teva entered into unlawful reverse-payment agreements. Gilead holds NDAs for the drugs Truvada and Atripla—both blockbuster drugs used in the treatment of HIV. The products were protected by patents that expired on various dates between 2017 and 2021. Teva filed ANDAs to market generic versions of both drugs in 2009, and was the first generic company to do so. Ordinarily, as the first filer, Teva would have been entitled to the 180-day period of generic exclusivity if it prevailed in patent litigation, but Appellants contend that, under the terms of the Hatch-Waxman Act Teva forfeited this right. *See* 21 U.S.C. § 355(j)(5)(D) (providing that forfeiture of 180-day generic exclusivity period occurs where, *inter alia*, generic applicant fails to obtain tentative approval for its product from FDA within 30 months).

Gilead sued Teva for patent infringement. The parties settled in 2014, after a bench trial but before the court ruled on the merits. The settlement agreement allowed Teva to launch generic versions of Truvada and Atripla six months before any other generic manufacturer licensed by Gilead. Appellants contend that this contractual period of generic exclusivity was highly lucrative to Teva—and amounted to a large and unjustified reverse payment—given that Teva had forfeited the statutory 180-day generic exclusivity period authorized by the Hatch-Waxman Act.

Following a trial, a jury returned a special verdict finding for Gilead and Teva on two independent grounds. First, the jury found that Appellants did not "prove that Gilead had market power within the relevant market(s) that included Truvada and/or Atripla." ECF 2057 at 2. Second, although the verdict form instructed the jury to skip the remaining questions if it found no market power, the jury proceeded to answer the next question and found that Appellants did not prove that the "patent settlement agreement between Gilead and Teva included a 'reverse payment' from Gilead to Teva so that Teva would delay its entry into the market and Gilead could thereby avoid the risk of generic

competition." *Id.* The jury did not reach the antitrust injury questions on the verdict form, which asked whether Appellants had proven that the defendants' conduct caused entry of generic Truvada or generic Atripla to be delayed, thereby causing any one or more of the … plaintiffs to pay some amount more for the drug than they would have paid if generic entry had not been delayed." *Id.* at 3.

Appellants moved for a new trial (ECF 2088), but the district court denied the motion, holding that sufficient evidence supported the jury's answers to both questions. ECF 2129.

ARGUMENT

The Commission takes no position on the jury's finding that Appellants failed to prove Gilead had sufficient market power, which would be a sufficient basis for the judgment. But at various points in the case, the district court misapplied the law regarding reverse payments in a way that could impede future law enforcement efforts by the FTC and other government antitrust enforcers. If the Court reaches the question of whether the agreement between Gilead and Teva included a reverse payment to delay Teva's market entry, it should correct these errors.

I. THE BRAND COMPANY'S SAVED LITIGATION COSTS ARE THE RELEVANT BENCHMARK FOR DETERMINING WHETHER A REVERSE PAYMENT WAS LARGE.

Under *Actavis*, a plaintiff must present evidence that a reverse payment was "large and unjustified" at the first step of the rule-of-reason analysis. *Actavis*, 570 U.S. at 158; *see also Impax*, 994 F.3d at 493-94. The benchmark for determining whether a reverse payment is large is "its scale in relation to the [brand's] anticipated future litigation costs." *Actavis*, 570 U.S. at 159.[4] In this case, Appellants moved *in limine* to exclude evidence and arguments regarding benchmarks other than avoided litigation costs. The district court denied the motion, allowing the defendants to introduce evidence and make arguments that the payment was not "large" in comparison to the brand's monopoly profits and/or the size of the relevant market. ECF 1716 at 12-14. The district court's ruling misapplied *Actavis* and is contrary to the decisions of other courts of appeals.

[4] If the payment, or part of it, was legitimately for "compensation for … services that the generic has promised to perform," *see Actavis*, 570 U.S. at 156, then that portion may be excluded when assessing whether the payment was "large." In this case, however, there is no claim that the payment was justified as compensation for services.

Actavis makes clear that the focus of the inquiry is on the payment's size relative to avoided litigation costs. The Supreme Court was concerned that the brand might be using "a share of its monopoly profits" to "induce the generic challenger to abandon its claim." *Actavis*, 570 U.S. at 154. The Court explained that this concern is not present when the payment "amount[s] to no more than a rough approximation of the litigation expenses saved through the settlement." *Actavis*, 570 U.S. at 156 ("Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs … there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.").

If the brand is paying more than saved litigation costs (and the payment is not explained by something else the brand is purchasing), that additional money replaces profits the generic misses out on by not competing. As a result, the generic "presumably agrees to an [] entry date that is later than it would have otherwise accepted." *King Drug Co.*, 791 F.3d at 405.

Nowhere in *Actavis* does the Supreme Court identify the brand's monopoly profits or the size of the overall market as a benchmark for

"large." Instead, the Court observed that "patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the [patent] litigation and entered the market." *Actavis*, 570 U.S. at 154. And it then cited an academic article explaining that the generic's expected profits are usually only a small portion of the brand's pre-competition monopoly profits. *See C. Scott Hemphill*, Paying for Delay, 81 N.Y.U. L.R. 1553, 1580-81 (2006). That is, even a very small slice of the brand's monopoly profits may be enough to induce a generic to abandon its patent challenge and delay market entry.

Other courts applying the *Actavis* framework have properly recognized that the inquiry focuses on the brand's avoided litigation costs rather than on monopoly or market profits. For example, in *FTC v. AbbVie, Inc.*, 976 F.3d 327 (3d Cir. 2020), the Third Circuit held that the FTC plausibly alleged that a reverse payment was "large" where it conferred "extremely valuable" rights to the generic that "far exceeded the litigation costs [the parties] saved by settling." *Id.* at 356.; *see also In re Lipitor Antitrust Litig,*, 868 F.3d 231, 253-54 (3d Cir. 2017) (plaintiffs plausibly alleged that reverse payment was large where it far

exceeded saved litigation costs); *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 555 F. Supp. 3d 829, 865 (N.D. Cal. 2021) ("Payments may be sufficiently 'large' because they allegedly are 'extremely valuable' and exceed litigation costs saved through settlement.").

In reaching a contrary conclusion, the district court relied on language from *Actavis* stating that a reverse payment may not be unlawful if it "reflect[s] compensation for other services that the generic has promised to perform" or there are "other justifications." ECF 1716 at 12-13 (quoting *Actavis*, 570 U.S. at 156). But these factors do not go to whether the reverse payment is "large."[5] Rather, the Court discussed these factors in a paragraph addressing whether a payment is "unjustified." *Actavis*, 570 U.S. at 156. The fact that a defendant may be able to justify a large reverse payment has no bearing on what benchmark should be used to assess whether the payment is in fact "large." And nothing about the passages the district court quoted from *Actavis* suggests that the size of the payment can be judged against the brand's monopoly profits.

[5] Moreover, as noted above, there is no claim in this case that the payment was justified as compensation for services.

The district court also held that using avoided litigation costs as the relevant benchmark "essentially assumes that Gilead's monopoly profits were not based on a lawful monopoly arising from the patent but rather based on an unlawful monopoly because the patent is either invalid or not infringed." ECF 1716 at 13-14. But analyzing the size of the payment in accordance with the factors identified by the Supreme Court involves no judgment as to the validity or infringement of the patent.[6] Indeed, the problem with using monopoly profits as a benchmark for "large" is not that doing so would impugn those profits as illegitimate; it is that the comparison sheds no light on whether the size of the payment could induce the generic not to compete.

The district court also misread the Supreme Court's observation in *Actavis* that "the owner of a particularly valuable patent might contend that even a small risk of invalidity justifies a large payment." *Actavis*, 570 U.S. at 157. The district court read this language as "suggest[ing]" that the brand's profits may be considered in assessing "whether the size of a reverse payment is large." ECF 1716 at 14. In fact, the

[6] Patent validity is also irrelevant to the antitrust rule-of-reason analysis, as discussed in Part II.

Supreme Court was making the opposite point. The next two sentences in *Actavis* state: "But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And … that consequence constitutes the relevant anticompetitive harm." *Actavis*, 570 U.S. at 157. In other words, a large and unexplained reverse payment raises anticompetitive concerns even when it protects a valuable patent facing only "a small risk of invalidity," *Actavis*, 570 U.S. at 157. The district court's interpretation that having a valuable patent with large monopoly profits entitles a brand company to lawfully make a larger reverse payment thus misapprehends the Supreme Court's meaning.

Finally, the district court erred in relying upon an unreported district court case holding without explanation or analysis that defendants in a reverse payment case could introduce evidence that the value of their drug franchise was a legitimate benchmark for evaluating whether a payment was large. ECF 1716 at 13. *In re Namenda Indirect Purchaser Antitrust Litig.*, No. 1:15-cv-6549, 2022 WL 3362429, at *2 (S.D.N.Y. Aug. 15, 2022). Like the district court's reasoning here, this conclusion is inconsistent with what *Actavis* actually says. This Court

should follow *Actavis* and the Third Circuit and hold that saved litigation costs are the appropriate benchmark for determining whether a reverse payment is large.

II. PATENT MERITS ARE NOT RELEVANT TO THE RULE-OF-REASON ANALYSIS THAT DETERMINES WHETHER A REVERSE PAYMENT IS UNLAWFUL.

Actavis makes clear that whether a reverse-payment agreement violates the antitrust laws does not depend on the strength of the brand's patent (*i.e.*, whether the patent is likely to be held invalid in patent litigation). The Court held that "it is normally not necessary to litigate patent validity to answer the antitrust question." *Actavis*, 570 U.S. at 157. It explained that "a small risk of invalidity" does not justify a large payment, because the payment still "likely seeks to prevent the risk of competition," which "constitutes the relevant anticompetitive harm." *Id.*

The district court strayed from these principles. It allowed the defendants to argue to the jury that, in assessing anticompetitive effects under the rule of reason: "if there were a payment, if that payment did not result in delayed entry by Teva, the Defense wins this case." ECF 2046 at 3287-88. The defendants then argued at length as to why

Gilead's patents would have been upheld regardless of the payment. *See* ECF 2046 at 3305-25. Later, in denying Appellants' motion for a new trial, the district court accepted the defendants' arguments that "even if there were some kind of payment to Teva, there was no payment *for delay* (*i.e.*, no quid pro quo) because there was evidence that Gilead's patents were strong and the strength of Gilead's patents explained the entry date" provided for in the settlement agreement. ECF 2129 at 19. The court also specifically rejected Appellants' arguments that the patent merits are relevant only to causation, holding that "even though a large and unexplained reverse payment *allows* a jury to infer pay-for-delay, that does not mean that a defendant is barred from arguing no pay-for-delay because the patent owned by defendant was strong. Defendants made such a showing here and supported it with substantial evidence" *Id.* at 20.

This analysis reflects two basic errors. First, the district court improperly held that evidence of the patent merits could support the jury's conclusion that the Gilead-Teva settlement did not include a reverse payment. Second, the court conflated the question of whether an antitrust violation occurred—that is, whether an unlawful reverse

payment was made—with the entirely separate question of whether any violation caused the plaintiffs' antitrust injury.

The strength of a patent is irrelevant to whether a reverse payment has anticompetitive effects—which are instead established by proving a large and unjustified payment.[7] The harm from a reverse payment is that it forestalls any possibility that the generic will win the patent case and be allowed to compete. As the *Actavis* district court explained on remand: "[T]he actual validity of the patent is irrelevant to the question of whether the reverse payments violated the antitrust laws. Paying the generics to stay out of the market for the purpose of avoiding the risk of competition is an antitrust harm, *regardless* of whether or not the patent is actually valid and infringed." *FTC v. Actavis, Inc. (In re Androgel Antitrust Litig. (No. II))*, No. 1:09-cv-955, 2018 WL 2984873, at *11 (N.D. Ga. June 14, 2018).

The Supreme Court's exclusion of patent merits from the rule-of-reason analysis reflects the practical reality that "the impact of an

[7] As discussed above in Section I, whether a reverse payment is large turns on the size of the payment relative to avoided litigation costs, and whether it is justified turns on the reason for making a large payment—for example, if the payment represents compensation for services rendered.

agreement on competition is assessed at the time it was adopted." *Impax*, 994 F.3d at 496. When a reverse-payment agreement is adopted, the outcome of the patent litigation is uncertain, but the presence of a large and unjustified reverse payment shows that the parties perceived a risk of competition and were working to reduce it. As the Supreme Court of California has explained (interpreting *Actavis* and applying the state law analog to the Sherman Act), "[i]f a brand is willing to pay a generic more than the costs of continued litigation, and more than the value of any collateral benefits, in order to settle and keep the generic out of the market, there is cause to believe some portion of the consideration is payment for exclusion beyond the point that would have resulted, on average, from simply litigating the case to its conclusion." *In re Cipro Cases I & II*, 348 P.3d 845, 867 (Cal. 2015). "Otherwise, the brand would have had little incentive to settle at such a high price." *Id.*

Conversely, a generic company that receives a large and unjustified payment "presumably agrees to an [] entry date that is later than it would have otherwise accepted" since the generic is presumably agreeing to an entry date later than it when it would be entitled to

enter if it won the lawsuit. *King Drug*, 791 F.3d at 405. Regardless of whether the parties viewed the patent as "strong" or "weak," a large and unjustified reverse payment only serves to reduce the potential for competition compared to what the parties believed it otherwise would have been.

The district court's misstatement about the relevance of the patent merits appears to have stemmed at least partly from its conflation of, on the one hand, the rule-of-reason analysis applicable when determining the existence of an antitrust violation—and, on the other hand, the causation and antitrust injury analyses applicable in suits brought by private plaintiffs. To establish that a reverse payment caused antitrust injury, a private plaintiff may need to show that the payment actually caused the generic to enter the market (and introduce price competition) later than it otherwise would have. This may entail an assessment of whether the generic would have prevailed in the patent case. *See, e.g.*, *Wellbutrin*, 868 F.3d at 164-65. But the question of whether a private plaintiff can show an antitrust injury is distinct from whether an antitrust violation (*i.e.*, large and unjustified reverse payment) has occurred. *See Nexium*, 842 F.3d at 60; *see also Atl.*

Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 344 (1990) ("[P]roof of a[n antitrust] violation and of antitrust injury are distinct matters that must be shown independently."). It is important to address these issues separately because the antitrust injury requirement applies only to private plaintiffs, not to the government.

Here, the district court did not separate the question of antitrust injury—*i.e.*, whether the payment caused delay by inducing Teva to enter the market with generics at a later date than it would have done absent the agreement—from the question of whether there was a reverse payment that violated the antitrust laws. *See* ECF 2129 at 19. The district court acknowledged that it "under[stood]" this legal distinction," but did "not see a need for this distinction to be made" in this case because Appellants needed to show antitrust injury and damages in addition to proving a violation. ECF 1861 at 63. That was legal error.

As the First Circuit explained in correcting a similar error, the conclusion that a reverse payment did not actually delay the generic's entry establishes that, "*notwithstanding the existence of an antitrust violation*, the plaintiffs failed to establish an antitrust injury that

entitled them to monetary relief." *Nexium*, 842 F.3d at 60 (emphasis added). In this case, the jury never reached the antitrust injury question because it found that no violation had occurred. Since patent merits are at most relevant to antitrust injury, it was error for the court to allow an argument that the patent would have been upheld as part of the rule-of-reason analysis. This distinction is not merely academic: Because government antitrust enforcers do not need to prove antitrust injury, conflating the two standards can improperly increase the government's burden in a public antitrust case and hinder effective government enforcement.

CONCLUSION

If the Court reaches the reverse-payment issues, it should correct the district court's errors.

Respectfully submitted,

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CERTIFICATES

I certify that the foregoing brief complies with Federal Rule of Appellate Procedure 29(a)(5), in that it contains 5,101 words.

I further certify that on September 24, 2024, I filed the foregoing brief with the Court's appellate CM/ECF system. Counsel for all parties are registered users of the Court's appellate CM/ECF system.

September 24, 2024

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