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

SUPPLEMENTAL BRIEF FOR THE PETITIONER

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This supplemental brief is filed pursuant to Rule 15.8 of the Rules of this Court, to address the arguments presented by the United States in its brief as amicus curiae ("U.S. Br."). The United States acknowledges many of the key factors that support the grant of certiorari: that the antitrust treatment of patent settlements involving "reverse" or exclusion payments is an important and unsettled issue (U.S. Br. 8, 19, 20); that settlements involving such payments pose risks for competition and consumers (*id*. at 8); that such payments "can be a device for the sharing of monopoly rents" (*id.* at 9); and that the potential for consumer harm is particularly acute in cases involving pharmaceuticals subject to the Hatch-Waxman Act, where settlements can delay the marketing of low-cost generic drugs for many years (*id*. at 9-10).

Despite the acknowledged importance of the legal issue presented by the petition, the United States asks that the Court await a hypothetically more suitable vehicle for review. The reasons it advances, however, fail to refute the Commission's showing that plenary review is both appropriate and much needed. In its observations on the merits, the United States fails to appreciate the extent to which the ruling below will place pharmaceutical patent settlements beyond antitrust scrutiny, or the fundamental inconsistency between such a rule of law and the policies of Congress, as set forth in the Hatch-Waxman Act. The United States also overstates the difficulty this Court would have in reversing a court of appeals ruling that wholly disregards the proper standard of review of administrative factfinding.

Most importantly, however, the United States does not address the urgent practical reasons why immediate review is needed. As the Commission and several amici have explained, the economic impact of the ruling below on consumers of prescription drugs – including the States – is staggering. See Pet. 24-25; States Br. 11-14; AARP Br. 9-14; Waxman Br. 2-3; NACDS Br. 4-6. Indeed, billions of dollars in added prescription drug costs *annually* are at stake. See Pet. 25 & n.23. The decision below has "opened a Pandora's box" of anticompetitive settlements between brands and generic competitors.[1] Although there was a five-year lull in pay-offs to potential competitors after the Commission commenced enforcement

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[1] Stephanie Kirchgaessner and Patti Waldmeir, *Drug patent payoffs bring a scrutiny of side-effects*, Financial Times UK, Apr. 25, 2006, 2006 WLNR 6910048 (quoting Cowen & Co. analyst's report on decision below). The same article points out "how damaging" a single settlement in this area can be, noting that American consumers saved $2.5 billion due to the early entry of a generic form of the drug Prozac, but only after the branded company refused to pay off the generic challenger, due in part to antitrust concerns, and a court ruled in the generic's favor.

actions aimed at exclusion-payment settlements, pharmaceutical companies have once again started entering into settlement agreements that include both compensation in various forms to generic challengers and restrictions on generic market entry.[2] Harm is very likely ongoing each day that the decision below prevails.

1. In arguing that immediate review is not needed, the United States misreads the court of appeals' ruling, supposing that the ruling would permit an antitrust plaintiff to establish liability on the basis of a *post hoc*, "direct" evaluation of the patent litigation merits. See U.S. Br. 11-12, 17-19. We have explained previously why it is apparent that the court of appeals' reasoning extends to any non-"sham" assertion of patent coverage, within the nominal term of the patent. See Pet. 14-16; Pet. Reply 2-3. It is incongruous to suppose, as the United States apparently does, that the court of appeals is prepared to accept a rule that liability may be based on a "limited examination" of the patent merits, U.S. Br. 17, 11 n.1, when that court has rejected a subsequent authoritative adjudication of patent invalidity as a basis for condemning an exclusion-payment settlement. See *Valley Drug Co.* v. *Geneva Pharms., Inc.*, 344 F.3d 1294, 1306-1307, 1309 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004).[3] Other courts have understood the ruling below to demand only an inquiry into the nominal reach of the patent, and not an assessment of the

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[2] FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005–A Report by the Bureau of Competition*, at 3, <www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>.

[3] Moreover, the United States, like the court of appeals, further errs in supposing that the administrative law judge ("ALJ") assessed the strength of the patent. U.S. Br. 18. On the contrary, the ALJ disavowed any such analysis, concluding that "[o]pinions on the merits of cases that settle before the court decides them can never be tested." Pet. App. 265a.

likelihood that the patent-holder could successfully effect exclusion through patent litigation. See, *e.g.*, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 539 (E.D.N.Y. 2005), *appeal docketed*, No. 05-2851 (2d Cir. June 7, 2005) ("*Cipro*") (the ruling below "is more fairly read as requiring an evaluation of the scope of the patent's claims, and not a *post hoc* analysis of the patent's validity"). Indeed, as the United States acknowledges, the Second Circuit's ruling in *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) ("*Tamoxifen*"), expressly embraces the "sham" standard, while also expressly following the ruling below. U.S. Br. 19; see 429 F.3d at 396-397.

Furthermore, any suggestion in the United States' brief that a "mini-trial" on the patent merits is a required part of every antitrust analysis conflicts with rule of reason principles, and only adds to the array of conflicting positions on the issue presented. As the Commission explained in its opinion, such a *post hoc* review may be appropriate in some circumstances – most particularly in private actions where damages are at issue – but it was neither necessary nor helpful in the present case. See Pet. App. 80a-87a. A key drawback to such an approach – discussed in the Commission's opinion, but not addressed in the United States' brief – is that it places parties contemplating settlement in the predicament of not knowing, at the time of settlement, whether particular settlement terms will appear unreasonable to a future antitrust tribunal. See Pet. App. 86a-87a. More fundamentally, such an after-the-fact assessment is simply unnecessary where, as here, the contemporaneous actions of knowledgeable economic actors – particularly the generic firms' refusal to defer entry absent substantial payments by the patent-holder – provide a more reliable indication of the strength of the patent, and of the exclusionary nature of

the agreement.[4] See Pet. App. 85a-86a. Imposition of a rigid requirement that a "direct" assessment of the strength of the patent is necessary in all such cases would be at odds with this Court's teachings that the Commission is entitled to rely upon "common sense and economic theory," *FTC* v. *Indiana Federation of Dentists*, 476 U.S. 447, 456 (1986), and that antitrust analysis under the rule of reason is a flexible enterprise, requiring "an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint," *California Dental Ass'n* v. *FTC*, 526 U.S. 756, 781 (1999).

Far from supporting the denial of review in the present case, the United States' proffer of yet another approach to this difficult issue simply adds to the disarray among the lower courts – and the state and federal authorities that enforce the antitrust laws – that warrants this Court's attention.

2. The ruling below not only conflicts with basic antitrust principles, but it vitiates specific congressional policies of the Hatch-Waxman Act. See Pet. 3-6, 20-22. The United States makes the same error as the court below when it concludes that the profitability of collusive patent settlements under the Act provides "unique justifications" for such collusion. U.S. Br. 10; see *id*. at 7 (exclusion-payment settlements are a "'natural by-product of the Hatch-Waxman process'" (quoting Pet. App. 32a)). The United States indicates that exclusion payments may be necessary to redress "gross disparities in the litigants' respective risks," occasioned by the generics' ability to "force" a branded company into litigation prior to "actual infringement." U.S. Br. 10. But Congress itself has spoken to the

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[4] In the present case, moreover, the Commission found substantial *additional* evidence of the parties' expectations regarding likely generic entry. Pet. App. 68a-70a. Further, respondents failed to adduce evidence to rebut complaint counsel's prima facie case, such as benefits to a "cash starved" generic company or the effects of differing assessments and degrees of risk aversion by the parties. Pet. App. 89a-90a.

"conflicting policy considerations" the United States discusses. *Ibid.* It is the prerogative of Congress to define the act of infringement that gives rise to an infringement suit, to determine whether and how to encourage the early litigation of weak patent claims, and otherwise to decide how to facilitate the early market entry of generic drugs. The court of appeals' decision, reflecting *its* view of "policy," Pet. App. 35a, flouts that of Congress itself. See Pet. 4-5; 20-22; see also Waxman Br. A proper respect for the powers of Congress ought to compel at least a full examination of the arguments in this case.

In any event, the United States is mistaken in supposing that a branded company may be "forced" into such litigation. The choice remains with the branded company whether to take advantage of the 30-month stay that comes with prompt initiation of litigation, or instead shift the risk to the generic by waiting to sue until the generic has made the difficult choice of entering the market despite the risk of damages. See Pet. 3-4; see also *Teva Pharms. USA, Inc.* v. *Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005) (denying standing of generic applicant to compel adjudication of patent dispute by means of a declaratory judgment action, where the branded company has declined to commence an infringement action). Regardless of when the branded company elects to sue, however, both sides have much at stake, in terms of losses of anticipated future revenues, and may seek to limit those losses by means of settlement. As shown by industry experience during the years prior to the court of appeals' ruling in this case, litigants in such cases were in fact able to settle cases, *without* exclusion payments, by other means – most notably by compromising on entry dates.[5] See Pet. 22 (citing FTC report

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[5] As the Commission has noted (Pet. 18), a settlement that contains the parties' compromise on an entry date without cash payments presumably would reflect the parties' own assessment of the strength of the patent, and thus does not normally raise antitrust concerns. See Pet. App. 75a-76a.

on FY 2004 Hatch-Waxman settlements).[6] Thus, although the United States is correct to be concerned that an overly stringent rule might "frustrate[]" the public policy favoring settlements, U.S. Br. 10-11, the history of patent settlements in the pharmaceutical industry shows that the Commission's rule of reason analysis, drawing reasonable inferences from the existence of substantial exclusion payments, has not chilled legitimate settlements.

3. a. The United States also errs in suggesting that factual complexity or "unusual circumstances" make this case an unsuitable vehicle for consideration of the important antitrust issues presented. U.S. Br. 14, 15. As to the factual issue regarding the agreement between Schering and Upsher, the United States overstates the difficulty of this Court's task. Although the underlying evidentiary record is substantial, the Commission's opinion carefully recounts its review of the record evidence and its reasons for arriving at findings different from those of the ALJ. See, *e.g.*, Pet. App. 92a-96a, 108a-110a, 130a-133a. One need look no further than these passages and the corresponding ALJ findings to recognize that the Commission's findings were well grounded in the record, and, accordingly, that the court of appeals' ruling at best represents the choice of one possible set of inferences over that of the Commission, on the basis of a mixed evidentiary record. Such appellate factfinding is flatly contrary to this Court's directives. See *FTC* v. *Indiana Federation of Dentists*, 476 U.S. at 454 (reviewing court may not choose among "uncertain and conflicting inferences") (citation omitted).

The court of appeals' rote utterance of correct legal standards (Pet. App. 10a-11a) should not insulate its errors from

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[6] FTC, *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*, <www.ftc.gov/os/2005/01/050107medicareactrpt.pdf>.

review. Just this Term, in a case arising in another context in which Congress has prescribed deferential review of a designated factfinder, the Court reversed a court of appeals that had "recited the proper standard of review," but "improperly substituted its evaluation of the record for that of the [lower tribunal]." *Rice* v. *Collins*, 126 S. Ct. 969, 971 (2006) (habeas corpus review under 28 U.S.C. 2254). The present court of appeals' egregious misapplication of "settled rules that limit its role and authority," *id.* at 972, similarly warrants this Court's attention, and certainly should not preclude review of the vitally important underlying issue.

b. In any event, the agreement between Schering and ESI continues to provide an independent basis for this Court's review of Question 1 of the petition. The United States draws precisely the wrong conclusion from the fact that $10 million of Schering's payment to ESI was contingent on FDA approval of ESI's generic drug, citing that undisputed fact as somehow a complicating factor in analyzing the reverse-payment settlement. U.S. Br. 15. The conditioning of this payment on FDA approval, however, corroborates the conclusion that the $10 million was indeed an *exclusionary* payment: it was triggered only as ESI became a more imminent competitive threat, and was therefore a naked payment to stay out of the market. The contingent nature of the payment is an illuminating factor in this Court's understanding of the reverse-payment dynamic, rather than a complicating one. Similarly, the fact that the ESI settlement resulted from a court-assisted mediation process (U.S. Br. 14-15) does not militate against review, because the court of appeals' broad ruling applies to all exclusion-payment settlements, no matter how they are reached.

4. Although it is always possible for an issue dividing the lower courts to become more clearly defined through further litigation, there is substantial tension in the approaches adopted by the lower courts to date. The court below, now joined by the Second Circuit, condones pharmaceutical patent settlements as

long as exclusion is within the nominal scope of non-"sham" patent claims. See Pet. Reply 2-3; *Tamoxifen*, 429 F.3d at 396-397. By contrast, the Sixth Circuit has adopted a line of reasoning that appears to lead in a very different direction, recognizing the potential of such agreements "to bolster the patent's effectiveness" by "paying the only potential competitor * * * to stay out of the market." *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003), *cert. denied*, 543 U.S. 949 (2004); see also *Andrx Pharms., Inc.* v. *Biovail Corp. Int'l*, 256 F.3d 799, 809, 813 (D.C. Cir. 2001) (recognizing, in rejecting arguments for dismissal of antitrust claim for supposed lack of injury, that payment to generic may support inference that it was quid pro quo for delayed entry). Although certain aspects of the *Cardizem* ruling made it an unsuitable vehicle for review (U.S. Br. 17; Pet. 23 n.18), it and the present case nevertheless reflect an uncertainty in the law that can only be addressed by this Court.

Nor is there any reason to believe that pending or future private litigation will afford this Court a superior and timely opportunity to address this issue. Although the United States points to the possibility of review in the *Cipro* litigation (U.S. Br. 16), the Second Circuit has already staked out a position parallel to that of the court of appeals in the present case, as discussed above. In the absence of en banc reconsideration in the *Tamoxifen* case, the pending appeal in *Cipro* is unlikely to shed further light on the issue.[7]

Further, this Court's exercise of its broad discretion to grant certiorari is guided by many factors, including the importance of a lower court ruling to the Nation's economy. See, *e.g.*, *Texaco Inc.* v. *Dagher*, 126 S. Ct. 1276, 1279 (2006). The United States and the Commission recently advised the Court

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[7] In light of the pendency of the petition for rehearing in *Tamoxifen*, and the possibility of the filing of a petition for certiorari in that case, the Court may wish to hold the present case pending final resolution of that case.

to grant certiorari in another antitrust case, despite the lack of a "square * * * conflict" in the lower courts, because it presents an important antitrust issue "in the context of a complete factual record," and because the court of appeals ruling "threatens to chill procompetitive conduct" by firms subject to suit in the Ninth Circuit. See Brief for the United States as Amicus Curiae, *Weyerhaeuser Co.* v. *Ross-Simmons Hardwood Lumber Co., Inc.*, No. 05-381, at 19-20 & n.13 (filed May 26, 2006). The present ruling also follows a thorough adjudication, and insulates imminent anticompetitive conduct from Commission enforcement actions nationwide. See Pet. 23-24. Review is even more urgently needed in the present case, to protect consumers of prescription drugs from extensive economic injury.

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For the foregoing reasons and those stated in our petition and reply, the petition for a writ of certiorari should be granted.

Respectfully submitted.

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