No. 19-60394

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

IMPAX LABORATORIES LLC,

Petitioner,

v.

FEDERAL TRADE COMMISSION,

Respondent.

On Petition for Review from
The Federal Trade Commission
No. 9373

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER, URGING REVERSAL

Richard A. Samp
Cory L. Andrews
Washington Legal Foundation
2009 Massachusetts Avenue, NW
Washington, DC 20036
202-588-0302
rsamp@wlf.org

October 10, 2019

CERTIFICATE OF INTERESTED PERSONS

No. 19-60394

IMPAX LABORATORIES LLC,
Petitioner,

v.

FEDERAL TRADE COMMISSION,
Respondent.

The undersigned counsel of record certifies that all interested persons and entities described in the fourth sentence of Rule 28.2.1 who have an interest in the outcome of this case are listed in the Certificate of Interested Persons in Petitioner's brief, except for the following listed persons and entities. These representations are made in order that the judges of this Court may evaluate possible disqualification.

1. The Washington Legal Foundation (WLF), an *amicus curiae*. WLF is a nonprofit corporation organized under § 501(c)(3) of the Internal Revenue Code. WLF has no parent corporation, nor has it issued any stock owned by a publicly held company.

2. Richard A. Samp and Cory L. Andrews are counsel for WLF in this matter.

Richard A. Samp
Cory L. Andrews
Washington Legal Foundation
2009 Massachusetts Avenue, NW
Washington, DC 20036
202-588-0302

/s/ Richard A. Samp
Richard A. Samp
Counsel for Washington Legal Foundation

TABLE OF CONTENTS

Page

CERTIFICATE OF INTERESTED PERSONS i

TABLE OF AUTHORITIES iv

INTRODUCTION AND INTEREST OF *AMICUS CURIAE* 1

STATEMENT OF THE CASE 3

SUMMARY OF ARGUMENT 6

ARGUMENT 11

I. *ACTAVIS* REQUIRES COURTS REVIEWING PATENT-LITIGATION SETTLEMENTS TO BALANCE THE GOALS OF PATENT LAW AND ANTITRUST LAW 11

A. *Actavis* Rejected The FTC's Claim That "Reverse Payment" Settlements Are Presumptively Anticompetitive 11

B. The Rule-of-Reason Analysis Mandated By *Actavis* Requires Reviewing Courts To Examine All Relevant Factors To Determine Whether an Agreement Harms Competition 13

II. THE FTC IMPOSED ANTITRUST LIABILITY WITHOUT CONDUCTING THE RULE-OF-REASON ANALYSIS REQUIRED BY *ACTAVIS* 15

A. The FTC Failed To Show That The Endo-Impax Settlement Harmed Competition 15

B. The FTC Erred By Refusing To Consider The Procompetitive Benefits Of The Endo-Impax Settlement 19

Page

C. The FTC Failed To Show That The Settlement's Procompetitive Benefits Could Have Been Achieved By A Means Less Harmful To Competition 22

III. *ACTAVIS* DID NOT AUTHORIZE ANTITRUST SCRUTINY FOR NON-CASH "NO-AG" AGREEMENTS OF THE SORT AT ISSUE HERE 24

IV. THE FTC'S DECISION EFFECTIVELY OUTLAWS ANY SETTLEMENTS THAT PROVIDE SUBSTANTIAL BENEFIT FOR GENERIC DRUG MANUFACTURERS—THEREBY RENDERING SETTLEMENTS EXCEEDINGLY DIFFICULT 26

CONCLUSION 29

TABLE OF AUTHORITIES

Page(s)

Cases:

Asahi Glass Co. v. Pentech Pharms., Inc.,
289 F. Supp. 2d 986 (N.D. Ill. 2003) 27

Calif. Dental Ass'n v. FTC,
526 U.S. 756 (1999) 14

E. Bement & Sons v. Nat'l Harrow Co.,
186 U.S. 70 (1902) 25

FTC v. Actavis, Inc.,
570 U.S. 136 (2013) . . . . . *passim*

In re K-Dur Antitrust Litigation,
686 F.3d 2012 (3d Cir. 2012), *vacated*, 570 U.S. 913 (2013) 7

In re Nexium Antitrust Litig.,
842 F.3d 34 (1st Cir. 2016) 17

In re: Tamoxifen Citrate Antitrust Litigation,
466 F.3d 187 (2d Cir. 2006),
cert denied, 551 U.S. 1144 (2007). 7

Kimble v. Marvel Entertainment Group, LLC,
135 S. Ct. 2401 (2015) 25

Leegin Creative Leather Products, Inc. v. PSKS, Inc. ,
551 U.S. 877 (2007) 15

North Texas Specialty Physicians v. FTC,
528 F.3d 346 (5th Cir. 2008) 21

Page(s)

Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.,
472 U.S. 284 (1985) 14

Ohio v. American Express Co.,
138 S. Ct. 2274 (2018) 8, 14

Schering-Plough Corp. v. FTC,
402 F.3d 1056 (11th Cir. 2005),
cert denied, 548 U.S. 919 (2006) 1, 17

Simpson v. Union Oil Co.,
377 U.S. 13 (1964) 7

Standard Oil Co. (Indiana) v. United States,
283 U.S. 163 (1931) 20

United States v. Line Material Co.,
333 U.S. 287 (1948) 12

Statutes and Constitutional Provisions:

Federal Trade Commission Act § 5, 15 U.S.C. § 45 5

Hatch-Waxman Act, Pub. L. No. 98-417 (1984) 1, 26, 29

Sherman Act, 15 U.S.C. § 1 . . . . . 12, 20, 25

35 U.S.C. § 261 . . . . . 10, 25

Miscellaneous:

Kevin McDonald, "Because I Said So: On the Competitive Rationale
of *FTC v. Actavis*," 28 ANTITRUST 36 (2013) 29

INTRODUCTION AND INTEREST OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public-interest law firm and policy center with supporters in all 50 States.[1] WLF promotes and defends free enterprise, individual rights, a limited and accountable government, and the rule of law. WLF has filed briefs in numerous federal court cases involving the intersection of patent rights and antitrust law. *See, e.g., FTC v. Actavis*, 570 U.S. 136 (2013); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2004), *cert. denied*, 548 U.S. 919 (2006).

The FTC's decision represents a major expansion of antitrust law and directly conflicts with *Actavis*. WLF is concerned that the decision not only will make it exceedingly difficult for parties to settle drug-patent disputes but will seriously erode drug companies' incentives to develop and market innovative, life-saving products.

Developing innovative drugs both saves lives and saves consumers billions of dollars each year. Congress recognized these pro-competitive aspects of new drug development when it adopted the patent laws and the Hatch-Waxman Act. Those laws offer large financial benefits to companies that risk the huge sums

---

[1] Under Fed.R.App.P. 29(a)(4)(E), WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief. All parties have consented to the filing of the brief.

necessary to run the Food and Drug Administration (FDA) regulatory gauntlet and that eventually succeed in winning marketing approval for innovative medical products.

The decision below ignored the substantial benefits to competition derived from enforcing the patent laws. Instead, the FTC focused solely on the short-term benefits to consumers brought about by introducing generic competition before an innovative drug's patents are set to expire. The Commission concluded that virtually every litigation-related action by a brand-name drug company to protect its patent is subject to searching scrutiny under the antitrust law. Yet the Commission never even acknowledged that such scrutiny inevitably devalues patents and thus undermines Congress's efforts to promote competition-enhancing drug development.

Such one-sided emphasis on antitrust-law enforcement runs directly counter to the Supreme Court's decision in *Actavis*. *Actavis* emphasized the need to "balance" the antitrust and patent laws. It held that transfers of value from a brand-name drug company to a generic company in connection with a patent-litigation settlement "sometimes" should be subject to antitrust scrutiny and "sometimes" not. And for those cases in which antitrust scrutiny is warranted, *Actavis* rejected the FTC's arguments that "reverse payment" settlements are presumptively

unlawful and that reviewing courts should proceed via a "quick look" approach. Rather, FTC challenges to patent settlements must proceed under a rule-of-reason approach that weighs *all* the circumstances of the case.

The FTC gave lip service to the rule of reason, but its analysis mirrored the "quick look" approach rejected by *Actavis*. The Commission simply presumed, without examining the evidence, that the challenged patent settlement had substantial anticompetitive effects. Worse still, it held that the procompetitive effects of the patent settlement, when considered as a whole, were not relevant to the rule-of-reason analysis; it held that the only relevant procompetitive effects were those that arose directly from the settlement provisions (the "No-AG Agreement" and the "Endo Credit") challenged by the FTC. The FTC's revisionist application of the rule of reason conflicts with *Actavis* and requires reversal.

STATEMENT OF THE CASE

In 2006, Endo Pharmaceuticals, Inc. received FDA approval for and launched Opana ER, an extended release formulation of oxymorphone, an opioid used to treat pain. In 2007, Petitioner Impax Laboratories LLC filed with FDA an Abbreviated New Drug Application (ANDA), seeking approval to market a generic version of Opana ER. Because the ANDA certified that Endo's patents were invalid and would not be infringed by Impax's marketing plans, the ANDA filing

counted as an infringing act, essentially forcing Endo to sue for patent infringement.

After years of contentious litigation, Endo and Impax signed a settlement agreement in June 2010. The principal settlement terms: (1) Endo granted Impax a license to market its generic product in January 2013, eight months before the last of three Endo patents was set to expire; it also granted Impax a license covering any patents that Endo might later obtain for Opana ER; (2) Endo agreed not to market its own generic version of Opana ER for the first 180 days after Impax began marketing (the "No Authorized Generic" or "No-AG" Agreement); (3) in the event that Endo ceased marketing the original formulation of Opana ER before 2013 (as Impax feared it might), thereby reducing demand for Impax's product, Impax would be entitled to certain credits (the "Endo Credit"); and (4) Impax agreed to drop its challenge to Endo's patents and not to market its generic product before 2013.

These principal settlement terms did not entail the payment of cash from one party to the other.[2] Attorneys at the FTC nonetheless characterized the settlement

[2] The parties also entered into a separate Development and Co-Promotion Agreement (DCA), under which they agreed to cooperate in the development of a new drug for the treatment of Parkinson's disease. Under the DCA, Endo was to make certain cash payments to Impax. Following a trial, the FTC's Administrative Law Judge determined that Endo received full value for the money it paid under

as a "reverse payment" settlement (*i.e.*, one in which payments flowed from the patentee to the alleged infringer) and charged that the agreement violated Section 5 of the Federal Trade Commission Act.

The case against Impax proceeded to trial before an ALJ. The ALJ dismissed the complaint, concluding that the evidence at trial failed to prove that the settlement caused any anticompetitive harm. In particular, he found it "unlikely" that generic competition would have begun before January 2013 (the date that Impax began marketing) even if the parties had not settled. He also found that the settlement provided "real and substantial procompetitive benefits to consumers" that outweighed any anticompetitive effect.

Complaint Counsel appealed to the Commission, which reversed the ALJ's decision and held that Impax violated the antitrust laws by entering into the settlement agreement. Under *Actavis*, the Commission stated, anticompetitive harm can be established by demonstrating that an agreement eliminates "the risk of competition"; the plaintiff need not prove that generic competition "would actually or probably have occurred earlier" but for the challenged agreement. Comm. Op. at 23. It determined that: (1) as of June 2010, Impax was legally permitted to

---

the DCA. The Commission did not challenge that finding, and the DCA played no role in the FTC's determination that the settlement violated antitrust laws.

launch its generic product while litigation continued, albeit a launch would have placed it "at risk" of a later award of potentially bankrupting infringement damages; and therefore (2) there was a "plausible risk" that Impax would have entered the market before January 2013 but for the settlement agreement. *Id.* at 24.

The Commission also held that Impax failed to show any procompetitive rationale for the agreement. *Id.* at 31-39. While conceding that various provisions of the settlement were likely procompetitive, it held that those provisions were irrelevant to the rule-of-reason analysis because Impax failed adequately to link the procompetitive effects to "the challenged restraint," which the Commission identified as "the use of a reverse payment to eliminate the risk of generic entry before January 2013." *Id.* at 32. The Commission held in the alternative that even if Impax had demonstrated relevant procompetitive benefits, Complaint Counsel demonstrated that Impax could have obtained the same benefits "by settling without a reverse payment for delayed entry—which is a practical, less restrictive alternative." *Id.* at 40.

SUMMARY OF ARGUMENT

In establishing a patent system, Congress recognized the value of temporary restraints on trade for the purpose of providing financial incentives designed to spur innovation and thereby promote competition over the longer term. While

even temporary restraints on competition cut against the goals of antitrust law in many contexts, Congress mandated that courts should strive to maintain a balance between patent law and antitrust law, and that antitrust law should not be used to shortchange the rights of patent holders. *Simpson v. Union Oil Co.,* 377 U.S. 13, 14 (1964).

In its *Actavis* decision, the Supreme Court sought to maintain that balance in the context of drug-patent litigation settlements between brand-name and generic drug companies. It sought to steer a middle ground between the "presumption of unreasonable restraint" approach espoused by the FTC and adopted by the Third Circuit,[3] under which settlements involving payments from a patentee to the alleged infringer were rebuttably presumed to violate antitrust laws, and the "scope of the patent" test adopted by other federal appeals courts,[4] under which such "reverse payment" settlements were not subject to antitrust scrutiny so long as their anticompetitive effects did not extend beyond the exclusionary potential of the underlying patents. *Actavis*, 570 U.S. at 158-60.

The Supreme Court held that when a generic drug company agrees, in

---

[3] *In re K-Dur Antitrust Litigation*, 686 F.3d 2012 (3d Cir. 2012), *vacated*, 570 U.S. 913 (2013).

[4] *See, e.g.*, *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).

connection with a patent litigation settlement, to postpone efforts to market a generic version of the patented drug, the agreement is subject to antitrust scrutiny if the settlement includes a "large" and "unjustified" payment from the brand-name drug company to the generic company. *Id.* at 158.[5] But the Court rejected the FTC's position that "reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a 'quick look' approach rather than applying a 'rule of reason.'" *Id.* at 158-59. It explained that "the likelihood of reverse payment bringing about anticompetitive effects" depends on a wide variety of "complexities" and thus that "the FTC must prove its case as in other rule-of-reason cases." *Id.* at 159.

Under the rule of reason, "the plaintiff has the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market." *Ohio v. American Express Co.*, 138 S. Ct. 2274, 2284 (2018). The decision below must be reversed because the FTC failed to make that initial showing. Indeed, the FTC did not even attempt to show that consumers

[5] The Court focused its attention on settlements in which an alleged infringer with no claims for damages "walks away with money," *id*. at 152; it did not directly address settlements (as here) in which the defendant benefitted from the settlement but did not receive cash. The Court said that "cash" payments are highly unusual and may suggest an anticompetitive intent; it said that such payments to an alleged infringer that owns no patents of its own are "virtually unheard of outside of pharmaceuticals." *Id.* at 155.

were harmed. Rather, the FTC held that it could meet its evidentiary burden merely by demonstrating that the settlement agreement reduced *the risk* of competition, regardless whether competition was actually likely to increase in the absence of a settlement. That holding is inconsistent with *Actavis*'s rule-of-reason mandate; the FTC is simply attempting to reintroduce its rejected "quick look" approach under a new name.

The FTC also erred in failing to consider the numerous procompetitive features of the settlement agreement identified by Impax. The FTC conceded that the settlement had numerous procompetitive features—*e.g.*, the patent licenses that gave consumers access to a generic drug they would not have had in the absence of the licenses. The FTC contended that those features were irrelevant to its antitrust analysis because they supposedly were not directly linked to the two challenged settlement provisions—the No-AG Agreement and the Endo Credit. That contention is nonsensical. When parties agree to settle a lawsuit following negotiations, they do so in reliance on all features of the settlement agreement. The FTC has no basis for concluding that the settlement features to which it objects would have remained in place in the absence of the features that (the FTC concedes) promoted competition.

Moreover, the No-AG Agreement simply is not the sort of settlement

provision *Actavis* had in mind when it authorized antitrust scrutiny of "large" and "unjustified" payments to an alleged infringer. A No-AG Agreement is not a cash transaction; it is a patent holder's grant of an exclusive license to market a generic form of its patented product. There is nothing "unjustified" about exclusive licenses; they are expressly authorized by federal patent law. *See* 35 U.S.C. § 261. The grant of an exclusive license, an action whose effect is to restrict competition as compared to a non-exclusive license, has long been upheld by the Supreme Court as an integral part of a patent holder's right to utilize its patent so as to maximize profits.

The likely result of the FTC's approach: settlements of drug patent litigation will become exceedingly difficult. That result is inconsistent with *Actavis*, which recognized the pro-competitive desirability of such settlements and sought to preserve the ability of drug-patent litigants to settle their disputes.

ARGUMENT

I. *ACTAVIS* REQUIRES COURTS REVIEWING PATENT-LITIGATION SETTLEMENTS TO BALANCE THE GOALS OF PATENT LAW AND ANTITRUST LAW

A. *Actavis* Rejected The FTC's Claim That "Reverse Payment" Settlements Are Presumptively Anticompetitive

In *Actavis*, the Supreme Court addressed an FTC antitrust challenge to a patent-litigation settlement under which the patent holder, Solvay Pharmaceuticals, allegedly had agreed to make hundreds of millions of dollars in cash payments to several generic drug companies in return for those companies' agreeing not to market generic versions of the patented drug for another nine years. The drug companies argued that the settlement should be immune from antitrust scrutiny because the settlement was within the scope of the patent; *i.e.*, the patent at issue was not scheduled to expire until 2021, while the agreement permitted the generic companies to begin marketing in August 2015—65 months sooner. The FTC argued, on the other hand, that the "large and unjustified" cash payments from Solvay indicated that Solvay was paying potential competitors not to enter the market, and therefore that the agreement should be *presumed* to constitute an illegal conspiracy in restraint of trade, subject to the defendants' right to attempt to demonstrate that the agreement actually promoted competition.

The Supreme Court rejected both arguments and instead adopted a

compromise position that attempted to balance the competing demands of antitrust law and patent law. It concluded that litigation settlements in which the brand-name company transfers something of value to the generic company can "sometimes" be subject to antitrust scrutiny and can "sometimes" violate the antitrust laws. *Actavis*, 570 U.S. at 141. The Court repeatedly stated that courts hearing antitrust challenges to patent settlement agreements must seek to "balance" the often-conflicting principles of antitrust and patent law. *See, e.g., id.* at 148 (describing decision in *United States v. Line Material Co.*, 333 U.S. 287 (1948), as an effort to "strike [a] balance" between "the lawful restraint of trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act."); *ibid* (stating that "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust immunity—that is conferred by a patent."). The Court held that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects" and thus subject a patent settlement to antitrust scrutiny—particularly when "parties may well find ways to settle patent disputes without use of reverse payments." *Id.* at 158.[6]

[6] The Court said that while "large and unexplained" *cash* payments are subject to antitrust scrutiny, antitrust immunity is granted to patent settlements in which a transfer of value to the alleged infringer takes other forms. For example,

The Supreme Court also rejected the FTC's assertion that reverse-payment settlements are "presumptively unlawful" and that "courts reviewing such agreements should proceed via a 'quick look' approach, rather than applying a 'rule of reason.'" *Id.* at 158-59. The Court explained that "abandonment of the 'rule of reason' in favor of presumptive rules (or a 'quick look' approach) is appropriate only where an observer with even a rudimentary understanding of economics would conclude that the arrangements in question would have an anticompetitive effect on customers and markets." *Id.* at 159 (citation omitted).

B. The Rule-of-Reason Analysis Mandated By *Actavis* Requires Reviewing Courts To Examine All Relevant Factors To Determine Whether an Agreement Harms Competition

Actavis explained that a rule-of-reason analysis was required because "the likelihood of a reverse payment bringing about anticompetitive effects" depended on a large number of factors, including the nature of the industry in question. 570 U.S. at 159. The Court declined to dictate "the structuring of the present rule-of-reason antitrust litigation," leaving that task to lower courts in the first instance.

---

the Court held that no antitrust scrutiny is warranted if the generic company drops its patent invalidity claim in return for a license to market its product in advance of the patent's expiration—even if, as will often be the case, the early-entry license is worth many millions of dollars to the generic company. *Ibid.* Nor is scrutiny warranted if the patent holder "pays" the alleged infringer by settling damage claims for considerably less than originally sought in a lawsuit, no matter how likely the patent holder might have been to prevail on those claims. *Id.* at 151-52.

Id. at 160. But it made clear it was requiring the FTC to "prove its case *as in other rule-of-reason cases*." *Id.* at 159 (emphasis added).

The Supreme Court has prescribed a three-step, burden-shifting framework for conducting a rule-of-reason analysis:

> Under this framework, the plaintiff has the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market. If the plaintiff carries its burden, then the burden shifts to the defendant to show a procompetitive rationale for the restraint. If the defendant makes this showing, then the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means.

American Express, 138 S. Ct. at 2284 (citations omitted). Thus, the FTC bears the initial burden of demonstrating both that Impax's conduct had "a substantial anticompetitive effect" and that consumers were harmed.

The Court has repeatedly cautioned against applying presumptions regarding anticompetitive effects, limiting them to cases where sufficient experience has shown that the challenged conduct "always or almost always tends to restrict competition and decrease output." *Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284, 289-90 (1985). "[T]he plausibility of competing claims about the effects of the [conduct at issue] rules out the indulgently abbreviated review." *Calif. Dental Ass'n v. FTC*, 526 U.S. 756, 778

(1999). Under the rule of reason, "the accepted standard for testing whether a practice restrains trade in violation of" the antitrust laws, "the factfinder weighs *all* the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition." *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877, 885 (2007) (citation omitted) (emphasis added).

II. THE FTC IMPOSED ANTITRUST LIABILITY WITHOUT CONDUCTING THE RULE-OF-REASON ANALYSIS REQUIRED BY *ACTAVIS*

A. The FTC Failed To Show That The Endo-Impax Settlement Harmed Competition

After conducting a trial, the ALJ dismissed the complaint, concluding that the evidence at trial failed to prove that the settlement caused any anticompetitive harm. In particular, he found it "unlikely" that generic competition would have begun before January 2013 (the date that Impax began marketing) even if the parties had not entered into the settlement agreement. He noted that in the absence of a settlement, the patent-infringement litigation (including review by the Federal Circuit) probably would not have concluded by January 2013.[7] Thus, the

[7] This Court is well-positioned to judge for itself the unlikelihood that between June 2010 and January 1, 2013, all of the following would have occurred: (1) the trial court conducts a trial; (2) the trier of fact issues a verdict; (3) the parties file post-trial motions; (4) the trial court rules on those motions: (5) the losing party appeals; (6) the parties file appellate briefs; (7) the appeals court hears

marketing of a generic form of Opana ER could have begun earlier than the date specified in the settlement agreement only if Impax: (1) declined to settle; and (2) began marketing "at risk" while the litigation continued. That is, Impax would have had to assume the risk of a bankrupting damages award if the courts held that Endo's patent was valid and infringed—a risk that very few generic drug companies are willing to assume. The ALJ determined, based on the evidence at trial, that Impax would not have launched "at risk"—and thus that the settlement agreement did not have a substantial anticompetitive effect that harmed consumers.

In reversing the ALJ, the Commission did not directly challenge the ALJ's factual findings. Rather, it modified the evidentiary burden normally applicable in a rule-of-reason case so as to relieve itself of the burden of demonstrating that the settlement agreement was likely to cause actual harm to consumers. Under what amounted to a "quick look" analysis, the Commission held that anticompetitive harm can be established by demonstrating that an agreement eliminates "the risk of competition"; the plaintiff need not prove that generic competition "would actually or probably have occurred earlier" but for the challenged agreement. Comm. Op. at 23. Because it found a "plausible risk" that Impax would have launched "at

---

oral argument; and (8) the appeals court issues a written decision and rules on any rehearing petitions.

risk" before January 2013 but for the settlement agreement (even though it did not dispute the ALJ's finding that an at-risk launch was unlikely), the Commission held that Complaint Counsel met its burden of proving a substantial anticompetitive effect that harms consumers in the relevant market. *Id.* at 24.

The FTC's highly relaxed evidentiary standard finds no support in rule-of-reason case law.[8] That case law requires proof of likelihood of harm by a preponderance of the evidence, not a mere "risk" of harm without regard to the likelihood of occurrence. *See, e.g.., In re Nexium Antitrust Litig.*, 842 F.3d 34, 63 (1st Cir. 2016) (plaintiff failed to demonstrate anticompetitive harm by alleging possibility that generic drug company would launch at risk; the plaintiff cannot demonstrate causation in the absence of evidence of patent invalidity because "a valid patent independently precludes competition apart from any agreement and an 'at risk' launch is unlawful absent a later finding of patent invalidity or non-infringement.") (citation omitted). Under the FTC's standard, it should prevail even if the likelihood of an at-risk launch was no more than 1 in 20.

The FTC seeks to justify its reduced evidentiary burden in patent-settlement

---

[8] On review of FTC decisions, this Court reviews issues of law *de novo*. Although courts afford some degree of deference to FTC factual findings, the courts examine the Commission's factual findings "more closely when they differ from those of the ALJ." *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1062 (11th Cir. 2005) (collecting cases).

cases by pointing to language in *Actavis* that large and unexplained reverse payments "likely seek to prevent the risk of competition." *Id.* at 23 (quoting *Actavis*, 570 U.S. at 157). But the FTC has wrenched that language out of context. The Supreme Court majority was explaining why antitrust scrutiny should apply to such payments (in response to three dissenting justices who argued against *any* antitrust scrutiny of restraints that fall within the scope of the patent), not establishing a new and more plaintiff-friendly standard for meeting evidentiary burdens in rule-of-reason cases. Indeed, the five-justice majority went on to emphasize that it was *not* instructing lower courts on how to conduct their rule-of-reason analysis on remand. *Actavis*, 570 U.S. at 160. And it expressly held that "the FTC must prove its case *as in other rule-of-reason cases*." *Id.* at 159 (emphasis added).

Nor did the No-AG Agreement reduce competition after January 2013. Indeed, as the FTC recognized, Endo likely never intended to market an "authorized generic" version of Opana ER; rather, its plan all along was to introduce a reformulated version of Opana ER, to cease marketing "old" Opana ER, and to convince consumers to purchase the reformulated version instead. Marketing a generic version of the first drug would have undermined that strategy.

In sum, the judgment below should be reversed because the FTC failed to

prove that the Endo-Impax settlement caused any anticompetitive harm.

B. The FTC Erred By Refusing To Consider The Procompetitive Benefits Of The Endo-Impax Settlement

After finding anticompetitive harm based on an erroneous evidentiary standard, the FTC compounded its error by refusing to consider the numerous procompetitive benefits of the settlement agreement identified by Impax. The FTC did not dispute the existence of those benefits; rather, it held that those benefits were irrelevant to the rule-of-reason analysis. The FTC stated that it challenged two specific provisions of the agreement—the No-AG Agreement and the Endo Credit—and that Impax bore the burden of demonstrating procompetitive benefits arising directly from those provisions, not from the agreement as a whole. FTC Op. at 32 (stating that "Impax does not make any argument that the No-AG Commitment or Endo Credit ... have *themselves* protected Impax from the threat of patent litigation or that it needed to accept these payments in order to enjoy the procompetitive benefits of the patent license"). Not surprisingly, the Commission cited no federal-court case law in support of its novel interpretation of Impax's evidentiary burden under the rule of reason.

In examining patent-litigation agreements for potential antitrust infractions, the Supreme Court has routinely examined the *entire agreement*'s impact on

competition, not simply the impact of a single challenged provision. For example, *Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163 (1931), involved an antitrust challenge to agreements among holders of competing patents not to sue one another and to pool fixed-rate royalties earned on their patents. The Court subjected the agreements to a rule-of-reason analysis, holding that

> the primary defendants own competing processes for manufacturing an unpatented product which is sold in interstate commerce; and agreements concerning such processes are likely to engender the evils to which the Sherman Act was directed. ... We must, therefore, examine the evidence to ascertain the operation and effect of the challenged contracts.

Id. at 175. But after examining the agreements *as a whole*, Justice Brandeis (writing for a unanimous Court) found no antitrust violation because "[n]o monopoly, or restriction on competition, in the business of licensing patented cracking processes resulted from the execution of these agreements." *Ibid*. The Court did not separately examine individual provisions in the agreements (for example, the provision mandating the pooling of fixed royalties) to determine whether those provisions were designed to eliminate a "risk of competition."

Nothing in *Actavis* suggests that the Court intended to abandon the focus-on-the-entire-agreement rule-of-reason analysis adopted in *Standard Oil*. Indeed, *Actavis* favorably cited *Standard Oil* as an example of the Court properly "accommodat[ing] patent and antitrust policies." *Actavis*, 570 U.S. at 151.

The FTC's refusal to consider procompetitive aspects of the Endo-Impax agreement makes little sense as a matter of logic. The parties attempted to negotiate a settlement over the course of several years. Impax repeatedly sought a license to market generic Opana ER before 2013, and Endo repeatedly responded that it would never grant such a license. When they finally reached a settlement in June 2010, one can reasonably conclude that the parties did so in reliance on every negotiated provision. There is no reason to assume (as does the FTC) that the two provisions to which the FTC objects were negotiated totally independently of all other settlement provisions, including the provisions with procompetitive effects. Accordingly, those other provisions are highly relevant to the rule-of-reason analysis. *See North Texas Specialty Physicians v. FTC*, 528 F.3d 346, 369 (5th Cir. 2008) (procompetitive effects proffered by the defendant are relevant to the antitrust analysis if they are "connected to" the challenged conduct). When parties settle patent litigation, all settlement provisions that relate to use of the patent will, by definition, be "connected to" one another.

The numerous procompetitive benefits of the Endo-Impax settlement include the following:

* As recognized in *Actavis*, settlement of litigation is always procompetitive;

* Enforcing the patent laws is procompetitive because those laws encourage

the development of innovative drugs that save lives and save consumers billions of dollars each year;

* The settlement permitted generic competition (with its attendant lower prices) nearly a year before the expiration of the last of Endo's three patents that existed at the time of the settlement;

* The settlement licensed Impax to continue selling Opana ER even if Endo later acquired new patents for the drug. At the time of settlement, Impax suspected (correctly) that Endo would soon obtain additional patents, and those patents were held valid in litigation instigated by other generic manufacturers. Thus, in the absence of the settlement, *no* company would now be authorized to market a generic version of Opana ER, and the product would be unavailable to consumers.

In sum, even if the FTC had demonstrated anticompetitive harm, Impax met its evidentiary burden of demonstrating that the settlement agreement had procompetitive effects. The FTC erred in refusing to consider those effects as part of its rule-of-reason analysis.

C. The FTC Failed To Show That The Settlement's Procompetitive Benefits Could Have Been Achieved By A Means Less Harmful To Competition

The final stage in rule-of-reason burden-shifting requires the plaintiff to demonstrate that the procompetitive efficiencies identified by the plaintiff could reasonably be achieved through less anticompetitive means. The FTC's analysis of this third stage is also deficient.

The FTC's proffered less-anticompetitive alternative is a settlement: (1) that

does not include the No-AG Agreement and the Endo Credit; and (2) in which Endo grants Impax a license to market a generic product on some date before 2013. Comm. Op. 39-42. There is a major problem with that alternative: all the evidence at trial indicates that Endo repeatedly rejected Impax's requests for pre-2013 entry. Based on that evidence, the ALJ made a factual finding that earlier entry was not an available settlement alternative. No problem, says the FTC; its evidence suggests that no-payment settlements are feasible in at least some cases. So the FTC unilaterally reversed the burden of proof: it imposed on Impax the burden of proving that a no-payment settlement with an earlier entry date was "impossible." *Id.* at 41. The FTC cited no case law in support of its burden-shifting ruling, which openly defies repeated Supreme Court rulings that places the burden on the antitrust plaintiff to demonstrate a less anticompetitive alternative.

Moreover, the FTC's argument makes little sense on its own terms. Simply because the FTC's experience suggests that *some* pharmaceutical-patent litigation can be settled with no benefits flowing to the generic company says nothing about whether such a settlement was possible in this case. And the existence of no-payment settlements says nothing about whether the alleged infringer in those cases was able to negotiate an earlier entry date in return for forgoing other benefits.

III. *ACTAVIS* DID NOT AUTHORIZE ANTITRUST SCRUTINY FOR NON-CASH "NO-AG" AGREEMENTS OF THE SORT AT ISSUE HERE

The Court should reverse because, under a properly constructed rule-of-reason analysis, Impax's conduct did not violate the antitrust laws. But reversal is also required for a more fundamental reason: the antitrust laws are inapplicable to patent-litigation settlements of this sort. The No-AG Agreement is simply not the sort of settlement provision *Actavis* had in mind when it authorized antitrust scrutiny of "large" and "unjustified" payments to an alleged infringer.

As noted above, *Actavis* focused principally on reverse payments in the form of "cash." *See* 570 U.S. at 151, 152, 154, 158. One can reasonably assume that the Court was equally concerned about reverse payments taking the form of cash-equivalents—*e.g.*, stock, bonds, or gold bullion. But the Court explicitly *exempted* from antitrust scrutiny certain types of settlement benefits that flow to the infringer. *See* Note 6, *supra* (*e.g., Actavis* states that no antitrust scrutiny is warranted if the generic company drops its patent invalidity claim in return for a license to market its product in advance of the patent's expiration—even if, as will often be the case, the early-entry license is worth many millions of dollars to the generic company).

No-AG Agreements should be similarly exempt. *Actavis* exempted

"traditional" forms of settlement from antitrust scrutiny, 570 U.S. at 154, and the granting of licenses to alleged infringers is a very common feature of patent-infringement settlements. A No-AG Agreement is not a cash transaction; it is a patent holder's grant of an exclusive license to market a generic form of its patented product.

There is nothing "unjustified" about exclusive licenses; they are expressly authorized by federal patent law. *See* 35 U.S.C. § 261. The grant of an exclusive license, an action whose effect is to restrict competition as compared to a non-exclusive license, has long been upheld by the Supreme Court as an integral part of a patent holder's right to utilize its patent so as to maximize profits. *See, e.g., E. Bement & Sons v. Nat'l Harrow* Co., 186 U.S. 70, 82 (1902); *Kimble v. Marvel Entertainment, LLC*, 135 S. Ct. 2401, 2408, 2413 (2015) (broadly endorsing right of patentees to enter into licensing agreements while acknowledging, "The patent laws—unlike the Sherman Act—do not aim to maximize competition (to a large extent, the opposite).").

Actavis stated that "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust immunity—that is conferred by a patent." 576 U.S. at 148. Given the well-established pedigree of exclusive patent licenses, their inclusion in settlement

agreements easily qualifies as the type of "traditional settlement form" that *Actavis* deemed protected by patent law against antitrust scrutiny.

IV. THE FTC'S DECISION EFFECTIVELY OUTLAWS ANY SETTLEMENTS THAT PROVIDE SUBSTANTIAL BENEFIT FOR GENERIC DRUG MANUFACTURERS—THEREBY RENDERING SETTLEMENTS EXCEEDINGLY DIFFICULT

Actavis was decided based on the assumption that it would still be possible for litigants to settle pharmaceutical patent-infringement litigation in a manner that complies with the antitrust laws. Yet in light of the FTC's attempted expansion of what constitutes anticompetitive harm and its refusal to consider procompetitive effects of litigation settlements, it becomes exceedingly difficult for such litigation to settle.

The immense obstacles to settlement under the FTC's antitrust standards are the result of unique litigation dynamics created by the Hatch-Waxman Act, Pub. L. No. 98-417. Unlike the defendants in patent-infringement litigation that arises in other contexts, a generic drug company that initiates infringement litigation (by filing a "Paragraph IV certification" with FDA and thereby essentially forcing a brand-name company to file an infringement lawsuit) cannot be held liable for damages because it has not marketed any infringing products.[9] Of course, no

[9] In contrast, patent-infringement litigation arising in other contexts generally involves defendants who are alleged to be committing more concrete

litigant will agree to a settlement unless he perceives that it is advantageous. Accordingly, if a patentee cannot transfer anything of "considerable value" to a generic drug company without facing antitrust scrutiny, and if there only rarely are potential damages that a patentee could offer to forgo, there will be very few settlements of drug-patent litigation because a patentee will be unable to offer lawful settlement terms that a generic drug company would find sufficiently attractive to induce it to abandon the huge financial rewards that Hatch-Waxman offers to drug-patent challengers.

As Judge Posner has cogently observed:

> [A]ny settlement agreement can be characterized as involving "compensation" to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden "reverse payment," we shall have no more patent settlements.

Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003). The FTC's advocacy of antitrust criteria that would halt most future drug-patent litigation settlements cannot be squared with *Actavis*, given that decision's stated intent to create a standard under which settlements could still flourish. *Actavis* recognized "a general legal policy favoring the settlement of disputes" and

---

infringing acts. Such defendants face severe, potentially-bankrupting damages awards if the trial court sustains the infringement claim.

"the value of settlements." *Actavis*, 570 U.S. at 153.

There exist potential settlement terms that make it attractive for any party to settle litigation. Moreover, there are numerous disadvantages to any decision to continue with patent litigation—its outcome is always uncertain, and its costs (both in terms of dollars and the diversion of executives' attention away from competitive, money-making activities) are enormous. But settlements can occur only if patent litigants are given the tools required to reach a point at which both parties are satisfied with the settlement terms.

Arriving at terms that satisfy both parties will often be impossible if the only permissible settlement tool is an early-entry agreement along the lines endorsed by the FTC. For example, let us assume that the sole item being negotiated in settlement talks is the precise early-entry date and that parties are six month apart in terms of what each party considers an acceptable date. The virtual impossibility of bridging that gap and arriving at a settlement arises because for every day that the early-entry date moves backward in time, the potential losses to the brand-name company are many times larger than the potential gains to the generic company. Under those circumstances, even huge financial concessions by the brand-name company (concessions (as here) it is unlikely to be willing to make) will not achieve a settlement because they will confer very little financial benefit on the

generic. *See* Kevin McDonald, "Because I Said So: On the Competitive Rationale of *FTC v. Actavis*," 28 ANTITRUST 36, 37 (2013). If, as *Actavis* indicated, the means to settle patent litigation should be readily available, parties must be provided assurance that no antitrust liability is warranted if (on balance) the settlement is pro-competitive—even if the settlement can be characterized as one involving a "reverse payment." In the absence of that assurance, generic drug companies will have considerably fewer incentives to file Paragraph IV certifications in the first place, the precise opposite of the effect intended by Congress when it adopted the Hatch-Waxman Act.

CONCLUSION

The Court should reverse the FTC's decision.

Respectfully submitted,

/s/ Richard A. Samp
Richard A. Samp
Cory L. Andrews
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
Tel.: 202-588-0302
Fax: 202-588-0386
rsamp@wlf.org

Dated: October 10, 2019

CERTIFICATE OF SERVICE

I hereby certify that on October 10, 2019, I electronically filed the brief of *amicus curiae* Washington Legal Foundation with the Clerk of the Court of the U.S. Court of Appeals for the Fifth Circuit by 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 appellate CM/ECF system.

/s/ Richard A. Samp
Richard A. Samp

CERTIFICATE OF COMPLIANCE

I am an attorney for *amicus curiae* Washington Legal Foundation (WLF). Pursuant to Fed.R.App.P. 32(a)(7)©, I hereby certify that the foregoing brief of WLF is in 14-point, proportionately spaced Times New Roman type. According to the word processing system used to prepare this brief (WordPerfect X5), the word count of the brief is 6,393, not including the certificate of interested parties, table of contents, table of authorities, certificate of service, and this certificate of compliance.

/s/ Richard A. Samp
Richard A. Samp

Dated: October 10, 2019