No. 05-273

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

SCHERING-PLOUGH CORPORATION, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

1. Whether the antitrust laws prohibit a brand name drug patent holder and a prospective generic competitor from settling patent infringement litigation by agreeing that the generic manufacturer will not enter the market before a future date within the term of the patent and that the patent holder will make a substantial payment to the generic manufacturer.

2. Whether the court of appeals erred in concluding that "substantial evidence" did not support the Federal Trade Commission's factual finding that a payment from a patent holder to an allegedly infringing generic manufacturer was consideration for the generic manufacturer's delayed entry into the market rather than a separate royalty for a license concerning a different product.

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This brief is submitted in response to the order of this Court inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied. The decision below does not conflict with any decisions of this Court or the courts of appeals, and the only important but unsettled issues of federal law that are raised by the petition are not well presented in this case.

STATEMENT

Respondent Schering-Plough Corporation (Schering), a pharmaceutical company, produces and markets a brand-name drug, K-Dur 20, for treating high blood pressure and congestive heart disease. K-Dur 20 contains unpatented potassium chloride encapsulated in an extended release coating that is protected by Schering's United States patent number

4,863,743 (the '743 patent), which expires on September 5, 2006. Pet. App. 2a-3a. Schering sued two of its competitors for proposing to market generic drugs that allegedly would infringe that patent. Thereafter, the parties to those respective suits entered into settlement agreements providing that (1) the defendants would be free to market generic versions of K-Dur 20 as of specified future dates that were earlier than the expiration of the '743 patent, and (2) Schering would make substantial payments to the defendants. The Federal Trade Commission (FTC or Commission) challenged the settlements and held that they violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45. The court of appeals vacated the FTC's order. Pet. App. 1a-35a.

1. The two settlements at issue in this case arose in the statutory context created by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585. The Hatch-Waxman Act establishes procedures designed to facilitate the market entry of lower-priced generic drugs while maintaining incentives to invest in new drug development. Under the Act, a company seeking approval from the Food and Drug Administration (FDA) to market a new drug (a "brand name" drug) must file a New Drug Application (NDA) demonstrating the safety and efficacy of its product. 21 U.S.C. 355(b). Once an NDA has been approved, a firm seeking to market a generic version of that drug may file an Abbreviated New Drug Application (ANDA) demonstrating that its product is bioequivalent to the brand-name counterpart. 21 U.S.C. 355(j). The FDA may approve the marketing of a generic drug before the expiration of a patent relating to the brand name drug if the applicant makes a "paragraph IV certification" that the patent in question is invalid or is not infringed by the generic product. 21 U.S.C. 355(j)(2)(A)(vii)(IV). If the patent holder files a patent infringement suit within 45 days after receiving notification

of such a certification, however, the FDA's approval is automatically stayed for 30 months, unless the patent expires or is judicially determined to be invalid or not infringed before that time. 21 U.S.C. 355(j)(5)(B)(iii). The first company to file an ANDA with a paragraph IV certification relating to a particular brand name drug is granted the exclusive right to market a generic version until 180 days after the earlier of two dates: when it begins commercial marketing or when a court holds the patent invalid or not infringed. 21 U.S.C. 355(j)(5)(B)(iv).

2. In 1995, two competitors, Upsher-Smith Laboratories (Upsher) and ESI Lederle, Inc. (ESI), separately filed ANDAs that contained paragraph IV certifications and sought FDA approval to market generic versions of K-Dur-20. Pet. App. 3a-4a & n. 2, 6a n.5. Schering responded by suing each company for patent infringement. In 1997, Schering and Upsher engaged in settlement negotiations, and agreed that Upsher's generic could be marketed on September 1, 2001, five years before expiration of the '743 patent. Upsher, however, "insisted upon its need for cash prior to the agreed entry date," while Schering stated that it "refused to pay Upsher to simply 'stay off the market.'" *Id.* at 4a; see *id.* at 100a, 188a. Ultimately, the parties negotiated, as part of the settlement, an exclusive license under which Schering paid $60 million to Upsher and received the exclusive right to market several Upsher products outside North America, including Upsher's Niacor-SR (Niacor), a cholesterol-reducing drug. *Id.* at 195a-197a.

In the ESI litigation, the court appointed a magistrate judge to supervise mediation. More than a year later, in December 1997, under what the FTC termed "intense, and perhaps unseemly, judicial pressure to settle the patent litigation," Pet. App. 144a, Schering offered to permit ESI to market its generic on January 1, 2004, more than two years before

expiration of the '743 patent. ESI agreed on the date but insisted on a payment. At the magistrate judge's suggestion, Schering then offered $5 million in legal fees. ESI insisted on more, and the magistrate judge and Schering devised a settlement that included an additional payment of $10 million conditioned on ESI's receiving FDA approval for its generic drug by a specified date. *Id.* at 7a.

3. In March 2001, the FTC issued an administrative complaint alleging that the two agreements unreasonably restrained competition in violation of Section 5 of the FTC Act, 15 U.S.C. 45. Pet. App. 48a-49a, 145a; Complaint ¶¶ 68, 69, at 9, *Schering-Plough Corp.*, Docket No. 9297, 2003 WL 22989651 (FTC Dec. 8, 2003). The core allegation was that Schering's cash payments induced Upsher and ESI "to delay launching generic versions of K-Dur 20. Absent those payments, neither Upsher[] nor ESI would have agreed to delay its entry for so long." Complaint ¶ 64, at 8-9.

a. After a two-month administrative trial, the administrative law judge (ALJ) concluded that the challenged agreements "did not unreasonably restrain competition" and dismissed the complaint. Pet. App. 340a. The ALJ found that Complaint Counsel had failed to prove that either payment by Schering was made in exchange for delayed entry. The ALJ determined that the evidence showed that the Upsher licensing agreement was a bona fide agreement and that the $60 million payment from Schering to Upsher represented a fair value for the licenses. *Id.* at 316a-324a. The ALJ also found no "substantial, reliable evidence to conclude that the $15 million was paid [to ESI] only for unlawful delay." *Id.* at 325a.

The ALJ also reasoned that, in order to establish that the settlements had the alleged anticompetitive effect, Complaint Counsel needed to "prove that better settlement agreements or litigation results would have resulted in Upsher[] and ESI

selling their generic equivalents prior to September 1, 2001 and January 1, 2004," *i.e.*, the entry dates agreed upon in the two settlements. Pet. App. 310a. Because Complaint Counsel could not prove that, absent the settlement agreements, either company would have entered the market before the expiration of Schering's patent, *id.* at 310a-312a, 315a, the ALJ concluded that Complaint Counsel had failed to meet its burden of proof, *id.* at 313a-314a.

b. The Commission reversed. Pet. App. 36a-153a. With respect to the Upsher agreement, the FTC found that "there was a direct nexus between Schering's payment and Upsher's agreement to delay its competitive entry and that the magnitude of the payment was not based on Schering's evaluation of the Upsher licenses." *Id.* at 141a. The FTC therefore concluded that "Schering did in fact pay Upsher for delayed entry." *Ibid.* Likewise, because it found no other satisfactory explanation for the $10 million payment from Schering to ESI, the FTC concluded that the ESI payment was in exchange for delayed entry. *Id.* at 144a-145a; see *id.* at 142a n.101.

The FTC explained that the question whether the payments violated the antitrust laws turned on "whether these unconditional payments were likely to have anticompetitive effects because they delayed generic entry beyond the dates that would have been agreed upon in the absence of the payments." Pet. App. 54a. In the Commission's view, that "question can be answered without an inquiry into the merits of the patent litigation." *Ibid.* The FTC reasoned:

> If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it 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.

Id. at 76a-77a (footnote omitted). Finding no proof of other offsetting consideration for the payments to either Upsher or ESI, the Commission found the agreements illegal. *Id.* at 87a-93a, 141a-145a.

3. The court of appeals set aside the FTC's decision and vacated its remedial order. Pet. App. 1a-35a. In the court's view, it was undisputed that the '743 patent gave Schering "the lawful right to exclude infringing products from the market until September 5, 2006," *i.e.*, the patent's expiration date. *Id.* at 20a. The court found it significant that Complaint Counsel "acknowledged that it could not prove that Upsher and ESI could have entered the market on their own prior to the '743 patent's expiration on September 5, 2006," and that the absence of proof of an alternative entry date "reinforces the validity and strength of the patent." *Ibid.*

The court then turned to the question whether there was "substantial evidence to support the Commission's conclusion that the challenged agreements restricted competition beyond the exclusionary effects of the '743 patent." Pet. App. 20a. With respect to the Upsher agreement, the court noted that the "FTC concede[d] that its position fails if it cannot prove a direct causal link" between the $60 million payment and Upsher's delayed entry into the market. *Id.* at 21a. The court concluded that "the substantial and overwhelming evidence" supported the ALJ's conclusion that the $60 million payment to Upsher represented a bona-fide license payment for Upsher's products. *Id.* at 26a.

With respect to the ESI agreement, the court stated that "there is far less development of the factual record" to support the FTC's conclusion that the ESI settlement was unreasonable. Pet. App. 27a. Moreover, the court observed that the FTC had not rebutted the testimony of Schering's experts

"who posited that Schering would have won the patent case" and that the agreed entry date "reasonably reflected the strength of Schering's case." *Ibid.* The court accordingly found "the terms of the settlement to be within the patent's exclusionary power." *Id.* at 28a. The court attributed the FTC's contrary holding to the assumption "that but for the payments, the parties would have fashioned different settlements with different entry dates." *Id.* at 30a. The court found, however, that "no evidence in the record" supports the FTC's assumption that "the parties could have attained an earlier entry without the role of payments." *Ibid.*

The court concluded that antitrust liability should be determined by "the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection." Pet. App. 35a. The court observed that "[r]everse payments are a natural by-product of the Hatch-Waxman process," which weakened the relative bargaining power of a drug patent holder in settlement negotiations with an allegedly infringing generic manufacturer. *Id.* at 32a (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003)). For instance, the court observed, "[d]ue to the 'asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.'" *Id.* at 34a (quoting *Valley Drug Co.* v. *Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003), cert. denied, 543 U.S. 939 (2004)). As a result, "the mere presence of" a reverse payment could not provide "the sole basis for a violation of antitrust law." *Id.* at 34a, 35a. Rather, the court explained, there is also a "need to evaluate the strength of the patent." *Id.* at 35a.

DISCUSSION

The petition raises important and complex issues concerning the antitrust treatment of settlements in patent cases, particularly settlements that provide for delayed entry into the market combined with a "reverse" payment from the patent holder to the alleged infringer. As the petition explains (at 15-21), such settlements may pose a risk of restricting competition in ways that are not justified by a lawful patent, to the detriment of consumers. This case, however, does not present an appropriate opportunity for this Court to determine the proper standards for distinguishing legitimate patent settlements, which further the important goals of encouraging innovation and minimizing unnecessary litigation, from illegitimate settlements that impermissibly restrain trade in violation of the antitrust laws.

I. The Petition Raises Important And Complex Issues

Although "public policy wisely encourages settlements" of legal disputes, *McDermott, Inc.* v. *AmClyde*, 511 U.S. 202, 215 (1994), it does not follow that all settlements are consistent with the public interest. Settlements of patent infringement claims are often predicated on an agreement that the alleged infringer will not make and sell the allegedly infringing product in competition with the patentee and its licensees, or that it will do so only pursuant to the terms of a license agreement. Were it not for the existence of the patent and the allegation of infringement, a court would likely treat such an agreement as an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

In the patent context, however, a settlement involving restrictions on the sale of the products in question is not necessarily impermissible. The Patent Act provides that "[e]very patent shall contain * * * a grant * * * of the right to exclude others from making, using, offering for sale, or selling

the invention." 35 U.S.C. 154(a)(1). A valid patent thus confers on the patent holder the lawful "right to exclude others from profiting by the patented invention." *Dawson Chem. Co.* v. *Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). Patent holders can lawfully refuse to license competitors to produce the patented article, or can grant exclusive territorial or other limited licenses to one or more chosen licensees. *Ibid.*; 35 U.S.C. 261, 271(d)(4); *In re Independent Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000), cert. denied, 531 U.S. 1143 (2001).

At the same time, competitive restraints adopted as part of a patent litigation settlement are subject to invalidation under the antitrust laws if the patent holder obtains "protection from competition which the patent law, unaided by restrictive agreements, does not afford," *United States* v. *Masonite Corp.*, 316 U.S. 265, 279 (1942). There may be particular reason for concern about the competitive consequences of a settlement that includes substantial payments from the patent holder to the alleged infringer. Such payments can be a device for the sharing of monopoly rents made possible by the alleged infringer's exclusion from the market, and may result in less competition than would likely have prevailed in the absence of the payment. Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1749 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. Econ. 391, 408 (2003).

Reverse payments made in cases subject to the Hatch-Waxman Act may raise additional concerns when the brand name patent holder settles with the first generic competitor to file an ANDA. "It is widely understood that the 180-day exclusivity period," which is granted to the first ANDA filer and is not triggered until the first filer's entering the market or a finding of invalidity or non-infringement, creates an incentive for the parties to "settle the litigation with a 'non-en-

try' payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market indefinitely." Hovenkamp, 87 Minn. L. Rev. at 1755; see 21 U.S.C. 355(j)(5)(B)(iv). On the other hand, the Hatch-Waxman Act may also create unique justifications for reverse payments, because the ability of prospective generic competitors in effect to force patent holders to initiate infringement litigation upon the filing of ANDAs, before any actual infringement has occurred, reduces the litigation risk for the generic manufacturers. In combination with the inherent difficulties in predicting litigation outcomes and the potentially devastating consequences for the patent holder if it were to lose the litigation, the resulting gross disparities in the litigants' respective risks may tend to increase the cost of settlement for patentees in the Hatch-Waxman context and make reverse payments more likely, even when the patentee's legal claims are strong. See Pet. App. 31a; *In re Tamoxifen Citrate Antitrust Litig.* (*Tamoxifen*), 429 F.3d 370, 390-395 (2d Cir. 2005).

Patent litigation settlements that include reverse payments thus implicate conflicting policy considerations and complex legal issues at the intersection of patent and antitrust law, with further complexity introduced in the pharmaceutical context by the dynamics of the Hatch-Waxman Act. On the one hand, the interests in consumer welfare protected by the antitrust laws militate against adoption of a legal standard that would facilitate patent holders' efforts to preserve weak patents by dividing their monopoly profits with settling challengers. The risks are magnified when the settling parties are in a position to utilize the Hatch-Waxman exclusivity period to further constrain competition from other generic manufacturers. On the other hand, the public policy favoring settlements, and the statutory right of patentees to exclude com-

petition within the scope of their patents, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation. And the Hatch-Waxman context creates a litigation dynamic that makes some settlements reasonable.

Those competing considerations suggest that the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful. Rather, an appropriate legal standard should take into account the relative likelihood of success of the parties' claims, viewed *ex ante*. Cf. States Amici Br. 18 (suggesting that an "appropriate analysis of an antitrust challenge of a patent infringement settlements * * * assesses the strength of the patent in the context of the infringement settlement itself").[1]

The FTC, however, apparently rejects any direct effort to evaluate the likelihood that the patent holder would prevail on its claim. Pet. App. 54a, 57a, 80a-87a, 143a; accord Pet. 16-19. The FTC apparently prefers to assess the "expected value" of the patent holder's lawsuit against the generic and then uses that as part of its evaluation of the settlement. Pet. 19 n.12; Pet. Reply 6. The FTC's petition emphasizes what it calls the the "'probabilistic' nature of the property interest created by the patent laws" and the view that "a patent is not a right to exclude, but rather a right to *try* to exclude." Pet. 16 (cita-

[1] A court would not need to conduct a full trial on the merits of the patent claims in order to make a determination regarding the likelihood of a patent owner's litigation success. Rather, a court could conduct a limited examination into the relative merits of the patent claims and other relevant factors surrounding the parties' negotiations. Cf. *Weinberger* v. *Kendrick*, 698 F.2d 61, 74 (2d Cir. 1982) (Friendly, J.) (district court reviewing proposed class action settlement must form "an intelligent and objective opinion of the probabilities of ultimate success should the claim be litigated," but need not conduct a trial) (quoting *Protective Comm. for Indep. Stockholders of TMT Trailer Ferry, Inc.* v. *Anderson*, 390 U.S. 414, 424-425 (1968)), cert. denied, 464 U.S. 818 (1983).

tions omitted); cf. 35 U.S.C. 154(a)(1) (patent grants "right to exclude"), 282 (presumption of patent validity). In the end, the record below does not explore differences in outcome that might result from the FTC's emphasis on expected value and the apparently different emphasis of the court of appeals. On the other hand, the differences may not be substantial, as the expected value of the lawsuit should be a product of the relative strength of the competing claims. The FTC's approach, however, appears to place undue weight on the parties' subjective views of the strength of the claims as reflected in the settlement agreement, as opposed to a more objective assessment of the claims based on evidence extrinsic to the settlement. Likewise, the FTC's approach seems to reflect a high degree of suspicion of any reverse settlement payment. Under the FTC's view, the presence of a reverse payment (in the absence of an ancillary explanation for the payment, such as legal fees) has necessarily rendered consumers worse off and lessened competition, either because "a settlement with an earlier date might be compromised, *or* because continuation of the litigation without settlement would yield a greater prospect of competition." Pet. 19 & n.12. But cf. *Asahi Glass Co.* v. *Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation), appeal dismisssed, 104 Fed. Appx. 178 (Fed. Cir. 2004) .

II. This Case Does Not Provide A Good Vehicle For Addressing The Questions Presented

Whatever the correct standard for determining the antitrust treatment of patent settlements involving reverse payments, this case does not present an appropriate occasion to address that question or to assess the validity of the FTC's approach.

1. The court of appeals determined that Schering's $60 million payment to Upsher was not compensation for delayed

market entry by Upsher, but was instead an independent and bona fide royalty payment by Schering to license Upsher's products. Pet. App. 21a-26a. After correctly articulating the well-settled principles of deference to agency fact-finding under the substantial-evidence standard of review (*id.* at 10a-12a), the court of appeals held that the evidence overwhelmingly supported the ALJ's conclusion that the payment was not linked to Upsher's delay in entering the market. *Id.* at 22a-26a. Unless overturned, that determination forecloses any antitrust challenge to the Upsher settlement, *even under the FTC's theory*.

The FTC asks this Court to determine whether "the court of appeals grossly misapplied" the substantial-evidence test by not deferring to the Commission's finding that the payment was for delay. Pet. I. There is, of course, no gainsaying the importance of appropriate deference to agency fact-finding. Nonetheless, plenary review of the court of appeals' application of the substantial-evidence standard in this case would not be an appropriate exercise of this Court's certiorari jurisdiction. Sup. Ct. R. 10. As the FTC recognizes (Pet. 26), "the task of determining whether substantial evidence supports agency findings is ordinarily left to the courts of appeals." Unless this Court departs from its normal practice, reviews the record, and determines for itself that substantial evidence supported the Commission's factual findings, there will be no occasion to consider the application of the antitrust laws to reverse payments with respect to the Upsher settlement.

The FTC argues that this Court "need not canvass the record itself and resolve the ultimate issue whether substantial evidence supported the Commission's findings, but may remand to the court of appeals for review of the factual issues under a proper standard." Pet. Reply 8. But the court of appeals set forth, and purported to apply, the "proper stan-

dard." Pet. App. 10a-12a. The FTC instead disagrees with the court's *application* of that well-established standard to the particular findings and record in this case. Accordingly, this case is not a candidate for a "correction" of the legal standard with a remand for the lower courts to apply the new standard.

Moreover, one of the principles of administrative law that was correctly articulated by the court of appeals is that a review for substantial evidence requires "a review of the record as a whole, which include[s] the ALJ's decision." Pet. App. 11a (citing *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, 493 (1951)). Thus, this Court's resolution of whether the court properly deferred to the FTC would require review of not only the FTC's extensive findings, *id.* at 93a-141a, but also the ALJ's even more detailed findings, *id.* at 184a-249a, 316a-324a, which were made after a three-month trial that "covered 8,629 pages of transcript, involved forty-one witnesses, and included thousands of exhibits," *id.* at 8a, 22a. While there may well be valid grounds for taking issue with the court of appeals' application of the substantial-evidence standard to the Commission's careful findings, this Court generally does not sit as a court of errors to reexamine such determinations, and the complexity of this case renders it a poor candidate for an exception to that general practice.

2. Nor does Schering's $10 million payment to ESI provide an appropriate vehicle for resolution of the difficult and unsettled antitrust issues posed by the FTC. The Commission observed that "[a]s a matter of prosecutorial discretion, [it] might not have brought a stand-alone case based on [the] relatively limited evidence" involving the ESI agreement. Pet. App. 145a. Moreover, the payment was negotiated through a process involving the active participation of a magistrate judge, *id.* at 7a, who exerted "intense, and perhaps unseemly, judicial pressure to settle," *id.* at 144a. In finding

liability, the Commission stated that it wanted to "signal [its] disapproval of the way that Schering responded to judicial pressures," *id.* at 145a, but it did not suggest that such concerns are typical of reverse-payment settlements.

Finally, the $10 million reverse payment to ESI was conditioned on FDA approval of ESI's generic drug; "Schering doubted the likelihood of this contingency happening," and thus "if Schering's prediction proved true, it would not have to pay the $10 million." Pet. App. 7a. In short, the unusual circumstances surrounding the ESI payment suggest that it is unlikely to provide a factual setting conducive to the Court's identification and application of the appropriate legal standard to govern reverse-payment settlements generally. Cf. *id.* at 28a (noting that the FTC's invalidation of the ESI payment "would leave settlements, including those endorsed and facilitated by a federal court, with little confidence").

3. Further militating against review is the fact that the court of appeals did not squarely address the theory of antitrust liability advanced by the FTC in this Court. The court of appeals did not interpret the FTC's decision to be based on the notion that a patent holder may lawfully exclude infringing products only to the extent of the "expected value" of the patent holder's lawsuit against the generic. Pet. 19 n.12. The court instead understood the FTC's theory of liability to "require[] the conclusion that but for the payments, the parties would have fashioned different settlements with different," and earlier, entry dates. Pet. App. 30a; see *id.* at 17a n.15. And the court found "no evidence in the record" to support a conclusion that the parties could have, let alone would have, reached a more pro-competitive settlement in the absence of any reverse payments. *Id.* at 30a.

The FTC argues that the court of appeals misconstrued the Commission's rationale, for example, by attributing to the FTC a focus on the entry date of a hypothetical non-cash set-

tlement. But even the FTC concedes that such analysis played some role in its decision. Pet. 18; Pet. Reply 6. In any event, any disconnect between the court of appeals' understanding of the FTC's view and the FTC's own understanding of its rationale hardly counsels in favor of using this case as a vehicle for plenary review.[2]

Nor has any other court of appeals expressly considered the "expected value" analysis emphasized by the FTC. Indeed, only a district court thus far has examined, and rejected, the view that a patent gives the holder merely a potential right to exclude infringing competitors from the market. *In re Ciprofloxacin Hydrochloride Antitrust Litig.* (*Ciprofloxacin*), 363 F. Supp. 2d 514, 531-533 (E.D.N.Y. 2005), appeal docketed, No. 05-2851 (2d Cir. June 7, 2005). The Second Circuit may address the validity of that theory in its consideration of that case. That prospect further counsels against plenary review at this juncture.

III. There Is No Circuit Split Justifying This Court's Review

The FTC also argues (Pet. 23) that this Court's review is warranted to ensure national uniformity regarding the appropriate standard for assessing the validity of reverse payments. The FTC argues (Reply Br. 3 n.1) that the decision below is "at odds" with the Sixth Circuit's decision in *In re*

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[2] Portions of the FTC's decision suggest that the Commission was relying on the notion that an earlier settlement entry date was, in fact, achievable by the parties in the absence of a reverse payment. Pet. App. 54a ("The issue is whether these unconditional payments were likely to have anticompetitive effects because they delayed generic entry beyond the dates that would have been agreed upon in the absence of the payments."); *id.* at 82a ("we * * * focus on the effect that Schering's payment to Upsher was likely to have on the generic entry date which the parties would otherwise have agreed to in a settlement"); *ibid.* ("we * * * look * * * to determine whether * * * [the settlement] likely delayed generic entry beyond the date that would have been provided in a differently crafted settlement").

Cardizem CD Antitrust Litigation, 332 F.3d 896 (2003), cert. denied, 543 U.S. 939 (2004), which held that an interim settlement agreement with a reverse payment constituted a per se violation of the antitrust laws. As the United States and the FTC previously informed this Court, however, the Sixth Circuit's decision involved payments to exclude drugs that did *not* fall within the scope of the patent alleged to be infringed, and thus it is far from clear that the per se rule employed by the Sixth Circuit extends beyond the unique circumstances of that case. U.S. Amicus Br. at 11-15, *Andrx Pharmaceuticals, Inc.* v. *Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779).

The FTC also argues that the court of appeals' decision "has sharpened the tension between the Sixth and Eleventh Circuits," stating that the decision below, in conjunction with the Eleventh Circuit's previous decision in *Valley Drug, supra*, "effectively immunize" reverse payments from antitrust liability when the settlement is within the nominal outer bounds of the patent, absent proof that the patent litigation was a sham. Reply Br. 3; accord Pet. 14-15, 17, 19 n.12. But the decision below simply does not speak to the question, implicated in *Cardizem*, of the appropriate standard to govern a naked restraint of trade concerning drugs *not* covered by a patent, so it neither deepens nor sharpens the tensions, if any, between the approaches followed by the Sixth and Eleventh Circuits.

In any event, it is far from clear that the FTC is correct in construing the decision below as "complet[ing] the barrier against antitrust challenges to patent settlements." Reply Br. 3 n.1. The Eleventh Circuit in *Valley Drug* held that reverse payments were not subject to a per se rule, 344 F.3d at 1306, and rejected the imposition of antitrust liability "merely because" of a subsequent authoritative determination of patent invalidity, *id.* at 1308. Neither *Valley Drug* nor the decision below holds, however, that evidence of invalidity or non-in-

fringement available at the time of settlement would be irrelevant in assessing the permissibility of a reverse payment.

To be sure, the decision below notes that the FTC did not allege that the "infringement suits against Upsher and ESI were 'shams'" (Pet. App. 20a), but the court did not purport to hold that proof of "sham" litigation is a prerequisite to antitrust liability. Instead, the decision below states that the "proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* at 17a (citing *Valley Drug*, 344 F.3d at 1312). That holding does not expressly foreclose a party challenging a patent settlement from relying on an *ex ante* view of the strength of the infringement claim in determining whether the settlement, including any reverse payment, delayed entry beyond "the exclusionary potential of the patent." *Ibid.*

Because the FTC in this case eschewed any direct inquiry into the underlying merits of Schering's patent claims against Upsher or ESI, the court of appeals had no occasion to consider the appropriate nature or scope of such an inquiry. While the three-factor test articulated by the court of appeals does not expressly address the strength of the patent claim, portions of the court of appeals' decision suggest that the court approved of the ALJ's analysis, which assessed "the strength of the patent" in determining whether the reverse payment enabled Schering to achieve an anticompetitive outcome inconsistent with the patent's legitimate exclusionary reach. Pet. App. 9a, 15a; accord *id.* at 27a (observing that "Schering produced experts who posited that Schering would have won the patent case, and that the ESI's January 1, 2004, entry date reasonably reflected the strength of Schering's case."); *ibid.* (noting that "[t]he Commission * * * refused to consider the underlying patent litigation."). And in con-

cluding its opinion, the court of appeals again "underscore[d] the need to evaluate the strength of the patent." *Id.* at 35a. Accordingly, the decision below does not hold that a "sham litigation" standard should govern future antitrust challenges to reverse payment settlements.

After the FTC filed its reply brief in this Court, the Second Circuit decided *Tamoxifen*, 429 F.3d at 389, which held that reverse payments in patent settlement did not constitute a per se violation of the antitrust laws. That decision suggests that a sham standard governs the validity of settlements that do not exclude a patented product beyond the scope of the patent. *Id.* at 396-398 & n.27. Far from expressing any disagreement with the Eleventh Circuit's decision below, however, the Second Circuit explicitly approved of the Eleventh Circuit's focus on whether "the exclusionary effects of the agreement exceed the scope of the patent's protection," *id.* at 397 (internal quotation marks and citation omitted). In any event, to the extent that the Second Circuit's approach may differ from that followed below, review would not be warranted in this case, because the FTC's claims would fail under either approach. Moreover, the Second Circuit's decision did not involve drugs outside the patent claim and it thus does not create any split with the Sixth Circuit's *Cardizem* decision.

Finally, the above cases illustrate that the FTC is mistaken in suggesting (Pet. 24) that the Eleventh Circuit's decision forecloses further consideration of the issue by other courts of appeals. The FTC surmises (*ibid.*) that parties to patent settlement are likely to challenge any future action by the Commission in the Eleventh Circuit "without running the risk of a conflicting ruling from another circuit." But *private* parties (such as injured drug consumers) challenging reverse payments are just as likely to avoid bringing their claims in the Eleventh Circuit. Indeed, the challenges to reverse payments involved in the Sixth Circuit and Second Circuit deci-

sions were brought by private litigants. Moreover, the private party in *Ciprofloxacin*, 363 F. Supp. 2d at 531-533, challenged the patent settlement based on the FTC's theory of liability, and private parties and the State of Pennsylvania have brought suit in federal district court within the Third Circuit to challenge the very settlement agreements at issue in this case. *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517 (D. N.J. 2004). There is thus no basis for assuming that a conflict could not develop on the issue.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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