No. 19-60394

In the United States Court of Appeals for the Fifth Circuit

IMPAX LABORATORIES, INCORPORATED, a corporation,

Petitioner,

v.

FEDERAL TRADE COMMISSION,

Respondent.

Petition for Review on an Order of the Federal Trade Commission
(Federal Trade Commission Docket No. 9373)

BRIEF OF AARP AND AARP FOUNDATION AS AMICI CURIAE IN SUPPORT OF RESPONDENT

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CERTIFICATE OF INTERESTED PARTIES

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. Amici makes these representations so that the judges of this court may evaluate possible disqualification or recusal.

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The Internal Revenue Service has determined that AARP is organized and operated exclusively for the promotion of social welfare pursuant to Section 501(c)(4) of the Internal Revenue Code and is exempt from income tax. The Internal Revenue Service has determined that AARP Foundation is organized and operated exclusively for charitable purposes pursuant to Section 501(c)(3) of the Internal Revenue Code and is exempt from income tax. AARP and AARP Foundation are also organized and operated as nonprofit corporations under the District of Columbia Nonprofit Corporation Act.

Other legal entities related to AARP and AARP Foundation include AARP Services, Inc., and Legal Counsel for the Elderly. Neither AARP nor AARP Foundation has a parent corporation, nor has either issued shares or securities.

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STATEMENT OF THE IDENTITIES AND INTERESTS OF AMICI CURIAE[1]

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering Americans 50 and older to choose how they live as they age. With nearly 38 million members and offices in every state, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, AARP works to strengthen communities and advocate for what matters most to families, with a focus on health security, financial stability, and personal fulfillment. AARP's charitable affiliate, AARP Foundation, works to end senior poverty by helping vulnerable older adults build economic opportunity and social connectedness.

AARP and AARP Foundation advocate for access to affordable prescription drugs, by, among other things, participating as Amici Curiae in state and federal courts. *See, e.g.*, *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013*); King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015).

Amici have a strong interest in ensuring that all consumers, and older adults in particular, have access to affordable prescription drugs. Prescription drug prices

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[1] Amici Curiae certify that no party or party's counsel authored this brief in whole or in part, or contributed money intended to fund its preparation or submission. Amici curiae also certify that only Amici Curiae provided funds to prepare and submit this brief.

All parties have consented to the filing of this brief. FED. R. APP. P. 29(a)(2).

continue to skyrocket each year, with the prices of brand name drugs increasing at an exorbitant rate. In 2018, retail prices for 267 widely used brand name prescription drugs increased by 5.8 percent, more than twice the rate of inflation. Stephen W. Schondelmeyer and Leigh Purvis, *Rx Price Watch, Brand Name Drug Prices Increase More than Twice as Fast as Inflation in 2018*, AARP Pub. Pol'y Inst., 1 (Nov. 2019) [*AARP Brand Name Drugs Report*].[2] For over a decade, annual brand name drug price increases have exceeded the general inflation rate by two-fold to more than 100-fold. *Id*.

These ever-escalating prices disproportionately harm older adults, as they typically take more prescription drugs than younger adults and live on fixed or lower incomes. Many older adults take an average of 4.5 prescription medications each month and will need to take some, if not all, of those medications for the rest of their lives. *Id.* The high price of drugs forces some to sacrifice their health and welfare by not filling their prescriptions because they cannot afford the medication. Ashley Kirzinger, et al., *Data Note: Prescription Drugs and Older Adults*, Kaiser Fam. Foundation (Aug. 9, 2019).[3]

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[2] https://www.aarp.org/content/dam/aarp/ppi/2019/11/brand-name-drug-prices-increase-more-than-twice-as-fast-as-inflation.doi.10.26419-2Fppi.00073.005.pdf.

[3] https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/.

Amici's participation in the case will help the Court understand that delaying the market entry of generic drugs harms consumers by limiting their choices and thereby increasing their costs. Competition from generic drugs is an effective way to slow the spiraling price of drugs. Our participation will also help the Court understand that a decision reversing the Federal Trade Commission (Commission) order could return the pharmaceutical industry to the pre-*FTC v. Actavis* era when anticompetitive reverse payment settlements were common. This would impair consumers' access to generic drugs and vital savings. Amici urge this Court to deny the petition for review.

SUMMARY OF ARGUMENT

Reverse payment settlements, also known as "pay-for-delay" agreements, involve a brand manufacturer maintaining exclusivity over a brand name drug by paying a competitor to delay selling a less expensive generic version as part of a patent litigation settlement. Concerns about reverse payment settlements in the pharmaceutical industry trace back more than a decade. *See* Natasha Singer, *Deals to Restrain Generic Drugs Face a Ban*, N.Y. Times, Jan. 10, 2010.[4] These concerns are warranted because generic competition is one of the few time-tested ways to control prescription drug prices.

[4] https://www.nytimes.com/2010/01/13/business/13generic.html.

In 2018, generic drugs reduced the cost of prescription drugs by $293 billion. Association for Accessible Medicines, *The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report*, 4 (2019) [*The Case for Competition*].[5] Access to generic drugs benefits all consumers, but particularly older adults as they take more medications and often live on fixed or lower incomes. The high price of prescription drugs forces many older adults to forgo life-saving medication or take less than the prescribed amount. *See* Kirzinger, *supra*. Thus, having access to lower cost generic drugs is critical to preserving older adults' health and financial wellbeing. Any anticompetitive activity that limits generic competition is a serious threat to their lives and making prescription drugs affordable.

Anticompetitive reverse payment settlements limit competition and predictably increase drug costs. Indeed, without the legal limitations of antitrust law, branded and generic companies could eliminate the risk of their competition and share the resulting supracompetitive profits. Such deals can be highly lucrative for both sides. In other words, if branded firms are free to pay generic firms to settle patent litigation without legal recourse, they will likely choose that option. But this option leaves consumers holding the bag.

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[5] https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf.

As a result, applying the antitrust laws to reverse payment settlements ensures a competitive market. If antitrust laws are applied too leniently, brand and generic companies could exploit them to reach anticompetitive settlements.

If this Court were to reverse the Commission's decision, it would weaken antitrust laws and place consumers at greater risk of not being able to afford life-sustaining medication. The history of the legal treatment of reverse payments shows this to be true. Beginning in 2005, a series of courts adopted a rule of virtual *per se* legality for reverse payment settlements—the scope of the patent test. And reverse payment settlements with large payments became ubiquitous. During that time, the Commission estimated that anticompetitive reverse payment settlements delayed cost-saving generic competition by 17 months, almost a year-and-half, and would continue to do so if the practice was not prevented. Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, 2, 8-10 (Jan. 2010) [*2010 FTC Pay-for-Delay Report*].[6] They also cost consumers billions of dollars. *Id.*

The Supreme Court in *FTC v. Actavis* rejected the scope of the patent test and applied the rule-of-reason to patent settlements. In its aftermath, settlements with substantial reverse payments have largely disappeared, but branded and

[6] 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.

generic companies continue to settle patent litigation at a record pace – just without substantial reverse payments.

On appeal, Impax Laboratories, Inc. (Impax) invites this Court to alter the rule of reason analysis in ways that would effectively immunize many anticompetitive reverse payment settlements. It would return the industry to pre-*Actavis* days, weakening the rule of reason and the *Actavis* standard. This would be catastrophic for many American consumers and older Americans in particular. The scope of the patent rule cost consumers billions of dollars. *Actavis* has largely ended the practice. The Court should be leery of creating any loopholes that will encourage parties to once again enter into anticompetitive reverse payment settlements. The petition for review should be denied.

ARGUMENT

I. Delaying Generic Drugs From Entering The Market Harms Consumers By Preventing Competition.

Anticompetitive reverse payment settlements cause significant and unnecessary delays in consumer access to less costly generic drugs. Prescription drug spending in the United States has skyrocketed over the last decade. *AARP Brand Name Drugs Report*, *supra*, at 1. Most alarming, the prices of many brand name drugs are increasing so quickly that they are outpacing inflation. In 2018, retail prices for 267 widely used brand name prescription drugs increased by 5.8 percent, more than twice the rate of inflation. *Id.*

When clinically appropriate for a consumer, using a generic drug over a branded product is key to slowing the spiraling price of prescription drugs. Generic drugs typically sell for a fraction of the price of their branded counterparts and quickly capture the majority of unit sales. For example, a recent AARP study found that in 2017, while the average annual cost of therapy for widely used brand name drug products was $6,798, the average annual cost of therapy for widely used generic drug products was $365. Stephen W. Schondelmeyer and Leigh Purvis, *Rx Price Watch, Rx Price Watch Report: Price Growth for Brand Name and Specialty Drugs More Than Offset Price Decreases for Generic Drugs*, AARP Pub. Pol'y Inst., 1 (Sept. 2019).[7]

Moreover, in that same year, the retail prices for 390 generic drugs widely used by older adults fell by an average of 9.3 percent. Stephen W. Schondelmeyer and Leigh Purvis, *Rx Price Watch Report, Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update*, AARP Pub. Pol'y Inst., 3, 4 (Sept. 2019).[8] In contrast, the retail prices for 267 brand name

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[7] https://www.aarp.org/content/dam/aarp/ppi/2019/09/price-growth-for-brand-name-and-specialty-drugs-more-than-offset-price-decreases-for-generic-drugs.doi.10.26419-2Fppi.00073.004.pdf.

[8] https://www.aarp.org/content/dam/aarp/ppi/2019/09/trends-in-retail-prices-of-prescription-drugs-widely-used-by-older-americans.doi.10.26419-2Fppi.00073.003.pdf.

prescription drugs widely used by older adults increased by an average of 8.4 percent. *Id.*

These cost savings are vital to older adults because they are prescribed more prescription drugs than younger adults. Kirzinger, *supra*. Many older adults take an average of 4.5 prescription medications each month and could need those medications for the rest of their lives. *AARP Brand Name Drugs Report*, *supra*, at 1. However, nearly 25 percent of adults above age 65 have difficulty affording their prescription drugs. Kirzinger, *supra*. That number is much higher for older adults in fair or poor health (forty-five percent). *Id.* In addition, over twenty percent of older adults reported not filling a prescription, substituting an over-the-counter product for the prescribed product, or splitting pills due to cost. *Id.* For these consumers, access to lower-cost generic drugs often determines whether they can afford life-saving medication.

Other studies show that in addition to saving consumers billions each year, generic drugs also provide significant savings to the U.S. health care system overall. An Association for Accessible Medicines report showed that in 2018 alone, consumers having access to generic drugs saved the U.S. health care system nearly $293 billion. *The Case for Competition, supra*, at 9. Since 2010, generic drugs have saved the system $2 trillion. *Id.* at 10. Furthermore, even though nine

out of every ten prescriptions dispensed are generic drugs, generic drugs only accounted for twenty-two percent of prescription drug spending. *Id.* at 8.

As these studies show, consumers and the entire U.S. health care system benefit from having access to generic drugs on the market. Recognizing this, Congress sought to speed up generic entry by enacting the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355, as known as the Hatch-Waxman Act. This Act "institutionalize[d] and provide[d] incentive for a system of attacks on presumptively valid patents[,]" by generic manufacturers. *Innovation and Patent Law Reform: Hearings on H.R. 3285, H.R. 3286, and H.R. 3605 Before the Subcomm. on Courts, Civil Liberties, and the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 2d Sess., Part 1, 445 (1984).

In creating the incentive to challenge patents, Congress was not seeking to enrich the generic drug manufacturers. Hatch-Waxman challenges were supposed to be vehicles for earlier entry of generic drugs into the marketplace, thus giving consumers earlier access to lower-priced prescription drug alternatives. H.R. Rep. No. 98-857, pt. 1, at 1 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647 (explaining that the purpose of the Hatch-Waxman Act "is to make available more low cost generic drugs by establishing a generic drug approval procedure"). Indeed, generics make up nearly ninety percent of drugs dispensed today, yet constituted

only nineteen percent of prescription drugs dispensed before the Hatch-Waxman Act. PhRMA, *What is Hatch-Waxman?* (June 2018).[9]

Before the U.S. Supreme Court's 2013 *FTC v. Actavis* decision, agreements between brand manufacturers and generic drug companies to delay the entry of generic drugs dramatically affected competition and prescription drug prices. On average, these agreements delayed the entry of generic drugs by an average of seventeen months, costing billions of dollars in consumer savings. *2010 FTC Pay-for-Delay Report*, *supra*, at 8-10.

Here, the Commission found that Impax received millions in exchange for its agreement to delay its generic drug entering the market. *In Re Impax Labs.*, *Opinion of the Fed. Trade Comm'n*, Docket No. 9373, at 4 (FTC March 28, 2019) (public redacted version) [FTC Op.]. This delayed entry is the antithesis of what Congress intended when it enacted the Hatch-Waxman Act. *See In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) ("Congress sought to get generic drugs into the hands of patients at reasonable prices-fast."). Allowing this agreement to stand would flout Congress's intent and open the door for anticompetitive agreements to flood the landscape.

[9] https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Fact-Sheet_What-is-Hatch-Waxman_June-2018.pdf.

II. Weakening Existing Antitrust Rules Would Allow The Return Of Anticompetitive Reverse Payment Settlements That Increase Prescription Drug Costs For Consumers And The U.S. Health Care System.

In *FTC v. Actavis*, the Supreme Court held that courts should analyze federal antitrust challenges to reverse payment settlements under the rule of reason. *See Actavis, Inc.*, 570 U.S. at 159–60 (2013). The Commission applied this approach here. It found that brand manufacturer Endo Pharmaceuticals possessed market power, that the settlement eliminated the risk of competition, and that Impax received a large and unjustified payment. FTC Op. at 19, 24, 25. Those findings satisfy a prima facie case.

Impax asks this Court to change the rule of reason analysis in a way that would effectively immunize many anticompetitive reverse payment settlements. Impax argues that under the rule of reason, a plaintiff must prove what competition would have existed absent the agreement as a benchmark and that the agreement delayed entry relative to that benchmark. Pet. Br. at 32. It further argues that the mere fact that a company would not settle without a payment is a procompetitive justification. Pet. Br. at 53.

Impax's proposal would alter how courts apply the rule of reason to reverse payment settlements in two ways. First, it would make it harder to establish a prima facie case. Second, it would dramatically expand the scope of acceptable justifications. Combined, these changes would open a variety a possibilities for

anticompetitive settlements that would survive the condemnation that they should have under the antitrust laws. Adopting Impax's position would weaken antitrust enforcement, undermine competition, and effectively return the industry to the pre-*Actavis* era.

A. The Proliferation Of Anticompetitive Reverse Payment Settlements Before the 2013 *FTC v. Actavis* Decision Reveals The Dangers Of Weakening Antitrust Rules.

During the pre-*Actavis* era (2005 to 2013), the dominant approach that courts used to evaluate the legality of a reverse payment settlement was the scope of the patent test. Reviewing that era reveals that weakening antitrust rules prevents competition and harms consumers.

Under the scope of the patent rule, a patent holder could pay an alleged infringer any amount of money to accept an entry date unless the patent was obtained by fraud, the litigation was a sham, or the agreement delayed entry beyond the expiration of the patent. *See Schering Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.),* 429 F.3d 370, 396–97 (2d Cir. 2005); *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 544 F.3d 1323, 1335 (Fed. Cir. 2008). The scope of the patent test allowed those anticompetitive settlements to continue through the life of the patent. Beginning in 2005, three circuits adopted this rule. *Id.*

The scope of the patent test immediately and dramatically affected pharmaceutical patent settlements. The number of settlements involving substantial payments (more than seven million dollars) and a restriction on generic competition increased from zero in fiscal year 2004, the year before the Eleventh Circuit's *Schering* decision, to a record of thirty-three settlements in fiscal year 2012, the year before the *Actavis* decision. Fed. Trade Comm'n, Bureau of Competition, *Overview of Agreements Filed in FY 2016*, Exhibit 1 (2016) [*2016 FTC Report*].[10]

The proliferation of these agreements is not surprising due to the economic incentives. Because anticompetitive reverse payments (those that involve a payment to eliminate the risk of competition) are profitable, parties have an economic incentive to enter into those agreements to the extent the law allows. *See* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand. J. Econ. 391, 407–08 (2003); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 NYU L. Rev. 1553, 1579–83 (2006). Settlements with payments did not attract enough challengers to undermine that profitability. Market dynamics did not deter the practice. Michael Kades,

[10] https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf.

Competitive Edge: Underestimating the Cost of Underenforcing U.S. Antitrust Laws, Washington Ctr. For Equitable Growth, at tbl.1 (Dec. 13, 2019).[11]

Consumers paid a dear price for this conduct. During the scope of the patent era, reverse payments increased prescription drug costs by an estimated $66.1 billion. *Id.* According to a Commission Staff study, settlements in which the generic company receives compensation and agrees to restrict its entry delay competition by an average of seventeen months. *See 2010 FTC Pay-for-Delay Report*, *supra*, at 7–8. The cost of delaying generic entry was equal to seventy-seven percent of the brand's pre-generic sales. *Id.* at 8. In other words, if a branded product had sales of one billion dollars pre-generic entry, a one-year delay in generic competition costs consumers $770 million dollars. Adopting the scope of the patent test allowed substantial reverse payments that caused tens of billions of dollars in harm.

The Supreme Court rejected the scope of the patent test in *FTC v. Actavis.* That decision dramatically changed how parties settled patent infringement litigation. In 2016, there was only a single settlement with a substantial payment. *2016 FTC Report*, *supra*, at Exhibit 1. Parties continued to settle their pharmaceutical patent settlements, just without substantial reverse payments. The

[11] https://equitablegrowth.org/competitive-edge-underestimating-the-cost-of-underenforcing-u-s-antitrust-laws/.

number of pharmaceutical patent settlements increased from 140 in 2012 to 232 in 2016. *Id.*

The lesson from the scope of the patent experiment is clear: competitors are likely to engage in anticompetitive settlements when allowed to do so, and consumers will suffer. The economic incentives to exploit any weakening of the *FTC v. Actavis* rule are great. The result would be new anticompetitive patent settlements and escalating drug prices that too many Americans, and particularly older Americans, already struggle to afford.

B. Impax Laboratories' Proposed Analysis Would Weaken Antitrust Rules And Immunize Anticompetitive Patent Settlements.

Although Impax praises the *Actavis* decision in its brief, its argument would bury *Actavis* under new substantive burdens. The plaintiff would have to assess both the patent merits and litigation time, prove a counterfactual baseline of competition in the absence of the agreement, and account for after-the-agreement developments years later, whether they were foreseeable or not.

Even in the rare case when the plaintiff could satisfy these burdens, the mere fact that a company would not settle without a payment would be an acceptable procompetitive justification. In other words, just because a party wants to be paid not to compete, it would justify the reverse payment. Parties will easily be able to enter anticompetitive settlements that pass scrutiny under the antitrust laws.

These standards would not help courts identify anticompetitive patent settlements and distinguish them from procompetitive ones. Instead, Impax's proposed analysis would alter and undermine the rule of reason, create a practically insurmountable burden for establishing an antitrust violation, and create a *de facto* version of the rejected scope of the patent test.

Simply put, weakening antitrust protections against anticompetitive behavior, whether by increasing the plaintiff's burden or decreasing the defendant's burden, will lead to more anticompetitive patent settlements. This in turn will further escalate drug prices and harm consumers.

Here, the Commission applied the correct legal standard to a straightforward case. It focused on precisely what makes a reverse payment settlement anticompetitive: the parties used a payment to short-circuit the negotiation and reach an agreement that benefits the competitors and harms consumers. The Commission's decision should stand. It protects consumers and prevents antitrust rules from effectively eroding to a pre-*Actavis* period.

CONCLUSION

For the reasons described above, Amici respectfully urge the Court to deny the petition for review.

Dated: December 16, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This Petition complies with the type-volume limitation of Fed. R. App. P. 32(a)(7) and Circuit Rule 32(a)(2) because: this brief contains 3,305 words, (excluding the parts of the brief exempted by Fed. R. App. P. 32(f) as determined by the word counting feature of Microsoft Office Word 2016).

2. This Petition complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this Petition has been prepared in a proportionally spaced typeface using Microsoft Office Word 2016 14 point Times New Roman font.

Dated: December 16, 2019

/s/ Maame Gyamfi
Maame Gyamfi

CERTIFICATE OF SERVICE

I hereby certify that on December 16, 2019, the foregoing Brief of AARP and AARP Foundation as Amici Curiae In Support of Respondent was electronically filed with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: December 16, 2019

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