No. 05-273

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

SCHERING-PLOUGH CORPORATION, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals For the Eleventh Circuit

MOTION TO FILE *AMICUS CURIAE* BRIEF AND BRIEF OF BAYER CORPORATION AS *AMICUS CURIAE* IN OPPOSITION TO CERTIORARI

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MOTION TO FILE *AMICUS CURIAE* BRIEF OF BAYER CORPORATION IN OPPOSITION TO CERTIORARI

Bayer Corporation ("Bayer") respectfully moves for leave to file the attached amicus curiae brief, pursuant to Supreme Court Rule 37.2(b), in opposition to certiorari.

Bayer is a research and science driven company that is engaged in the research and manufacture of several different kinds of products, including pharmaceutical products.

The questions presented in the Petition significantly affect Bayer Corporation because it manufactures a variety of patented products including patented drugs, is involved in litigation with respect to those products, and has entered and may enter in the future into settlements of such litigation. Bayer Corporation is a co-defendant in an antitrust case arising from the settlement of patent litigation in which the district court recently granted summary judgment for defendants. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 523 (E.D.N.Y. 2005), *appeal filed,* No. 05-2851 (2d Cir.).

In accordance with Supreme Court Rule 37.2, Bayer represents that it obtained written consent from counsel for the petitioner to file amicus brief. Counsel for respondents Schering-Plough Corporation and Upsher-Smith Corporation declined to consent, however, thereby necessitating this motion. Sup. Ct. R. 37.2(b).

For these reasons and those set out in the accompanying brief, Bayer hereby moves the Court to allow it to appear as *Amicus Curiae*, and to submit its brief urging the Court to deny the petition for certiorari.

Respectfully submitted,

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STATEMENT OF INTEREST

The Statement of Interest of Bayer Corporation is included in the Motion to File.[1]

SUMMARY OF ARGUMENT

1. There is no circuit split or significant conflict as to the first question presented that warrants this Court's review. To the contrary, there now exists a significant body of uniform but still developing law holding both (i) that antitrust analysis of a pharmaceutical patent settlement must begin with an examination of the exclusionary effect of the patent and whether the settlement agreement exceeds that effect, and (ii) that payments from a patent holder to a potential infringer or challenger are not presumptively anticompetitive. The Petition fails to identify or address this growing body of case law, which contravenes the Commission's position here. Moreover, the Commission itself recently and correctly argued to this Court that there is no conflict in the circuits as to these issues.

2. Review is also unwarranted because the Petition asserts a theory of antitrust liability that was not the basis for the Commission's decision below and that has not been accepted by any circuit. The Commission's decision was based on the theory that the actual settlement chosen by the parties was unlawful because it prevented them from entering into a different settlement "better" for consumers. That position was rejected because it is contrary to the well-established rule that conduct does not run afoul of the antitrust laws solely because different conduct might yield greater competition.

The Petition now advances a different rationale, based on the proposition that patents confer only "probabilistic"

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[1] Pursuant to Supreme Court Rule 37.6, no person other than counsel identified on the cover participated in authoring this brief. No entities other than the *amicus* and counsel provided financial support for this brief.

rights, and that consumers have a property right in the possibility that a patent will be found invalid or not infringed. The Petition now contends that the settlement was therefore unlawful because it eliminated this "prospect" of competition. This new rationale does not merit review by this Court because it was not the basis of the Commission's decision and has not been accepted by any circuit. Because this theory would largely negate the value of patent rights and strongly deter most settlements of patent litigation, it should not be presented to this Court until further developed by the courts of appeals.

ARGUMENT

I. REVIEW OF THE EXCEPTIONALLY BROAD QUESTION PRESENTED IS NOT WARRANTED IN LIGHT OF THE ONGOING DEVELOPMENT OF THE LAW AND THE LACK OF ANY SPLIT IN THE CIRCUITS

The Petition primarily raises the broad question "[w]hether an agreement between a pharmaceutical patent holder and a would-be generic competitor, in which the patent holder makes a substantial payment to the challenger for the purpose of delaying the challenger's entry into the market, is an unreasonable restraint of trade." Pet. I. In mounting its attack on so-called "reverse payments" in patent settlements, the Petition criticizes as "startling" the conclusion of the court below that the antitrust analysis of a patent settlement must begin by examining the "exclusionary potential" of the patent and whether the agreements at issue had exceeded that potential. *Id.* at 11. Neither the Commission's surprise nor review of this question are warranted.

A. The Petition Ignores The Uniform Body Of Law Contrary To The Commission's Position Here

The Petition fails to acknowledge, much less to address, the significant and uniform body of law contrary to the two fundamental premises of the Commission's argument.

First, the courts have repeatedly held that antitrust analysis of a settlement agreement between a patent holder and a potential infringer must begin with an examination of the exclusionary effect of the patent and whether the agreement exceeded that effect. In reaching the same conclusion, Pet. App. 17a, the court below followed its prior ruling in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 125 S. Ct. 308 (2004), that, "[w]hen the exclusionary power of a patent is implicated . . . the antitrust analysis cannot ignore the scope of the patent exclusion." *Id.* at 1310. Thus, only those provisions of the agreements "found to have effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis." *Id.* at 1312.

This exclusionary effect analysis is wholly consistent with prior holdings by District of Columbia, Federal, Second, and Seventh Circuits.[2] Similarly, Judge Richard Posner, sitting as a district court judge, recently explained that conduct within the exclusionary effect of a patent could give rise to antitrust liability only where it is objectively baseless to assert that the patent is valid and infringed:

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[2] *See United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981) ("[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by the patent, and is otherwise legal. . . . None of these restraints go beyond what the patent itself authorizes."); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) ("The appropriate criterion is whether Mallinckrodt's restriction . . . has ventured beyond the patent grant. . . . Should the restriction be found to be reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims, that ends the [antitrust] inquiry."); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) ("[W]here a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws."); *USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 513 (7th Cir. 1982) (antitrust liability may lie "only upon proof of an anticompetitive effect beyond that implicit in grant of the patent").

> A firm that has received a patent from the patent office . . . and thus enjoys the presumption of validity that attaches to an issued patent, 35 U.S.C. § 282, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment.

Asahi Glass Co. Ltd. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 992-93 (N.D. Ill. 2003). Other District Courts agree that the exclusionary effect of the patent is the central inquiry of any antitrust analysis.[3]

Second, the courts have also consistently held that settlement payments from a patent holder to a potential generic manufacturer are *not* presumptively anticompetitive. Pet. App. 35a. The court below explained:

> We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a

[3] *See, e.g.*, *Ciprofloxacin*, 363 F. Supp. 2d at 523 ("The ultimate question — and this is the crux of the matter — is not whether Bayer and Barr had the power to adversely affect competition for ciprofloxacin as a whole, but whether any adverse effects on competition stemming from the Agreements were outside the exclusionary zone of the '444 Patent."); *In re Tamoxifen Citrate Antitrust Litig.*, 222 F. Supp. 2d 326, 331 (E.D.N.Y. 2002), *appeal pending*, No. 03-7641 (2d Cir.) (refusing to remand a suit challenging a Hatch-Waxman settlement because "plaintiffs cannot succeed on their claims without proving the invalidity or unenforceability of Zeneca's patent"). *But see In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517 (D.N.J. 2004). There, the court addressed the very same settlement by Schering-Plough that is the subject of the Petition here. In denying a motion to dismiss, the court followed the Commission's ruling that was reversed by the Eleventh Circuit in this case.

> potential infringer a substantial sum in settlement. . . . What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection.

Id. at 34a-35a (internal citations omitted). That conclusion was fully consistent with its prior decision in *Valley Drug*, where the court explained that "[i]f Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. The failure to produce the competing terazosin drug, rather than the payment of money, is the [alleged] exclusionary effect . . . ." 344 F.3d at 1309.

Moreover, the Eleventh Circuit's rulings on this point are entirely consistent with numerous other recent decisions. As Judge Posner also explained:

> "Reverse payment" patent settlements . . . are criticized and sometimes invalidated on the theory that they prevent competition. Whether it is a sound theory may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent. A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.

Asahi Glass, 289 F. Supp. 2d at 994 (citations omitted); *see also Ciprofloxacin*, 363 F. Supp. 2d at 540 ("The test for determining the validity of the so-called reverse or exclusion or exit payment and the only question remaining is whether the Agreements constrained competition beyond the scope of the patent claims."); *Tamoxifen*, 222 F. Supp. 2d at 331-32 (rejecting plaintiffs' argument that "the Settlement

Agreement was anticompetitive based on the amount of money Zeneca paid to Barr").[4]

As these decisions reflect, the law affecting the broad question presented is developing in a steady, and generally uniform, manner. Further decisions are pending. The Second Circuit is currently considering the appeal from the District Court decision in *Tamoxifen*, which has been argued and submitted for over a year. *See supra* note 3. The Second Circuit also has before it the appeal from the ruling in *Ciprofloxacin*. *See* p. i *supra*. In both cases, there are motions pending to transfer some or all of the appeals to the Federal Circuit. Additional district court cases challenging Hatch-Waxman settlements are pending in the Third and Ninth Circuits. *See K-Dur*, 338 F. Supp. 2d 517; *Kaiser Found. v. Abbott Labs.*, No. 2:02cv2443 (C.D. Cal. filed March 22, 2002). Given these ongoing developments, review by this Court of the Petition's initial question is inappropriate.

B. The Commission Has Recently And Correctly Argued To This Court That There Is No Circuit Split On The Primary Question Presented

This Court "normally grant[s] only petitions that present an important question of law on which the lower courts are in conflict." *Lebron v. Nat'l R.R. Passenger Corp.*, 513 U.S.

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4 For further criticism of the view that so-called reverse payment settlements are presumptively anticompetitive, *see, e.g.*, Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698, 704 (2004); James Langenfeld & Wenqing Li, *Intellectual Property and Agreements To Settle Patent Disputes: The Case of Settlement Agreements With Payments From Branded to Generic Drug Manufacturers*, 70 ANTITRUST L.J. 777 (2003); Richard J. Gilbert & Willard K. Tom, *Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later*, 69 ANTITRUST L.J. 43, 78 (2001); Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. Rev. 1789, 1802 (2003).

374, 408 (1995) (O'Connor, J., dissenting on the merits); *see also Lawson v. Murray*, 515 U.S. 1110, 1116 (1995) (Scalia, J., concurring in the denial of certiorari, where there was no "clear conflict with the decisions of other courts"). Here, the sole case that the Petition identifies as possibly in conflict with the caselaw described in Part I.A., *supra*, is *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharms. Inc. v. Kroger Co.*, 125 S. Ct. 307 (2004) (No. 03-779) ("*Cardizem*"). Pet. 23.

The Petition asserts that the Sixth Circuit in *Cardizem* has taken a "strikingly different approach" than has the Eleventh Circuit and describes *Cardizem* as "ruling that it may be per se unlawful for a patent holder to 'bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor . . . to stay out of the market.'" Pet. 23. Yet that description of *Cardizem* is "strikingly different" from the description of that case previously advanced by the FTC *to this Court* in *Cardizem* itself.

When the parties in *Cardizem* sought certiorari, this Court asked for the views of the United States. In response, the FTC joined the Solicitor General in an amicus brief explaining to the Court that *Cardizem* and the Eleventh Circuit's decision in *Valley Drug* "*do not present a square conflict* that necessitates this Court's review at this time." Brief for the United States as *Amicus Curiae* at 11, *Andrx*, No. 03-779 (U.S.) ("Br.") (emphasis added). The FTC told the Court that the Sixth Circuit had held a reverse payment settlement *per se* anticompetitive only where the "district court construed the Agreement at issue . . . to cover petitioner's marketing not only of allegedly infringing products but also of non-infringing or potentially non-infringing products that were not at issue in the patent litigation." Br. 7. Indeed, in its *amicus curiae* brief, the FTC emphasized two key facts of *Cardizem*: that the Agreement covered non-infringing competition and that it created a bottleneck – a barrier to the entry of future generic challengers. Br. 13.[5]

Nor did the FTC stop there. It also told the Court that, if *Cardizem* were construed to "require a per se rule" for "every settlement agreement that includes a reverse payment in exchange for the exclusion from the market of an allegedly infringing product," "the court of appeals decision would be *erroneous*." Br. 12 (emphasis added). The *Cardizem amicus* brief explained that "[r]everse payment settlements may have the salutary effect of facilitating efficient settlements that advance consumer welfare," and that "[c]ertain settlements of patent litigation may benefit consumers and the public, regardless of the presence of a payment to the alleged infringer, and thus application of a per se rule would be inappropriate." Br. 9, 12.

Having received these views of the United States, this Court denied certiorari in *Cardizem* and shortly thereafter denied certiorari in *Valley Drug*. *See* 125 S. Ct. 308 (2004) (No. 03-1175). It would thus be highly unusual for this Court to grant certiorari where the Court has recently denied certiorari on the same legal issue, and the petition fails to demonstrate a sharp conflict among the Circuits. As then-Justice Rehnquist once explained, absent a "square conflict," the Court's recent denial of certiorari in cases raising similar issues renders a grant of certiorari "doubtful":

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5 The *Cardizem amicus* brief also pointed out that, in the very sentence in *Cardizem* on which the Petition now relies for a *per se* rule, the Sixth Circuit cited with approval Judge Trager's decision, 332 F.3d at 908 n.13 (citing *Ciprofloxacin*, 261 F. Supp. at 242), which had rejected the *per se* rule for a settlement within the exclusionary effect of the patent. Based on this, the government's amicus brief said that *Cardizem* should be read "as limited to the particular agreement before the court, which had been construed by the district court to restrain petitioner from marketing *non-infringing* or *potentially non-infringing* versions of *Cardizem* CD." Br. 12-13 (emphasis added).

> Twice within the last year this Court has declined to review similar Fourth Amendment claims in strikingly similar cases. . . . [U]nless applicants can demonstrate a conflict among the Courts of Appeals of which this Court was unaware at the time of the previous denials of certiorari, or which has developed since then, applicants' petition for certiorari will not [be granted]. . . .

Miroyan v. United States, 439 U.S. 1338, 1338-39 (1978) (Rehnquist, J., denying application for stay). The Petition provides no reason for this Court to reverse its recent course and grant certiorari here.

II. THE PETITION'S RELIANCE ON A DIFFERENT THEORY OF ANTITRUST LIABILITY FROM THAT ACTUALLY EMPLOYED BY THE COMMISSION BELOW RENDERS THIS CASE INAPPROPRIATE FOR REVIEW

The Petition advances a theory of antitrust liability that was not the basis for the Commission's decision, was not evaluated by the Eleventh Circuit below, and has never been accepted by any Circuit Court. This Court has emphasized in reviewing past FTC orders that, "[o]nce the Commission has chosen a particular legal rationale for holding a practice to be unfair . . . familiar principles of administrative law dictate that its decision must stand or fall on that basis, and a reviewing court may not consider other reasons why the practice might be unfair." *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454-55 (1986). *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 246 (1972) (the Court "must look to the [FTC's] opinion, not to the arguments of its counsel, for the underpinnings of its order"). Under these principles, certiorari should be denied.

A. The Commission's Reliance Upon The "Better Settlement" Theory Was Contrary To Settled And Unchallenged Principles Of Antitrust Law

In its opinion below, the Commission advanced a theory that (it thought) would obviate the need to assess the exclusionary potential of the patent. The Commission thus stated that it would disregard what might have happened in the patent litigation, and focus instead on what might have happened during settlement negotiations. Pet. App. 81a-82a. The Commission expressly rejected the ALJ's conclusion that, "[s]ince complaint counsel did not prove either invalidity or non-infringement, . . . it was not possible to conclude that the settlement agreements in issue delayed generic entry that would otherwise have occurred." *Id.* at 53a. Instead, the Commission reasoned that there was another way to hypothesize generic entry, even if the generic drug would have been infringing:

> The issue is whether [the settlement's] 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. We explain below why this question can be answered without an inquiry into the merits of the patent litigation.

Id. at 54a (emphasis added). Thus, the Commission deemed the settlement that the parties actually chose to be anticompetitive because it prevented them from choosing a different settlement that the Commission would have regarded as better for consumers. *Id.* at 82a (agreement was "unreasonable" if it "delayed generic entry beyond the date that would have been provided in a differently crafted settlement").

The Commission's rationale, however, violates a fundamental principle of antitrust law: The requirement that conduct be unreasonably anticompetitive cannot be satisfied simply by positing alternative conduct that would be *more* competitive. As this Court has recently emphasized:

> The Sherman Act is indeed the Magna Carta of free enterprise, but it does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition.

Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 415-16 (2004) (internal quotation marks and citation omitted). The lower courts have long held that an antitrust tribunal may not conclude that "the availability of an alternative means of achieving the asserted business purpose renders the existing arrangement unlawful [because] that alternative would be less restrictive of competition. . . ." *Am. Motor Inns, Inc. v. Holiday Inns, Inc.*, 521 F.2d 1230, 1249 (3d Cir. 1975). The Second Circuit explained this point in rejecting a claim that blanket licenses in the music industry were more restrictive of competition than other potential licenses:

> Even if the evidence showed that most of the efficiencies of the [challenged] blanket licenses could be achieved under source licensing [the proposed alternative], it would not follow that the blanket license thereby becomes unlawful. The blanket license is not even amenable to scrutiny under section 1 unless it is a restraint of trade. The fact that it may be in some sense "unnecessary" does not make it a restraint.

Buffalo Broad. Co. v. ASCAP, 744 F.2d 917, 933 (2d Cir. 1984).[6]

This principle is undisputed in the courts and unchallenged in the Petition. Even for an alleged monopolist, the antitrust laws impose only the negative duty to refrain from harming competition, not the positive duty to improve it. *E.g., USM*, 694 F.2d at 513 (Posner, J.) ("There is a difference between positive and negative duties, and the antitrust laws . . . have generally been understood to impose

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[6] A less restrictive alternative may become relevant in the final step of a rule of reason analysis, that is, *after* a plaintiff shows an unreasonable restraint and the defendant counters with evidence of procompetitive benefits. But, as the Areeda Treatise warns, such an "[i]nquiry [is] relevant only after [the] threshold showing" of an unreasonable restraint. II Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1913c, at 306 (1988 Supp.).

only the latter."). Accordingly, as long as the settlement excludes no more competition than does the patent itself, "consumers have no right to second-guess whether some different agreement would have been more palatable." *Ciprofloxacin*, 363 F. Supp. 2d at 536 (citing *Trinko*, 540 U.S. at 415-16).

While this established law explains why the Commission's rationale has no judicial support, the "better settlement" theory fails on other grounds as well. The Commission's conclusion that "it is reasonable to assume that an agreed-on entry date, without cash payments, reflects a compromise of differing litigation expectations" is neither persuasive nor supported. Pet. App. 75a. The Commission crucially failed to consider the royalty rate that would accompany any such license with an early entry date. Depending on a variety of circumstances that the Commission ignored, a later entry date with a lower royalty rate could easily benefit consumers more (in the Commission's terms) than an earlier date with a higher royalty. Indeed, the courts recognize that the ability of the settling parties to set a royalty that would not materially lower consumer prices wholly undermines the Commission's conclusion that settlements with licenses are necessarily better for consumers than settlements with payments.[7] As one court recently explained, by choosing from a variety of

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[7] Judge Posner anticipated the same point over 20 years ago, when he explained that multiple licenses were no guarantee of consumer benefit

> if the [licensed] "competitors" were constrained by the terms of the patent license to charge the monopoly price. And they would be. As a rational profit-maximizer [the patentee] would charge its licensees a royalty designed to extract from them all the monopoly profits that the patent made possible; and the licensees would raise their prices to consumers to cover the royalty expense. The price to the consumer would be the same as it is, today, with . . . only [one] seller in the market.

Brunswick Corp. v. Riegel Textile Corp., 752 F.2d 261, 267 (7th Cir. 1984).

licensing terms, "the parties to a Hatch-Waxman patent litigation could settle on an early entry date with a license calibrated to achieve a similar financial result to the parties as an exclusion payment." *Ciprofloxacin*, 363 F. Supp. 2d at 537 (noting that a license with exclusive geographic territories could accomplish the same result).

Finally, the Eleventh Circuit also rejected the Commission's "better settlement" rationale on factual grounds that the Petition does not contest. The Eleventh Circuit concluded that "[t]here is simply no evidence in the record" to support a conclusion that the parties would have "attained an earlier entry date without the role of payments." Pet. App. 30a. This conclusion was fatal because "[t]he FTC concedes that its position fails if it cannot prove a direct causal link between the payments and the delay." *Id.* at 21a. While the Petition now contends that the Commission merely used "a *hypothetical* no-payment compromise as a benchmark" (a contention we discuss below), it does not dispute the absence of any evidence that a "better" settlement would have occurred.

Accordingly, even if the rationale that the Commission actually employed were being defended by the Petition, it would not be appropriate for certiorari. The Commission's rationale was plainly contrary to settled law on which there is no split in the lower courts. Certiorari does not lie to determine whether the Circuit Court correctly applied principles of law that the Petition does not question, nor to consider the existence of substantial evidence that the Petition makes no claim to exist.

B. Because The Commission's New "Probabilistic Property" Theory Has Not Been Accepted By Any Circuit, And Was Not Even Applied By The Commission Below, Review by this Court Is Inappropriate

1. To remedy the weakness of the Commission's actual rationale, the Petition seeks to substitute a new one. The Petition has abandoned the Commission's reasoning in favor

of a theory of "probabilistic property," based on the following propositions: (1) the property right conveyed to a patent is merely "probabilistic" because it consists only of the right to go to Court and "*try* to exclude," Pet. 16; (2) the uncertainty and complexity of all patent litigation mean that there is always some chance that the generic challenger will win the patent suit, *id.*; (3) the "chance" of generic entry in each case must be deemed a consumer property right, *id.* at 14 & 18; and (4) the parties' settlement is therefore anticompetitive unless it conveys to consumers the full value of that property right in the form of a license with an entry date in advance of patent expiration. *Id.* at 18-19.

In support of this rationale, the Petition argues that the Eleventh Circuit's opinion "ignores the most salient factor . . ., the existence of *uncertainty* regarding" the exclusionary effect of the patent. Pet. 15 (original emphasis). That uncertainty, they maintain, "requires that the boundaries of the patent's coverage be delimited . . . ." *Id.* at 16. According to the Petition, when Hatch-Waxman litigants settle, therefore, "the elimination of the *prospect* of competition, even if uncertain, harms consumers." *Id.* at 14 (emphasis added). To illustrate, the Petition asserts that, if "there is a 50-50 chance that a patent holder will prevail in litigation," a settlement that precludes that generic's entry for the life of the patent is anticompetitive because "consumers would lose the 50 percent chance they had of enjoying the benefits of competition." *Id.* at 17-18.

For purposes of certiorari, the initial problem with this rationale is that it cannot be found in the Commission's opinion. The Petition may now assert that "the Commission's analytical approach did not turn on 'the untenable supposition that without a payment there would have been different settlements . . ., resulting in earlier entry dates,'" Pet. 18, but that is precisely what the Commission said, on multiple occasions.[8] Indeed, the Commission specifically denied that its rationale was related to the "prospect" that one or the other of the litigants would prevail in the litigation:

> We cannot assume that Schering had a right to exclude Upsher's generic competition for the life of the patent any more than we can assume that Upsher had the right to enter earlier. In fact, *we make neither assumption*, but rather 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.

Pet. App. 81a-82a (emphasis added).

Equally as important for purposes of certiorari, the Eleventh Circuit made no reference to, and hence engaged in no analysis of, the "probabilistic" theory. Instead, the Court of Appeals took the Commission at its word: "The Commission's opinion requires the conclusion that but for the payments, the parties would have fashioned different settlements with different entry dates." Pet. App. 30a. The court below rejected that conclusion both for its flawed "logic," *id.*, and for the (now conceded) lack of evidence to support it. *Id.* at 30a-31a. The underlying merits of the patent litigation, however, whether based on probabilities or expected values of unknown judicial outcomes, were neither mentioned nor evaluated by the Court, because "FTC complaint counsel conceded 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." *Id.* at 20a.

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[8] The controlling issue, according to the Commission, was whether the settlement payments "delayed generic entry beyond the dates that would have been agreed upon in the absence of the payments." Pet. App. 54a. *See id.* at 82a (agreement was "unreasonable" if it "delayed generic entry beyond the date that would have been provided in a differently crafted settlement").

Certiorari is routinely denied where a given legal doctrine has not been adequately tested and analyzed by the lower courts. That ensures that the Court's review will benefit from the wisdom of those who have considered and applied the doctrine before it. Certiorari is particularly inappropriate where, as here, the proposed rationale has not even been considered in the case for which the writ is sought.

2. The "probabilistic" theory on which the Petition now rests was first advanced by an economist, Professor Shapiro, and has been echoed in a law review article by Professor Hovenkamp and two co-authors.[9] On this basis, the Petition represents that the theory is advanced by "both economists and legal scholars." Pet. 16. But the Petition cites no court decision embracing or even discussing the theory, and for good reason. No circuit court decision has yet to consider it. A few district courts, though not cited in the Petition, have addressed the theory in the Hatch-Waxman context. Judge Posner, sitting by designation as a District Judge and citing both the Shapiro article and the Hovenkamp article, observed that, "[w]hether it is a sound theory may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent." *Asahi Glass*, 289 F. Supp. 2d at 994. And Judge Trager, moreover, rejected the theory in a detailed analysis, as legally and conceptually flawed. *Ciprofloxacin*, 363 F. Supp. 2d at 531-34.

As these decisions and other critiques of the theory show, it is not yet sufficiently developed to merit review in this Court.[10] As noted, the theory posits that the possibility that

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[9] Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003).

[10] In fact, there is evidence that the probabilistic theory is still developing not only in the Courts, but in the minds of its authors as well. The initial premise of the theory is that "unlike forms of property that are

the generic challenger may win the patent case constitutes a form of "consumer surplus" that the settling parties are obligated to convey through their settlement. *Ciprofloxacin*, 363 F. Supp. 2d at 531. "'Effectively, consumers have a "property right" to the level competition that would have prevailed, on average, had the two parties litigated the patent dispute to a resolution in the courts.'" *Id.* (quoting Shapiro, *supra*, 34 RAND J. OF ECON. at 396). The professor put the term "property right" in quotation marks, and rightfully so. As the *Ciprofloxacin* court observed, "there is no support in the law" for the "concept of a public property right in the outcome of private lawsuits." *Id.* In fact, this probabilistic

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defined in terms of title to tangible items," patents are "probabilistic." Pet. 16. Thus, in the Minnesota Law Review, Professors Hovenkamp, Janis, and Lemley state: "As Carl Shapiro has pointed out, a patent is not a right to exclude, but rather a right to *try* to exclude." 87 MINN. L. REV. at 1761 (emphasis added). Yet, the current version of the Areeda Treatise, which also bears Professor Hovenkamp's name, takes a decidedly different approach:

> [A] patent is presumptively not a monopoly at all; it is merely *the right to exclude others* from copying a particular process or product. As such it is *no different from any other property right* — for example, ownership of an airplane or pipeline entails the right to exclude others from using it.

III Areeda & Hovenkamp, *supra*, ¶ 704, at 159 (2d ed. 2002) (emphasis added). This latter observation, while in conflict with the "probabilistic" theory, is in keeping with the mainstream view of patents as property: "Intellectual property is intangible, but the right to exclude is no different in principle from General Motors' right to exclude Ford from using its assembly line, or an apple grower's right to its own crop." Frank H. Easterbrook, *Intellectual Property Is Still Property*, 13 HARV. J.L. & PUB. POL'Y 108, 109 (1990). As Justice Holmes once said, the patentee's right to exclude is the same of that of an "owner of a five acre lot. A patent is property carried to the highest degree of abstraction — a right *in rem* to exclude, without a physical object or content." Letter from Holmes to Pollock, June 26, 1894, in 1 HOLMES-POLLOCK LETTERS: THE CORRESPONDENCE OF MR. JUSTICE HOLMES AND SIR FREDERICK POLLOCK, 1874-1932, at 53 (Harvard Univ. Press 1941).

theory is contrary to several general principles of established law:

First, a patent holder simply has "no duty to use patent-derived market power in a way that imposes the lowest monopoly rents on the consumer." *Id.* at 532 (citing *United States v. Studiengesellslchaft*, 670 F.2d at 1127). The notion that a settlement within the scope of a patent's exclusionary effect may still reduce competition because "every patent is 'a little bit invalid' results in undermining the presumption of validity that Congress has afforded patents." *Id.* at 533 (citing 35 U.S.C. § 282).

Second, even more generally, the law does not require private parties acting within the law to shape their agreements to advance the public interest. Thus, the Second Circuit emphatically rejected the argument that a settlement would injure the public interest by preserving a suspect trademark:

> We see no justification to force these defendants, who wish only to settle the present litigation, to act as unwilling private attorneys general and to bear the various costs and risks of litigation.

Nestle Co. v. Chester's Market, Inc., 756 F.2d 280, 284 (2d Cir. 1985).

Third, the probabilistic theory's attempt to substitute the possibility of harm (whether 50%, 10%, or 2%) for actual harm will not suffice to show a violation of the Sherman Act, which requires "an *actual* adverse effect on competition." *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 543 (2d Cir. 1993) (emphasis in original). Indeed, no area of the law permits a plaintiff to substitute the possibility of harm for proof of actual harm. *See, e.g.*, RESTATEMENT (SECOND) OF TORTS § 433B cmt. l (1965) ("A mere possibility of such causation is not enough; and when the matter remains one of pure speculation and conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant.").[11] Trying to determine in hindsight which party would have prevailed in patent litigation is entirely too speculative to convert possible competitive harm into actual competitive harm. *Ciprofloxacin,* 363 F. Supp. 2d at 531-34 (holding that plaintiffs' theory that but for the settlement the generic challenger would have prevailed in the patent litigation is too speculative to support injury-in-fact).

In addition to these legal problems, others have pointed to the probabilistic theory's theoretical flaws.[12] It purports to be focused on the evil of payments by the patentee, but its reasoning would label settlements employing licenses anticompetitive as well. All settlements remove the "chance" of a generic victory, and the terms of the license may or may not convey *any* "consumer surplus," or at least not enough to suit the FTC. *See Ciprofloxacin,* 363 F. Supp. 2d at 533 ("To open royalty-bearing patent license agreements to antitrust scrutiny simply because patents are often held invalid when tested in litigation would undermine the settled expectations of patentees and potential infringers/licensees across countless industries.").

The probabilistic theory is also unworkable in practice. Even if a settlement could properly be measured against the "expected" litigation outcome, that "consumer surplus . . . would first have to be quantified." *Id.* at 532.

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[11] *See In re Bell Petroleum Servs., Inc.*, 3 F.3d 889, 909 (5th Cir. 1993) (proof by less than "'fifty-one percent,' or to the extent of 'more likely than not,' . . . is unacceptably speculative, and amounts to mere *possibility*, not probability") (Parker, J., concurring in part and dissenting in part) (emphasis in original); *Gideon v. Johns-Manville Sales Corp.*, 761 F.2d 1129, 1137 (5th Cir. 1985) ("Possibility alone cannot serve as the basis for recovery, for mere possibility does not meet the preponderance of the evidence standard . . . .").

[12] *E.g.*, Crane, *supra*, 88 MINN. L. REV. at 704; Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1060-67 (2004).

Yet even the authors of the articles concede that they cannot account for such elementary factors as asymmetric expectations (the facts that the parties do not agree on the percentage "chance" of losing) and risk aversion (one party's willingness to pay more than another for the same chance of losing).[13] In the end, the probabilistic theory would substitute one inquiry already known to be speculative (who would have won the patent case?) with an inquiry vastly more speculative (what is the percentage "chance" of the patent being defeated to which consumers are entitled?). The resulting negative impact on incentives to settle would be obvious, as "[l]itigants would fear third-party challenges to settlements based on unknowable conceptions of what 'consumer surplus' might have occurred had litigation continued." *Ciprofloxacin*, 363 F. Supp. 2d at 532.

It is not the obligation of this Court to remedy the flaws and reconcile the inconsistent articulations of the probabilistic theory, when not a single Court of Appeals has addressed it. Certiorari should be denied unless and until the probabilistic theory is adequately addressed and applied by the lower courts, and — as an absolute minimum — actually employed in the case for which certiorari is sought.

CONCLUSION

For the foregoing reasons, the *Amicus Curiae* respectfully requests that the petition for certiorari be denied.

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[13] Shapiro, *supra*, 34 RAND J. ECON. at 397 ("The proper treatment of asymetric information . . . is beyond the scope of this article. Relaxing this assumption leads to a rich area for further research."); *id.* at 410 ("Risk aversion could also be included [in further research].").

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