IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

UFCW LOCAL 1500 WELFARE FUND, *ET AL.*,
Plaintiffs-Appellants,

v.

ABBVIE, INC., *ET AL.*,
Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of Illinois
No. 1:19-cv-01873
Hon. Manish S. Shah

BRIEF OF AMICUS CURIAE THE FEDERAL TRADE COMMISSION IN SUPPORT OF NO PARTY

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INTRODUCTION AND SUMMARY

Generic drug competition saves consumers hundreds of billions of dollars each year. To encourage such competition, Congress has established mechanisms to enable generic manufacturers to challenge patents associated with a brand-name drug. But antitrust problems can arise when parties settle these patent disputes with the patentee paying its would-be competitor to drop its challenge and stay off the market. These agreements are known as "reverse-payment" settlements because "a party with no claim for damages … walks away with money simply so it will stay away from the patentee's market." *FTC v. Actavis, Inc.*, 570 U.S. 136, 152 (2013). The antitrust concern with these settlements is that the brand manufacturer and its potential competitors may have agreed to preserve and share the brand's monopoly profits rather than compete. The drugmakers come out ahead, but consumers suffer because they are forced to continue paying higher, non-competitive prices.

In *Actavis*, the Supreme Court held that reverse-payment settlements create a "risk of significant anticompetitive effects" and must be analyzed under the antitrust rule of reason. *Id.* at 158-59. The potential anticompetitive harm from this type of agreement is that the payment "prevent[s] the risk of competition" and may allow the parties to "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.

Plaintiffs here allege—among other claims—that AbbVie, maker of the anti-inflammatory biologic drug Humira, paid its would-be biosimilar rivals to stop challenging AbbVie's patents and to refrain from selling their products in the United States for at least five years. The alleged payment consisted of AbbVie's agreement to grant patent licenses permitting lucrative competition in Europe. The district court dismissed the complaint in its entirety, concluding that its reverse-payment charges (and the other counts) failed to state a claim.

The Federal Trade Commission submits this amicus brief to assist the Court in evaluating the district court's decision to dismiss the reverse-payment counts. Although we take no position on the ultimate merits of this case or whether the allegations are sufficient to state a claim, we are concerned that the district court's analysis is inconsistent with *Actavis* in two critical ways that could impede enforcement of the antitrust laws if left uncorrected.

First, the court placed undue weight on the fact that the challenged settlements allowed "early" competition before AbbVie's patents expired. In parts of the opinion, the district court appeared to conclude that "early" entry automatically meant that the settlements could not have contained reverse payments. Op. 44-45. Elsewhere, the court seemed to reason that even if the settlements contained reverse payments, their provision for entry dates before the expiration of AbbVie's patents made them procompetitive as a matter of law. Op. 46-47. Either approach conflicts with *Actavis*, which overruled a line of decisions (known as the "scope-of-the-patent" test) holding that a reverse-payment settlement is exempt from

antitrust scrutiny solely because it involves entry before patent expiration. 570 U.S. at 147-48. Here, the district court's analysis—with its emphasis on the settlements' "early" entry dates—resembles the scope-of-the-patent test rejected by *Actavis*.

Instead, the *Actavis* inquiry focuses on whether a patent-holder has offered the challenger "a share of its monopoly profits" in exchange for the challenger's agreement to stop contesting the patents and stay out of the market for some period. *Id.* at 141, 153-54. Because those patents "may or may not be valid, and may or may not be infringed," reverse-payment settlements harm consumers if they amount to an agreement to share monopoly profits to eliminate the risk of earlier competition. *Id.* at 147. Accordingly, when parties settle with a reverse payment, the proper question under *Actavis* is why the parties did so. If the "basic reason" for the payment "is a desire to maintain and to share patent-generated monopoly profits," then the antitrust laws are likely to condemn it. *Id.* at 158.

Second, the district court opined that dismissing the complaint will help "encourag[e] patent litigants to settle worldwide patent disputes." Op. 46. Be that as it may, *Actavis* held that the public interest in promoting settlement "should not determine the result" in cases involving unjustified reverse payments that purchase additional monopoly time. 570 U.S. at 153-54.

INTEREST OF AMICUS CURIAE

The FTC is an independent federal agency charged with promoting a competitive marketplace and protecting consumer interests. As exemplified by its

role as petitioner in *Actavis*, the Commission has primary responsibility for federal antitrust enforcement in the pharmaceutical industry.

The Commission has used its law enforcement authority to challenge anticompetitive patent settlements administratively and in federal district courts.[1] In addition, the Commission has issued empirical studies addressing the competitive effects of generic substitution for brand-name drugs.[2] The Supreme Court and other federal courts have relied on those studies. *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). The FTC also obtains and reviews patent settlement agreements between drugmakers and works with the Food and Drug Administration to deter anticompetitive behavior in the burgeoning marketplace for biological medicines and follow-on biosimilar products.[3]

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[1] *See*, *e.g.*, *In re Impax Labs., Inc.*, No. 9373, 2019 WL 1552939 (F.T.C. Mar. 28, 2019), *appeal pending*, No. 19-60394 (5th Cir.); *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402 (E.D. Pa. 2015); *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-cv-955-TWT, 2018 WL 2984873, at *1 (N.D. Ga. June 14, 2018).

[2] *See* Fed. Trade Comm'n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011), http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf; Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

[3] *See*, *e.g.*, *Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace* (Feb. 3, 2020) ("*FDA-FTC Statement*"), https://www.ftc.gov/system/files/documents/public_statements/1565273/v190003fdaftcbiologicsstatement.pdf.

Because the Commission has a strong interest in ensuring the proper application of *Actavis*, we respectfully submit this brief under Fed. R. Civ. P. 29(a). We do not advocate for any particular result in this case, but write simply to correct two legal errors in the district court's treatment of *Actavis*.

STATEMENT

A. Principles For Analyzing Reverse-Payment Settlements

In most cases, drug companies may settle their patent disputes free of antitrust concerns by agreeing upon a date when the generic will enter the market "without the patentee paying the challenger to stay out prior to that point." *Actavis*, 570 U.S. at 158. Absent a reverse payment, the settlement's entry date presumably reflects the parties' "approximation of the expected level of competition that would have obtained had the parties litigated." *In re Cipro Cases I & II*, 348 P.3d 845, 865 (Cal. 2015).

It is another story when a drug patentee *pays* a would-be rival a share of its monopoly profits to drop its patent challenge and keep away from the market until a specific date. Unless the payment has some other, legitimate rationale—such as the patentee's saved litigation costs or compensation for bona fide services performed by the generic—it "would normally suggest that the patentee has serious doubts about the patent's survival." *Actavis*, 570 U.S. at 157. That "in turn suggests that the payment's objective is to maintain surpracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness." *Id.* The brand-name manufacturer is, in

effect, "leverag[ing] some part of its patent power … its supracompetitive profits" to eliminate the "risk of competition" prior to the licensed entry date. *Smithkline Beecham*, 791 F.3d at 406.

In *Actavis,* the Supreme Court held that reverse-payment patent settlements can violate the antitrust laws even if they allow competition before the brand's patents expire. 570 U.S. at 159-60. The FTC's complaint in that case had alleged that a brand manufacturer settled a challenge to its patent through agreements to pay generic rivals to stay off the market for nine years, and disguised those payments as compensation for services the generics would perform. *Id*. at 145. The settlement nonetheless allowed the generics to enter the market 65 months before the patent expired. *Id.* The district court dismissed the complaint, and the Eleventh Circuit affirmed. It reasoned that because the settlement allowed entry before patent expiration, it was "immune from antitrust attack" since the anticompetitive effects were all within "the scope of the exclusionary potential of the patent." *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012).

The Supreme Court reversed. The Court rejected the "scope-of-the-patent" test applied by the court of appeals and its resulting immunity for settlement agreements that allow entry before patent expiration. *Actavis*, 570 U.S. at 146-48. The Court explained that a reverse payment "in effect 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." *Id.* at 153-54. The payment "simply keeps prices

at patentee-set levels" while "dividing that return between the challenged patentee and the patent challenger." *Id.* at 154. As a result of this sharing of the rewards from avoiding competition, "[t]he patentee and the challenger gain" but "the consumer loses." *Id.*

The Court thus held that the FTC had stated a viable antitrust claim even though the settlement at issue allowed generics to compete more than five years before the brand's patent expired. *Id.* at 145. "Notwithstanding such 'early entry,' the antitrust problem was that … entry might have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered." *Smithkline Beecham*, 791 F.3d at 408. After *Actavis*, many federal courts have ruled that reverse-payment settlements may have been anticompetitive even though they allowed generics to launch years before the patents expired. *See, e.g.*, *id.* at 397 (37 months before expiration); *In re Aggrenox Antirust Litig.*, 94 F. Supp. 3d 224, 236 (D. Conn. 2015) (18 months); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 407, 419 (E.D. Pa. 2015) (three years).

Reverse payments may be either in cash or in-kind. In the earliest reverse payments, brand companies simply paid cash in exchange for the generic's abandonment of its patent challenge. Over time, as the FTC and courts began to scrutinize these settlements, parties found more sophisticated and less obvious ways to transfer value in exchange for staying off the market. The settlement in *Actavis*, for example, featured lucrative side deals in which the brand made payments that "[t]he companies described … as compensation for other services the

generics promised to perform," but which the FTC claimed "had little value." 570 U.S. at 145. Another common provision in these agreements involved the brand's commitment not to launch its own authorized generic (or "AG") to compete with, and take revenue from, the first generic once it enters. *See Smithkline Beecham*, 791 F.3d at 403-05.

A brand-name patentee may also make a reverse payment by giving its would-be generic rival some other type of noncash concession or consideration. For instance, in *In re Lipitor Antitrust Litigation*, 868 F.3d 231 (3d Cir. 2017), a generic manufacturer allegedly agreed to defer launch of generic Lipitor for over three years in exchange for a brand manufacturer's release of a damages claim worth hundreds of millions of dollars in a lawsuit over a different drug. *Id.* at 243-44, 253. The Third Circuit held that the plaintiffs alleged sufficient facts to show that the damages release plausibly served as a quid pro quo for the Lipitor patent settlement. *Id.* at 254-57.

Most recently, in *FTC v. AbbVie Inc.*, No. 18-2621, 2020 WL 5807873 (3d Cir. Sep. 30, 2020), AbbVie allegedly induced a rival to defer launching a generic version of AndroGel with a reverse payment in the form of an agreement to supply another AbbVie product, TriCor. For the generic company, the TriCor deal was worth "nearly $175 million over a four-year period," more than its projected earnings from selling generic AndroGel. *Id.* at *18. The Third Circuit reversed the district court's dismissal of the complaint's charge of an unlawful reverse payment. The lower court had wrongly refused to accept as true the allegation that the AndroGel and

TriCor deals were "linked" and that the supply agreement made economic sense only if it were a vehicle for AbbVie to compensate the generic for refraining from competition with brand-name AndroGel. *Id.* at *17-20. The Third Circuit stressed that "a reverse payment's legality depends mainly on its economic substance, not its form," *id.* at *17, and that to analyze the two deals separately would "elevate[] form over substance," *id.* at *19.

B. The Marketplace and Regulatory Framework for Biologics

Biological medicines—drugs derived from living organisms—can treat many otherwise untreatable conditions, but they come at a steep price: at a cost of up to $200,000 per patient per year, they account for 37 percent of all prescription spending.[4] A few biologics have faced competition from biosimilars, a generic analog for biological drugs, which are typically priced 15 to 35 percent lower than those of the original "reference" biologic.[5]

To foster biologic competition, Congress enacted the Biologics Price Competition and Innovation Act (BPCIA), Pub. L. No. 111-148, §§ 7001-7003, 124

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[4] *FDA-FTC Statement*, *supra* note 3, at 1; *Statement of the Federal Trade Comm'n to the Dep't of Health and Human Servs. Regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* at 8 (July 16, 2018) ("*FTC Blueprint Statement*"), https://www.ftc.gov/system/files/documents/advocacy_documents/statement-federal-trade-commission-department-health-human-services-regarding-hhs-blueprint-lower/v180008_commission_comment_to_hhs_re_blueprint_for_lower_drug_prices_and_costs.pdf.

[5] *FDA-FTC Statement*, *supra* note 3, at 2-3; *FTC Blueprint Statement*, *supra* note 4, at 11-12 & n.54.

Stat. 119, 804-21 (2010).[6] The BPCIA creates a streamlined pathway for regulatory approval of products demonstrated to be biosimilar to or interchangeable with a biologic. Four years after the FDA approves a biologic, a rival manufacturer may file an abbreviated biologic license application (ABLA) to market a biosimilar once the reference biologic has been approved for 12 years, 42 U.S.C. § 262(k)(7), 262(k)(2)(A).[7]

The statute also establishes a five-step process (often called the "patent dance") in which the biologic manufacturer and the would-be competitor attempt to resolve or refine any patent disputes. *See* 42 U.S.C. § 262(l). At the end of this process, the ABLA filer and the biologic manufacturer exchange a list of patents that will be subject to litigation. 42 U.S.C. § 262(l)(5). Within 30 days, the biologic manufacturer must sue to test the patents that appear on either party's list. 42 U.S.C. § 262(l)(6). The FDA may approve a new biosimilar or interchangeable product while patent litigation is pending, but the applicant must notify the biologic manufacturer 180 days before introducing its product. 42 U.S.C. § 262(l)(8)(A).

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[6] The BPCIA is similar in concept to the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), which governs the process for bringing generic conventional drugs to market. *See* Food & Drug Admin., *Implementation of the Biologics Price Competition and Innovation Act of 2009* (Feb. 12, 2016), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/implementation-biologics-price-competition-and-innovation-act-2009.

[7] The applicant needn't prove anew that the biosimilar is safe or effective so long as it shows that the product is "highly similar to the reference product notwithstanding minor differences in clinically inactive components," and has "no clinically meaningful differences … [from] the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. § 262(i)(2).

C. Proceedings Below

AbbVie's biologic Humira has been the highest-earning drug in the United States for the last six years, at a cost of up to $50,000 per patient per year. D. Ct. ECF No. 109 ¶¶ 2, 84. Several potential biosimilar competitors filed ABLAs and challenged AbbVie's patents, after which AbbVie sued. The parties allegedly agreed to settle the disputes, with AbbVie letting the competitors enter the European market almost immediately and the domestic market in 2023. *Id.* ¶¶ 151, 157-84, 203.

The complaint charges that AbbVie violated the antitrust laws in three ways. First, AbbVie allegedly obtained a "thicket" or "minefield" of over 100 deficient patents and, despite the weakness of its patents, embroiled its rivals in protracted litigation designed to deter them from launching. *Id.* ¶¶ 4, 296-98. Second, AbbVie allegedly entered into "market division" agreements with its rivals whereby AbbVie maintained its domestic monopoly in return for forfeiting its European one. *Id.* ¶¶ 9, 280-83. Third, the European licenses allegedly functioned as large and unjustified reverse payments by AbbVie to keep rivals out of the domestic market. *Id.* ¶¶ 203, 263-64. The net result, plaintiffs charge, is that "AbbVie has maintained its Humira monopoly in the U.S., where patients and customers are, in effect, subsidizing lower prices charged for biosimilars in Europe." *Id.* ¶ 206.

The district court dismissed the complaint for failure to state a claim. With respect to the reverse-payment claim, the court purported to accept the truth of the complaint's charge that the European licenses amounted to a "large" "transfer of value" to AbbVie's biosimilar competitors in exchange for an "AbbVie-friendly" U.S.

entry date. Op. 45-46. But it stated that "the package of global patent settlements" was not "an *Actavis*-like unlawful reverse-payment" since it merely "provided one early entry date for the European market and a different early entry date for the U.S. market—both permissible under *Actavis*." Op. 45. Moreover, in the court's view, the settlements' effect "was to increase, not restrain competition by bringing competitors into the market when patents otherwise prohibited the competition." Op. 46. As a result, "consumers won and the market for Humira (and its generics) became more competitive." Op. 47. The court also opined that the settlements served a "broader" systemic interest in "encouraging patent litigants to settle worldwide patent disputes." Op. 46.

ARGUMENT

The district court's analysis is flawed in two ways. First, the court seemingly held that because the settlements allowed biosimilars to compete on a global basis before AbbVie's patents expired, the agreements did not feature "*Actavis*-like" reverse payments and in fact "increase[d]" competition. *See* Op. 44-48. That is not the proper approach under *Actavis*, and indeed it resembles the scope-of-the-patent test, which the Supreme Court rejected. Instead, *Actavis* required the district court to ask whether plaintiffs sufficiently alleged that (1) AbbVie made a large payment to the biosimilars to induce them to stay off the domestic market, and (2) this payment cannot be explained or justified as something other than the parties' desire to share U.S. monopoly profits. 570 U.S. at 153-54, 156-59; *Lipitor*, 868 F.3d at 255-57. "Early" entry dates do not in and of themselves answer either question.

Second, the district court erred to the degree it dismissed the complaint based on the policy determination that doing so would encourage the settlement of worldwide patent disputes. *Actavis* held that such a policy benefit does not save an unjustified reverse-payment settlement from antitrust condemnation. 570 U.S. at 153-54.

We note that these errors do not by themselves mandate reversal or demonstrate that the complaint states a plausible antitrust claim. Our purpose is simply to provide this Court with guidance on the legal principles underlying *Actavis*. We take no position on whether the complaint sufficiently pleads a viable claim.

I. UNDER *ACTAVIS*, THE LEGALITY OF A PATENT SETTLEMENT TURNS ON THE PRESENCE OF A LARGE REVERSE PAYMENT AND THE REASONS FOR IT, NOT "EARLY" ENTRY

The district court erred by seemingly dismissing the complaint on the ground that the settlements allowed "early" competition before AbbVie's patents expired. The proper inquiry under *Actavis* is (1) whether the parties settled with a reverse payment to eliminate the risk of earlier competition, and (2) whether the payment has a legitimate justification apart from the parties' desire to share monopoly profits. 570 U.S. at 153-54, 156-59.

The court at first seemed to accept as true plaintiffs' charge that "AbbVie paid the biosimilar manufacturers" by "allow[ing] the biosimilars to enter the European market" in exchange for "settl[ing] the infringement litigation with an AbbVie-friendly U.S. early entry date," arrangements worth "hundreds of millions of dollars" to the biosimilars and "billions" in "lucrative monopoly time in the U.S."

to AbbVie. Op. 44-45 & n.17.[8] From there, however, the court went on to reason that the quid pro quo between AbbVie and the biosimilars was "not an *Actavis*-like unlawful reverse-payment" because the settlements merely allowed "early" competition in the U.S. and Europe—"both permissible under *Actavis*." Op. 45. According to the court, such "early" competition meant that the settlements were procompetitive—and therefore justified—as a matter of law. "The effect of the payment was to increase, not restrain competition by bringing competitors into the market when patents otherwise prohibited the competition." Op. 46.

The district court's focus on "early" entry evokes the very scope-of-the-patent test rejected in *Actavis*. *Actavis* held that, when the complaint plausibly alleges a large and unjustified reverse payment, settlements may violate the antitrust laws *even if* they allow "early" competition before the patents expire. 570 U.S. at 145-48, 153-54. The Court recognized that settling with an "early" entry date is unproblematic *only* when it comes "without the patentee paying the challenger to stay out prior to that point." *Id.* at 157-58; *see supra* pp. 5-7. But when the patentee offers "a share of its monopoly profits that would otherwise be lost in the competitive market," even an "early" entry settlement "has the 'potential for genuine adverse effects on competition.'" 570 U.S. at 153-54 (quoting *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986)).

[8] At the same time, the court observed that the complaint was marred by "potential inconsistencies" that "undermine[] the inference that th[e] European entry dates were worth all that much or were a bargaining chip in the U.S. settlements." Op. 45 n.17. The FTC takes no position on whether plaintiffs sufficiently pleaded the existence of a reverse payment despite these "potential inconsistencies."

The district court therefore was incorrect that the alleged reverse-payment settlement "increase[d]" competition when it permitted generic entry before the patents expired, for it relied on the proposition that the "patents otherwise prohibited the competition." Op. 46. But those untested patents "may or may not be valid, and may or may not be infringed." *Actavis*, 570 U.S. at 147. Unless a reverse payment reflects "traditional settlement considerations," it may amount to a monopolist's purchase of an "exclusive right to sell its product, a right it already claims but would lose" if the generic had prevailed in the patent litigation. *Id.* at 145-48, 153-54. This "payment in return for staying out of the market" guarantees that drug prices remain at "patentee-set," non-competitive, monopoly levels, with the brand and its would-be generic challenger sharing the resulting profits. *Id.* at 154. When this happens, "[t]he patentee and the challenger gain; the consumer loses." *Id.* The antitrust laws forbid drug companies from agreeing to avoid competition and share the rewards of monopoly—even if the conspiracy ends before the patents expire.

Indeed, as explained above, the settlements at issue in *Actavis* provided for generic entry more than five years before patent expiry. The Court determined that the FTC's complaint stated an antitrust claim because it alleged that the patentee had agreed "to compensate the generics for agreeing not to compete" prior to that date. *Id.* at 145, 158. Various lower courts have likewise held that allegations of reverse payments state a claim notwithstanding "early" entry when the complaint

plausibly alleges that early entry is accompanied by large and unjustified payments. *See supra* p. 7.

The *Actavis* analysis turns not on "early" entry but on whether brand and generic rivals agreed to share monopoly profits rather than compete. At the pleadings stage, all that *Actavis* requires are factual allegations sufficient to make it plausible that the patentee made a reverse payment that was large and unjustified. *Lipitor*, 868 F.3d at 257. A reverse payment exists when a settlement (1) provides the generic challenger with something of value that it could not have obtained had it won its litigation, *Actavis*, 570 U.S. at 147-48, and (2) enables the parties "to 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. Where both conditions are satisfied, the brand may be "using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement"; that paid-for avoidance is "the very anticompetitive consequence that underlies the claim of antitrust unlawfulness." *Id.* at 156-57.

As part of this analysis, the adjudicator asks whether the complaint sufficiently alleges that the payment cannot be explained as reflecting "traditional settlement considerations," such as "litigation expenses saved through the settlement" or "compensation for other services that the generic has promised to perform." *Id.* at 156. Where such a justification exists, "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." *Id.*

A settlement does not normally run afoul of the antitrust laws if it simply allows a competitor to enter the market before patent expiration, without a payment. This is true even if the settlement simultaneously resolves multiple patent litigations—whether on different drugs or in different jurisdictions. And the mere fact that, in a settlement of multiple litigations, one license may be worth more than the brand's avoided litigation costs does not automatically mean the arrangement fails to reflect traditional settlement considerations. *Cf.* Br. of Pls.-Appellants at 22-23.

At the same time, however, where there are multiple settlements, it is not enough for a court to determine separately—as the district court did here—that each settlement appears to consist solely of an entry date. Rather, the court must examine the economic substance of the alleged conduct as a whole to assess whether the plaintiffs have plausibly alleged a "payment in return for staying out the market." 570 U.S. at 154. For instance, in *AbbVie*, the Third Circuit recently overturned a district court ruling that had dismissed a reverse-payment challenge to two pharmaceutical agreements on the grounds that each agreement appeared to simply allow "early" entry. Such an approach, the Third Circuit explained, inappropriately "elevates form over substance" and fails to consider whether the arrangement as a whole included an "unexplained large transfer of value" from a patentholder to a generic challenger. 2020 WL 5807873, at *19 (cleaned up). Applying the appropriate standard, the Third Circuit concluded that the FTC had plausibly alleged that the agreements were "linked," with one agreement deferring

generic competition and the other serving as a transfer of monopoly profits in exchange for that deferral. *Id.*

Here, the district court did not fully consider whether the plaintiffs plausibly alleged that the European settlements served as a payment vehicle to induce the biosimilars to abandon their U.S. patent litigation and accept a deferred entry date. It may well be that the complaint alleges nothing more than entry dates in each settlement that reflect only an "approximation of the expected level of competition that would have obtained had the parties litigated." *Cipro*, 348 P.3d at 865. But if plaintiffs have alleged—and ultimately can prove—that the agreements are linked and taken together include a payment for which the "basic reason" is "a desire to maintain and to share patent-generated monopoly profits [in the United States], then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Actavis*, 570 U.S. at 158.

II. POLICIES FAVORING LITIGATION SETTLEMENT CANNOT MAKE LAWFUL A LARGE AND UNJUSTIFIED REVERSE PAYMENT

The district court further opined that "uphold[ing] these agreements under antitrust review" would "encourag[e] patent litigants to settle worldwide patent disputes." Op. 46-47. When the settlement is accompanied by a large and unjustified payment, *Actavis* directly rejected that concern as a basis for dismissal. The Court recognized a "general … policy favoring the settlement of disputes," but ruled that the policy "should not determine the result" in a reverse payment case. *Actavis*, 570 U.S. at 153-54. The antitrust laws forbid conspiracies to preserve a monopoly and carve up the resulting profits, even if they occur within the ambit of a

patent litigation settlement. *Id.* The Commission has likewise observed that, although "settling litigation is typically favored under the law, it is not a trump card." *In re Impax Labs., Inc.*, No. 9373, 2019 WL 1552939, at *38 (F.T.C. Mar. 28, 2019), *appeal pending*, No. 19-60394 (5th Cir.). The benefit of litigation settlement "does not immunize otherwise anticompetitive conduct." *Id.*

Actavis recognized that this principle does not prevent parties from settling their patent disputes. They may settle with reverse payments that reflect traditional settlement considerations, such as avoided litigation costs or fair value for services. *Actavis*, 570 U.S. at 156. Or they may "settle in other ways, for example, 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." *Id.* at 158. The Commission's own studies of drug-patent settlements confirm that the vast majority of drug-patent settlements have featured no compensation from the brand to the generic in excess of litigation fees. Indeed, in the most recent year analyzed, the number of drug-patent settlements reached an all-time high.[9]

[9] *See* Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Overview of Agreements Filed in FY 2016* (May 2019), https://www.ftc.gov/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-fy2016.

CONCLUSION

Regardless of its ruling on the ultimate merits, this Court should correct the foregoing legal errors committed by the district court.

Respectfully submitted,

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October 13, 2020

CERTIFICATE OF COMPLIANCE

This brief complies with Federal Rules of Appellate Procedure 29(d) and 32(a)(7) in that it contains 4,937 words, excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirement of Circuit Rule 32(b) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 12-point New Century Schoolbook.

Dated: October 13, 2020

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CERTIFICATE OF SERVICE

I hereby certify that on October 13, 2020, I filed and served the foregoing with the Court's appellate CM/ECF system. I certify that all counsel of record are registered as ECF filers and that they will be served by the CM/ECF system.

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