

No. 05-273

IN THE
Supreme Court of the United States\

FEDERAL TRADE COMMISSION,
Petitioner,

v.

**SCHERING-PLOUGH CORPORATION AND
UPsher-SMITH LABORATORIES, INC.,**
Respondents.

**On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Eleventh Circuit**

BRIEF IN OPPOSITION

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**COUNTERSTATEMENT
OF QUESTIONS PRESENTED**

1. Whether the Court of Appeals' application of the "substantial evidence" standard warrants this Court's rare intervention, where the Court of Appeals correctly stated the standard to be applied, said it was applying that standard, and detailed its reasons for finding that, on a review of the whole record, the Commission's findings were not supported by substantial evidence, and where the factual question at issue is one in which the agency has no expertise.

2. Whether a settlement of patent litigation between a pharmaceutical patent-holder and an alleged generic infringer that enabled generic entry years before patent expiration is an unreasonable restraint of trade simply because the settlement included a payment to the alleged infringer, regardless of the merits of the patent infringement claims and without any proof that some "better" settlement would have been achieved without a payment.

CORPORATE DISCLOSURE STATEMENTS

Pursuant to Rule 29.6 of the Rules of the Supreme Court of the United States:

Respondent Schering-Plough Corporation hereby advises the Court that:

- (1) Schering-Plough Corporation has no parent corporation; and
- (2) No publicly held company owns 10% or more of the stock of Schering-Plough Corporation.

Respondent Upsher-Smith Laboratories, Inc. hereby advises the Court that:

- (1) Upsher-Smith Laboratories, Inc. has no parent corporation; and
- (2) No publicly held company owns 10% or more of the stock of Upsher-Smith Laboratories, Inc.

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STATEMENT OF THE CASE

1. Introduction

This petition for a writ of certiorari arises out of the Federal Trade Commission's program of challenging pharmaceutical patent-infringement litigation settlements entered into in the 1990s where 1) the settlement included a payment from the patent holder to the alleged infringer and 2) the alleged infringer agreed to stay off the market for some portion of the remaining life of the patent.

In this case, the Federal Trade Commission ("Commission") challenged the settlement of two different patent-infringement lawsuits brought by Schering-Plough Corp. ("Schering"): one against Upsher-Smith Laboratories, Inc. ("Upsher-Smith"), and one against ESI Lederle Inc. ("ESI"). In each settlement, the parties compromised on a market entry date, permitting the alleged infringer to enter the market long before patent expiration. Both the Commission's Administrative Law Judge ("ALJ") and the Court of Appeals found that the Commission's challenges lacked any merit. The Commission seeks a writ of certiorari to review the Court of Appeals' decision.

This case is an exceedingly unappealing candidate for review by this Court, for several reasons.

A. The Commission lost its challenge to the principal settlement involved in this matter—the Schering/Upsher-Smith settlement—because of the Commission's inability to prove as a factual matter that there was a net "payment." As part of that settlement, Schering paid Upsher-Smith \$60 million for rights to Niacor-SR, a cholesterol treatment drug that Upsher-Smith was developing, and several other Upsher-

Smith products. Niacor-SR was in no way involved in the patent suit. The Commission conceded that if the \$60 million payment was a *bona fide* fair-value payment for the rights to Niacor-SR and the other products, then its case failed. Both the Commission's ALJ, who presided over the ten-week trial, and the Court of Appeals ruled against the Commission on this threshold fair-value question. This was a pure fact issue, and it is not suitable for review by this Court.

Nor does the Commission's challenge to the settlement of the Schering/ESI suit even remotely warrant review by this Court. The Commission introduced very little evidence about the ESI settlement at trial, and acknowledged in its decision that, "as a matter of prosecutorial discretion, we might not have brought a stand alone case based on such relatively limited evidence." Pet. App. at 145a. The ESI settlement was the product of fifteen months of court-supervised mediation. The relatively small payment of \$15 million was agreed to at the urging of the United States Magistrate Judge who functioned as the mediator. The expert testimony showed that Schering had an extremely strong patent case, and that the compromise entry date agreed to in the settlement fairly reflected the strength of that case. And, as the Court of Appeals observed, "[t]he FTC did not rebut this testimony, but rather ignored it." Pet. App. at 27a.

B. The Commission's claim that the Court of Appeals *misapplied* the standard of review of administrative agency fact finding does not raise a cert-worthy issue. The Court of Appeals fully, faithfully and correctly articulated the applicable standard of review in accordance with this Court's pronouncements in *Universal Camera v. NLRB*, 340 U.S. 474 (1951). This Court does not generally review claims that a "properly stated rule of law" was misapplied. *See* SUP. CT. R. 10.

C. The Commission's petition greatly overstates the extent to which the Court of Appeals' antitrust analysis differs from its own. The Court of Appeals, the Commission, and the Department of Justice *all agree* that the payment of money as part of a patent settlement in which the alleged infringer agrees to stay off the market for a period of time is *not a per se* violation of the antitrust laws. This is so because the patent may confer a *lawful* right to exclude the would-be competitor from the market. Consequently, all agree that the antitrust analysis must include a comparison of the exclusionary effect of the settlement agreement with the legitimate exclusionary power of the patent. *See* Pet. at 9. The problem for the Commission is that the Court of Appeals found that the Commission did not make this comparison correctly. This finding does not raise a cert-worthy issue either.

Notably, the Commission joined the Department of Justice in urging the Court to deny certiorari in a similar pharmaceutical patent-litigation case just last term in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharmaceuticals, Inc. v. Kroger Co.*, No. 03-779 (Oct. 12, 2004). *See Brief of United States as Amicus Curiae Opposing the Petition in Cardizem/Andrx*, 2004 WL 1562075 (July 2004). In their opposition to certiorari in *Cardizem/Andrx*, the Commission and the Department of Justice urged that both the absence of a circuit split on the antitrust analysis and the recent amendments to the Hatch-Waxman Act in 2003 counseled against certiorari. This issue was not worthy of certiorari last term, and it remains unworthy of certiorari today.

D. The claim in the Commission's petition—a petition that is not joined by the Department of Justice—that the decision of the Court of Appeals will have a substantial

effect on consumers is suspect.¹ Patent settlements involving payments to the allegedly infringing generic company do not appear to be recurring. The Commission itself stated in a recent report that since 1999 “the Commission is aware of no final settlements of patent litigation in the pharmaceutical industry in which the brand paid the generic to agree not to market its product.”²

2. The Patent Infringement Settlements

Schering owns a duly-issued patent covering the sustained-release mechanism in a potassium chloride supplement called K-Dur. That patent is valid and in effect today. It expires on September 1, 2006. Pet. App. at 50a. Notably, the active ingredient in K-Dur, potassium chloride, is widely used and unpatentable. *Id.* at 2a. Indeed, even before marketing its generic version of K-Dur, Upsher-Smith and many other pharmaceutical companies produced and marketed potassium chloride supplements used to treat the same potassium deficiency as K-Dur. Pet. App. at 165a-175a.

The Upsher-Smith Settlement

In late 1995, Upsher-Smith sought FDA approval to market a generic version of K-Dur, and Schering sued Upsher-Smith for patent infringement. After a year and a half of litigation, the parties settled the patent infringement

¹ See 15 U.S.C. § 56(a)(3)(A) (2005) (requiring the Commission to consult with the Solicitor General before petitioning for certiorari).

² Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004—A Report by the Bureau of Competition* (Jan. 7, 2005), <www.ftc.gov/os/2005/01/050107medicareactrpt.pdf> [§ II.B].

suit in June 1997, just before trial. Pet. App. at 50a. Under the terms of the settlement, Upsher-Smith could market its generic product after September 1, 2001, but not before. Pet. App. at 194a. This compromise market entry date was five years before the date Schering's patent expires. *Because of this settlement*, Upsher-Smith's generic product has been on the market for over four years as of the date of this filing. If the parties had continued the litigation and Schering had prevailed, Upsher-Smith's product would have been excluded from the market until Schering's patent expires in September 2006. *See* Pet. App. at 20a.

As part of the settlement, Schering paid \$60 million for the license rights to Niacor-SR, a sustained-release niacin product that Upsher-Smith was developing, and a bundle of other products. Pet. App. at 195a. Niacor-SR, a product in no way involved in the patent case, was the most valuable of these products.

The ESI Settlement

In late 1995, ESI sought FDA approval for a generic version of K-Dur, and Schering sued ESI for patent infringement. Pet. App. at 249a. In the fall of 1996, at the urging of the trial judge, the parties agreed to engage in court-supervised mediation. Pet. App. at 250a. United States Magistrate Judge Thomas Rueter was appointed as mediator, and he supervised numerous mediation sessions over the course of fifteen months. *Id.* Finally, in December 1997, the parties agreed on a compromise market entry date that would permit ESI to market its generic product after December 31, 2003 but not before. Pet. App. at 7a, 254a-255a. ESI still would not settle without a payment from Schering.

A settlement in principle finally was reached on January 23, 1998 in a late-night mediation session in Judge Rueter's chambers. Pet. App. at 256a-257a. Judge Rueter

prevailed upon Schering to pay ESI \$5 million, which he characterized as “nothing more than legal fees.” Pet. App. at 7a. Next, Judge Rueter and Schering discussed a concept under which Schering would pay ESI up to \$10 million more, but only if ESI received FDA approval by a certain date. Pet. App. at 7a, 257a-258a. Schering agreed, believing that ESI would *not* get its drug approved,³ and that Schering would never have to pay the additional \$10 million. *Id.* Judge Rueter asked the parties to write up the settlement terms and sign them that night. Pet. App. at 258a. It is undisputed that Judge Rueter was present at the preparation and signing of that January 23, 1998 handwritten agreement, and was aware of all the terms, including the payments from Schering to ESI. Pet. App. at 7a.

3. The FTC Complaint and the Trial

In April 2001, the Commission filed an administrative complaint alleging that Schering’s two patent-litigation settlements restrained trade in violation of the antitrust laws.

The Upsher-Smith Settlement: the Fair-Value Issue

The ALJ appointed by the Commission presided over a ten-week trial that included dozens of witnesses and thousands of documents admitted into evidence. The central fact issue at trial was whether the Upsher-Smith settlement contained a net “payment” from Schering to Upsher-Smith, or whether Schering’s \$60 million payment was a *bona fide* fair-value payment for Niacor-SR and the rights to the other Upsher-Smith products. The Commission had conceded that if Schering’s \$60 million payment was fair value for all those

³ Schering had recently learned that the FDA had twice rejected ESI’s clinical studies, and ESI was just beginning to re-do them. Pet. App. at 253a-254a.

rights, the Upsher-Smith settlement was lawful. Pet. App. at 92a. (“Complaint Counsel have conceded that there is no liability in this matter if the licenses that Upsher granted to Schering were adequate consideration for the \$60 million payment from Schering to Upsher.”).

The Schering employees who had evaluated Niacor-SR testified and were cross-examined fully at trial. They were unaware of the patent litigation when they conducted their evaluation. Pet. App. at 22a, 191a, 319a. They were well qualified for the task. Pet. App. at 217a-219a, 319a. They had access to the results of Upsher-Smith’s pivotal clinical trials for Niacor-SR. Pet. App. at 221a. And they testified that, in their best business judgment, the rights to Niacor-SR were worth more than \$60 million. *See* Pet. App. at 227a-228a. Their testimony was supported by contemporaneous documents showing that they had projected Niacor-SR sales to exceed \$100 million per year starting in its third year on the market, bringing Schering a profit stream with a net present value of \$225-\$265 million. Pet. App. at 224a-225a, 227a, 319a-320a.

Their testimony was also powerfully corroborated by testimony that another team within Schering had earlier evaluated another similar sustained-release niacin product, and had developed written sales projections for that product that were closely comparable to the Niacor-SR sales projections. Pet. App. at 6a, 22a, 111a, 115a, 209a, 213a, 318a. In addition, Schering called an independent pharmaceutical licensing expert who testified that Schering could have paid as much as \$100 million for Niacor-SR (i.e., \$40 million more than Schering paid for Niacor-SR *and* the bundle of other product licenses) and still made a substantial return based on the expert’s “conservative” estimate of Niacor-SR’s projected economic value. Pet. App. at 227a-228a.

Schering also introduced the testimony of independent members of its Board of Directors. Those directors testified that the Board had been asked to evaluate the Niacor-SR license (along with the bundle of other product licenses) *as a stand-alone deal*, and to approve the licenses only if they were sufficiently valuable to Schering, separate and apart from the settlement agreement. Pet. App. at 197a-198a. The Board concluded that they were, based on Schering's internal evaluation described above, and approved the payment for the licenses. Pet. App. at 199a. The Board was not asked to approve the settlement.⁴

By contrast, the Commission, in its case in chief, presented no fact witnesses on the valuation issue. Instead, the Commission's trial counsel relied solely on the testimony of one expert witness with experience in valuing rights to pharmaceutical products. Pet. App. at 320a. That expert's testimony was so badly discredited on cross-examination, however, that neither the ALJ *nor the Commission* relied on it. *See* Pet. App. at 130a, 320a-321a. The Commission again affirmatively disclaims any reliance on that expert in its petition. Pet. at 27.

The Upsher-Smith Settlement: the Antitrust Issue

The Commission presented an economic expert who testified that, as a matter of theory, a settlement with a payment necessarily would deliver less competition than

⁴ The petition asserts that Schering's presentation to its Board of Directors "explained that the payments represented lost revenue for the period Upsher stayed off the market." Pet. at 28 n.26. In fact, the presentation to the Board specifically informed the Board that Schering told Upsher-Smith "that any such deal should stand on its own merit independent of the settlement." Pet. App. at 198a. Schering's Board members testified expressly that they understood they were to evaluate the Niacor-SR license (and the bundle of other licenses) as a stand-alone deal, and that they did so. Pet App. at 199a.

continued litigation. Pet. App. at 75a-77a. In response, Schering called its own expert economist who testified that the Commission's theory was wrong; and that in order to determine whether a particular settlement is anticompetitive it is necessary to evaluate the strength of the underlying patent case. Pet. App. at 87a-89a.

Schering then introduced the expert testimony of an experienced patent litigator who had evaluated the objective strength of Schering's positions in both the Upsher-Smith and ESI patent cases. He testified that Schering's patent was valid and infringed; that Schering likely would have won both cases; and that the settlements reasonably reflected the strength of Schering's position in each case. *See* Pet. App. at 27a.⁵

The ESI Settlement

With regard to the ESI settlement, the Commission introduced almost no proof at all. The Commission called no fact witnesses to testify at trial about the ESI settlement, and the Commission's economic expert testified about the ESI case for only about fifteen minutes. Pet. App. at 261a. In its case, Schering presented expert testimony by an experienced patent litigator that Schering's patent case against ESI was very strong, and that the settlement's January 1, 2004 entry date reasonably reflected Schering's strong case. *See* Pet. App. at 27a. The Commission's trial counsel hired its own patent-litigator expert to review the record in the ESI patent case, *but he never testified about it.*

⁵ The Commission called its own patent-litigator expert. He testified about the Upsher-Smith patent case, but not about the ESI case. The Commission's opinion never mentions either Schering's or its own expert's testimony regarding the patent case.

4. The Decisions

The ALJ found that Schering's witnesses on the valuation issue were "credible and un rebutted," and that the Commission's trial counsel had failed to satisfy its conceded burden of proving that Schering's \$60 million payment to Upsher-Smith was not a *bona fide*, fair-value payment for Niacor-SR (and the bundle of other products). Pet. App. at 316a-318a, 325a-326a, 340a. The ALJ also found that the Commission had failed to prove that either settlement yielded less competition than litigation or any available alternative settlement would have yielded. Pet. App. at 310a-311a. Accordingly, the ALJ dismissed the complaint in its entirety.

The Commission reversed. It found that the rights to Niacor-SR and other products were not "adequate" consideration for Schering's \$60 million payment, thus refusing to credit the testimony of Schering's and Upsher-Smith's employees and Schering's expert witness on valuation. Pet. App. at 55a.⁶ The Commission declined to credit this testimony even though (1) the Commission's staff had presented no fact witness to testify about the value of Niacor-SR; (2) the Commission had no expert testimony on the valuation issue to rely on; (3) the Commission did not observe any of the witnesses whose testimony it refused to believe; and (4) the Commission has no expertise of its own in valuing pharmaceutical products.⁷

⁶ The petition similarly disregards evidence that even the Commission's opinion acknowledged. For example, the petition baldly states that Upsher-Smith demanded a payment "to stay off the market," Pet. at 7, but even the Commission's opinion admits that from the outset Upsher-Smith sought a payment *and* early entry. Pet. App. at 97a.

⁷ The author of the Commission's opinion has conceded that the Commission has no expertise in valuing licensing opportunities in the pharmaceutical industry: "[H]ow do we know whether the intellectual property acquired by the pioneer is genuinely worth the money paid or

Having overruled its own ALJ and concluded that there was a net “payment” from Schering to Upsher-Smith (i.e., a payment in excess of fair market value for Niacor-SR and the other Upsher-Smith licenses), the Commission turned to its antitrust analysis. First, it concluded that the “payments” did not render the settlements either *per se* violations of the antitrust laws, or “inherently suspect.” Pet. App. at 80a. The Commission explicitly endorsed a rule of reason analysis. Pet. App. at 54a-55a. It did so because Schering has a patent, giving it the lawful right to exclude competitors from the market. Therefore, the Commission undertook to compare the exclusionary impact of the agreements with the lawful exclusionary effect of the patent. Pet. at 9.

However, the Commission explicitly declined directly to evaluate the exclusionary power of Schering’s patent. Instead, the Commission concluded as a matter of theory that a payment would likely render the settlement agreement anticompetitive. Pet. App. at 76a-77a. The Commission treated the “payments” as shifting the burden to Schering and Upsher-Smith to prove that the settlements were not anticompetitive. Pet. App. at 90a-91a. But in its opinion, the Commission never considered, or even mentioned, the evidence placed in the record by Schering that presumably would have addressed any burden Schering might have had; namely, the proof comparing the strength of Schering’s patent case with the compromise entry dates in the settlement agreements.

whether the whole side deal is simply a roundabout way of making otherwise suspect reverse payments? The difficulty here, of course, is similar to the difficulty the Commission would face in evaluating the merits of a patent dispute, a subject discussed above: the fact that we are not very well equipped to place a value on intellectual property.” Commissioner Thomas B. Leary, “Antitrust Issues in the Settlement of Pharmaceutical Disputes, Part II,” May 17, 2001 at 6.

A panel of the Court of Appeals for the Eleventh Circuit unanimously set aside the Commission's opinion and vacated its Order. After a thorough review of the whole record under the "substantial evidence" standard, the Court of Appeals found that the Commission's finding of fact on the valuation issue was not supported by substantial evidence. The Court of Appeals also faulted the Commission's almost exclusive reliance on the purported existence of a payment as the basis for its conclusion that the patent-litigation settlements were anticompetitive. Instead, the Court of Appeals held that a factual inquiry into the exclusionary power of Schering's patent was required. Because the Commission failed to engage in such an inquiry, the Court of Appeals set aside the Commission's Opinion. Pet. App. at 34a-35a.

REASONS FOR DENYING THE WRIT

The petition should be denied for the following reasons.

- 1. The Commission Lost the Schering/Upsher-Smith Case on a Dispositive Threshold Issue of Fact.**

The great majority of the trial of this case was devoted to the question whether the \$60 million payment from Schering to Upsher-Smith was fair value for the rights to Niacor-SR and the other products. The Commission conceded in its opinion that its entire legal analysis hinged on this "critical valuation issue." Pet. App. at 92a. And the Commission's staff had conceded at trial that "there is no liability in this matter if the licenses that Upsher granted to Schering were adequate consideration for the \$60 million payment from Schering to Upsher." Pet. App. at 92a.

After a full trial on the fair value issue, the Commission's ALJ determined that the Respondents' "fact testimony . . . was un rebutted and credible in establishing that the licensing agreement was a bona fide arms-length transaction." Pet. App. at 317a-318a. And the Court of Appeals found that the Commission's contrary finding of fact on its *de novo* review of the record was unsupported by any substantial evidence.

The finding by the Court of Appeals is on a pure issue of fact with significance to this case and this case only. It disposes of the Commission's challenge to the Schering/Upsher-Smith settlement, and there is no reason to review it.

2. The Schering/ESI Settlement Does Not Warrant Review.

The Commission's half-hearted challenge to the Schering/ESI settlement also does not warrant review. The Commission itself conceded in its own opinion that, with respect to the ESI settlement, "as a matter of prosecutorial discretion, we might not have brought a stand alone case based on such relatively limited evidence." Pet. App. at 145a.

The evidence that *was* introduced showed that the settlement resulted from fifteen months of court-supervised mediation. The small payment was needed to break an impasse in the negotiations, and it was urged on the parties by the U.S. Magistrate Judge as a way of resolving the case. The resulting settlement was fair to consumers as well as to the parties: the un rebutted evidence showed that the compromise entry date fairly reflected the strength of Schering's patent case. Under a rule of reason analysis—which the Commission says is the appropriate analysis—the

ESI settlement presents only a fact-specific case correctly resolved by the Court of Appeals.

3. The Court of Appeals Did Not Misapply the Standard of Review of Agency Fact Finding; and in Any Event the Misapplication of a “Properly Stated Rule of Law” Does Not Warrant Certiorari.

It is undisputed that the Court of Appeals properly stated the standard that courts of appeals must follow when reviewing agency fact finding. Thus, the Court of Appeals explained that:

The FTC’s findings of fact, “if supported by evidence, shall be conclusive.” *This standard applies regardless whether the FTC agrees with the ALJ.* (emphasis added).

The Court of Appeals continued:

We are mindful that we do not review the record to draw our own conclusions that we then measure against an administrative agency; rather, we must consider all of the evidence when drawing our conclusions about the reasonableness of an agency’s findings of fact. The evidence must be such that it would be possible for a reviewing court to reach the same conclusions that the administrative fact-finder did. If this condition is not met, then the substantial evidence test requires that the administrative decision be reversed.

Pet. App. at 10a-12a (internal citations omitted) (emphasis added).

The Commission makes no claim that the Court of Appeals misstated the standard of review. Rather, the Commission complains that the Court of Appeals attached some weight to the ALJ's credibility determinations. But that is exactly what this Court has held a reviewing court of appeals ought to do. Thus, in *Universal Camera v. NLRB*, 340 U.S. 474, 496 (1950), this Court stated:

[E]vidence supporting a conclusion [by the agency] may be less substantial when an impartial, experienced examiner who has *observed the witnesses and lived with the case* has drawn conclusions different from the [agency's] than when he has reached the same conclusion. (emphasis added).

And this Court continued,

The significance of [the examiner's] report, of course, depends largely on the *importance of credibility* in the particular case.

Universal Camera, 340 U.S. at 496 (emphasis added).⁸

Credibility was very important in this case. If Respondents' witnesses on the valuation issue—who testified fully at trial—were believed, the Commission's challenge to the Upsher-Smith settlement would fail.

⁸ The Commission's petition omits any reference to these parts of the *Universal Camera* opinion.

In its opinion, the Court of Appeals correctly stated the applicable standard of review. The Commission is thus left to complain—with little or no basis—only that the Court of Appeals *misapplied* that standard in this particular case. Respondents strongly disagree. However, in either event, this Court’s rules state that “a petition for certiorari is rarely granted when the asserted error consists of . . . misapplication of a properly stated rule of law.” SUP. CT. R. 10.⁹ This case is not one of those rare instances.

4. The Petition Overstates the Difference in Antitrust Analysis Between the Court of Appeals and the Commission.

The Commission overstates the extent to which the Court of Appeals’ antitrust analysis differs from its own. There is indeed much common ground.

An agreement determining a potential competitor’s entry into the market would be illegal *per se* if there were no patent. Both the Commission and the Court of Appeals agree about this. As the Commission explains: “The starting point for this case, as the court of appeals recognized, is that an agreement between competitors in which one pays the other to stay out of a market is ‘clearly anticompetitive,’ and hence unlawful *unless excused by the lawful exercise of patent rights.*” See Pet. at 13 (emphasis added). Similarly, the Court of Appeals explained that, if not for a patent, an

⁹ The Commission also complains that the Court of Appeals did not afford sufficient “deference” to the Commission’s expertise. Pet. at 29. But the critical fact issue in this case was the valuation of Niacor-SR, a pharmaceutical product. And as noted above, the Commission has no expertise in valuing pharmaceutical products. This proposition was acknowledged by the author of the Commission’s opinion, Commissioner Thomas B. Leary. See *supra* n.7.

agreement to allocate markets is “clearly anticompetitive.” Pet. App. at 13a.

The Commission and the Court of Appeals also agree that a payment—if proved—would not make these settlements subject to *per se* treatment, because of the existence of Schering’s patent. Pet. at 9. Thus, the Commission explains that it “determined that *per se* condemnation was not warranted, given the complexities of the patent litigation context in which the agreements arose.” *Id.* Similarly, the Court of Appeals explained: “In the context of patent litigation . . . the anticompetitive effect [of the agreement] may be no more broad than the patent’s own exclusionary power.” Pet. App. at 13a.

Finally, the Commission and the Court of Appeals agree that the appropriate antitrust analysis must involve a comparison of the exclusionary effect of the settlement with the lawful exclusionary power of Schering’s patent. As the Commission states, it believes it should conduct precisely such an analysis in this case, comparing “the exclusionary impact of the agreements in relation to that of the patent itself.” Pet. at 9. Similarly, the Court of Appeals explained that it was comparing “(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreement exceeds the scope; and (3) the resulting anticompetitive effects.” Pet. App. at 17a.¹⁰

¹⁰ The Commission describes the Court of Appeals’ statement that the court would apply neither traditional rule of reason nor *per se* analysis as a “startling premise,” Pet. at 11, and suggests that this is a sharp point of difference between the Commission’s approach and the Court of Appeals’. It is not. If anything, it is a difference in label, not analysis. The Court of Appeals’ point is that a traditional rule of reason analysis would examine solely the market effects of generic entry. That, however, is not the pertinent inquiry here. Everyone already knows that generic entry will bring lower prices. *See, e.g., Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003), *cert. denied*

Officials of the Antitrust Division of the U.S. Department of Justice have similarly rejected *per se* treatment for patent settlement payments because of the importance of the exclusionary power of patents. For example, in 2003, the then-Acting Assistant Attorney General for the Antitrust Division explained:

[A]ssessing the competitive significance of settlements often depends on an evaluation of the underlying strength of patent rights. If a patent is valid and infringed, then any competitive entry allowed by a settlement is up to the patent holder. If a patent is invalid or not infringed, then there should be no impediment to competitive entry whatsoever. The problem is that we have no way definitively to know which situation applies *without evaluating the underlying IP rights*, a task that is outside our core expertise as antitrust enforcers.¹¹

Then-Assistant Attorney General Pate reiterated this view in a recent speech. Noting the fact that the Court of Appeals *in this case* had ruled just “months ago,” Mr. Pate explained that antitrust liability is difficult to assess:

sub nom. Walgreen Co. v. Abbott Labs., No. 03-1178 (Oct. 12, 2004). The important inquiry here, according to the Court of Appeals, is whether the settlement agreement’s exclusionary effects exceed the legitimate exclusionary power of the patent. *See* Pet. App. at 16a; *Valley Drug*, at 344 F.2d 1294, 1311 n.27. The Commission accepts this as the relevant inquiry, stating that it “considered the exclusionary impact of the agreements in relation to that of the patent itself.” Pet. at 9. The Commission calls this inquiry a rule of reason inquiry, and the Court of Appeals does not. But it is the same inquiry.

¹¹ R. Hewitt Pate, Acting Assistant Attorney General, Antitrust Division, “*Antitrust and Intellectual Property*,” January 24, 2003 (emphasis added).

unless one knows whether the patent owner could have won an infringement claim. If the patent is valid, all entry before its expiration is a competitive “gift,” but if it is invalid, any delay in entry due to threatened patent enforcement is a competitive harm.¹²

District courts have expressed similar views. *See, e.g., Asahi Glass Co. Ltd. v. Pentech Pharmaceuticals, Inc.*, 289 F.Supp.2d 986, 994 (N.D. Ill. 2003) (Posner, J. sitting by designation) (doubting correctness of theory that payments render settlements anticompetitive regardless of patent merits because “if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent”); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514, 540 (E.D.N.Y. 2005) (settlement with payments not anticompetitive if within scope of patent claims).

Thus, the Commission, the Court of Appeals and the Department of Justice agree on the basic framework for analyzing settlements of patent infringement suits that include payments. The problem in this case, however, arose when the Commission *implemented* that framework.

In its opinion in this case, the Commission relied solely on the purported fact of a payment, finding that the payment meant, as a matter of theory, that the settlement was anticompetitive. Pet. App. at 76a-77a (“[I]t is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.”).

¹² R. Hewitt Pate, Assistant Attorney General, Antitrust Division, “*Competition and Intellectual Property in the U.S.: Licensing Freedom and the Limits of Antitrust*,” June 3, 2005.

The Commission then shifted the burden to Schering and Upsher-Smith to prove that the settlements were not anticompetitive. Pet. App. at 90a-91a. But the Commission ignored the proof Respondents had placed in the record to meet that burden: proof comparing the strength of Schering's patent case to the compromise entry dates in the settlement agreements.

The problem, thus, was that the Commission's implementation of its announced rule of reason framework turned out in practice to be no different from the *per se* rule it purported to reject.

5. The Commission's Statements About the Real World Dangers of Patent Settlement Are Suspect.

The Commission does not assert that there is any conflict among the circuits on the issues presented by this case. The Commission states that the Sixth Circuit's decision in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharms., Inc. v. Kroger Co.*, No. 03-799 (October 12, 2004), represents a "different approach" from that of the Eleventh Circuit in this case, but the Commission expressly disagrees with the Sixth Circuit's approach. Pet. at 23. Moreover, as the Commission told this Court a year ago, there is no "square conflict" between the circuits because of dispositive factual differences between the *Cardizem/Andrx* case and the Eleventh Circuit's decision in a similar pharmaceutical patent case, *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).¹³ *Brief of United States as Amicus Curiae Opposing the Petition in Cardizem/Andrx*, 2004 WL

¹³ The Court of Appeals' decision in this case expressly follows its prior *Valley Drug* decision. Pet. App. at 12a-17a.

1562075 (July 2004), at *11. Nothing has changed in that regard.

Furthermore, the Commission and the Solicitor General urged in their opposition to certiorari last term in *Cardizem/Andrx* that “[s]ettlements with reverse payments in an amount far exceeding litigation costs . . . appear to be rare outside the Hatch-Waxman context;” and that Congress’ 2003 Amendments to the Hatch-Waxman Act reduced the risk of anticompetitive settlements in the pharmaceutical arena. *See* U.S. Br., 2004 WL 1562075, at *15-*19. Accordingly, the Commission urged that certiorari was not warranted.

The Commission and the Solicitor General also noted that Congress’ 2003 amendments to Hatch-Waxman requiring mandatory review of all pharmaceutical patent-litigation settlements by the antitrust agencies counseled against certiorari in *Cardizem/Andrx*. The Commission’s first annual report on this mandatory review of such settlements, published in January 2005, substantiates this view. Thus, the Commission states: “legitimate patent settlements continue to occur without hindrance from the Commission decision, using means other than payments by the patent holders to reach a compromise.” Pet. at 22. Indeed, the Commission’s January 2005 report goes further in stating that settlements involving payments to the alleged infringer are not a pressing issue:

The structure of brand-generic settlements has changed over time in that *settlements after 1999 do not appear to include a payment from the brand to the generic in exchange for the generic’s agreement not to market its product. . . .* In 1999, it was reported that the Federal Trade Commission was investigating agreements involving such

payments. *Since that time, the Commission is aware of no final settlements of patent litigation in the pharmaceutical industry in which the brand paid the generic to agree not to market its product.*¹⁴

It may well be that the Commission's actions in this case and others have had an *in terrorem* effect on subsequent settlements.

Despite its January 2005 report, the Commission speculates that future settlements may nonetheless raise antitrust concerns, and absent this Court's review, "any substantial pharmaceutical company involved in a further case of this sort could presumably obtain review in the Eleventh Circuit to take advantage of the ruling below without running the risk of a conflicting ruling from another circuit." Pet. at 24. The Commission's conjecture is unfounded, however. First, the Commission is free to bring an action in any district court in which a pharmaceutical company conducts business. 15 U.S.C. § 45(m) (2005). Second, private plaintiffs may also bring suit against pharmaceutical companies in any district in which such pharmaceutical company conducts business. 28 U.S.C. §1391(b) (2005). Third, the Commission could bring its cases in a manner consistent with the Eleventh Circuit's decision. A recent decision by the Eleventh Circuit shows that its decision in this case does not portend the death-knell of antitrust cases against pharmaceutical patent settlements, as the Commission speculates. *See Andrx Pharmaceuticals,*

¹⁴ Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004—A Report by the Bureau of Competition* (Jan. 7, 2005), <www.ftc.gov/os/2005/01/050107medicareactrpt.pdf> [§ II.B] (emphasis added).

Inc. v. Elan Corp., et al., ___ F.3d ___, 2005 WL 2061009 (11th Cir. Aug. 29, 2005) (refusing to dismiss antitrust complaint against pharmaceutical patent settlement: complaint successfully plead antitrust violation consistent with the Court of Appeals' *Schering-Plough* decision).

Finally, the Commission asserts that this Court's review is necessary because the Court of Appeals' decision will thwart congressional policy to encourage entry of generic pharmaceuticals. As the Commission concedes, however, the Hatch-Waxman Act attempts to balance its goal of encouraging generic entry with an equally important goal of "fully protecting legitimate patent claims." Pet. at 3. The Court of Appeals' decision in this case accommodates this balance. For example, Schering's settlement with Upsher-Smith split the remaining life of Schering's patent in half, and allowed generic entry five years *before* the expiration of Schering's patent. Without comparing the settlement to the exclusionary potential of Schering's patent, it is impossible to know whether generic entry was delayed or accelerated. In fact, the evidence adduced at trial established that, based on the strength of Schering's patent case, entry was likely accelerated.

As the Commission argued a year ago, this Court's review is not warranted. Nothing has changed to alter that conclusion.

CONCLUSION

For all of the foregoing reasons, the petition should be denied.

Respectfully submitted,

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September 30, 2005