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 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*)

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

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

v.

TEVA PHARMACEUICALS USA, INC.
Defendant-Appellee.
Case No. 24-1849

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INTRODUCTION AND INTERESTS OF

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 its law enforcement authority to address anticompetitive pharmaceutical patent settlements through 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 ph72.682 t10.3 (13.2 ()14C.6 (t))-4.9 (h72 (n)11.5

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 corred

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*

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) an injury of the type the antitrust laws were intended to prevent that costs such violations can cause.” Id.

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 rev

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.

“large.”

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.

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[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*

Supreme Court was making the opposite point. The next two sentences in *Actavis* state: "

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). Theart hed that "i t is normally not necessary to litigate patent validity to answr the antitrust question ."0Jc85 ( )]TJ/TT1 1 Tf-0.007

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

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[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 enter if it won the lawsuit. *King Drug*, 791 F.3d at 405. Regardless of

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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