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

REPLY BRIEF FOR THE PETITIONER

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The promotion of early market entry by low-cost generic drugs in competition with branded drugs is a national policy of critical importance. Respondents do not deny the major economic implications of delayed generic drug entry, not only to individual consumers but also to the States and other health care payors. Nor do respondents seriously dispute that Congress has repeatedly and expressly sought to promote early challenges to patent claims that stand in the way of such entry. Instead, they attempt to brush off the ruling below as a case-specific implementation of accepted principles, dependent on factual findings. In fact, however, the court of appeals fashioned a rule of law "reflect[ing]" its own notions of "policy," Pet. App. 35a, a rule that ignores basic antitrust principles, actively assails the congressional policies of the Hatch-Wax-

man Act, and provides pharmaceutical companies with a roadmap for sharing monopoly profits rather than competing. Given the number of pending patent cases involving generic drug challengers and potential consumer injury in the billions if patent holders can simply pay these challengers to go away, this Court's consideration of these issues is urgently needed.

1. a. This case puts into sharp focus an issue that is fundamental to antitrust doctrine in the Hatch-Waxman context: whether a branded drug seller can buy protection from potential generic competition so long as the competition excluded falls within the nominal scope of a non-sham patent claim. Respondents attempt to slough off the legal significance of the issue by emphasizing the "common ground" on which "*all agree*," Resp. Br. 3, 16, and characterizing the Commission's ruling as a flawed "implementation" of an agreed framework. *Id.* at 19-20. In reality, however, the court of appeals and the Commission have articulated and applied dramatically different rules of law, which have dramatically different consequences for competition and consumers.

As we have explained, Pet. 14-16, the court of appeals' ruling here must be understood in conjunction with its earlier decision in *Valley Drug Co.* v. *Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, No. 03-1175 (Oct. 12, 2004). In *Valley Drug*, the court of appeals ruled (correctly) that the reasonableness of any settlement agreement must be judged "at the time [it is] entered into," and, accordingly, ruled that a subsequent adjudication against the patent claims did not advance the antitrust claim. 344 F.3d at 1306, 1309. Thus, respondents' suggestion that a *post hoc* inquiry into the patent merits would satisfy the court of appeals, Resp. Br. 12, 18-19, is disingenuous, because *Valley Drug* precludes a conclusion of liability on that basis.

The present ruling goes beyond *Valley Drug* and completes the barrier against antitrust liability for patent settlements. *Valley Drug* held that a plaintiff cannot rely on a *post hoc*

inquiry into the merits, and the ruling below proceeds on the flatly erroneous premise that there is a presumption of both patent validity *and* infringement. These rulings together effectively immunize all payments to delay generic competition, provided the delay does not extend beyond the nominal scope of an untested patent, unless the patent claim is an obvious "sham," Pet. App. 20a, or the patentee "knew" that its claim was without merit, 344 F.3d at 1309.

b. The Commission, by contrast, recognized that allowing a branded drug company to "buy off" a would-be generic entrant is contrary to both basic antitrust principles and the clear directives of the Hatch-Waxman Act, even if the generic's prospects for successful entry are uncertain.[1] Contrary to the assertions of *amicus* Bayer Corporation, Br. 13-20, the Commission's antitrust analysis took account of the uncertainties inherent in patent litigation, and there was nothing novel about doing so. As the Commission pointed out,

> The uncertainty posed by patent litigation is, of course, only one of many types of uncertainty that affect whether a new product can be successfully introduced into a market. But the existence of such uncertainties cannot justify an agreement whose very purpose is to ensure against an increase in competition * * * .

Pet. App. 84a n.62. This holding derives from basic antitrust principles this Court has repeatedly recognized. See Pet. 15 (citing, *inter alia*, *Palmer* v. *BRG of Georgia, Inc.*, 498 U.S. 46

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[1] The legal analysis of the court below is also at odds with that of the Sixth Circuit, in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharms., Inc.* v. *Kroger Co.*, No. 03-779 (Oct. 12, 2004). See Pet. 23; States Br. 7 ("The Sixth Circuit and the Eleventh Circuit cannot both be correct"). The extent of the inconsistency between the Sixth and Eleventh Circuits was far less apparent before the ruling in this case, which completed the barrier against antitrust challenges to patent settlements. *Cf.* Resp. Br. 20; Bayer Br. 7-8.

(1990) (per curiam), and *United States* v. *Griffith*, 334 U.S. 100 (1948)). The Commission's ruling is not based on some theory of a "consumer property right" in such uncertainties, Bayer Br. 14, but on the common-sense notion that it is unlawful for a competitor to buy off threatened, albeit uncertain, competition.

Respondents and *amicus* are wrong, in any event, to deny the public interest in the judicial resolution of disputed patent claims. In *United States* v. *Singer Mfg. Co.*, 374 U.S. 174 (1963), Justice White explained that a patent interference settlement that was part of the conduct the Court held unlawful harmed the public interest because it prevented the possibility that the patent would be invalidated altogether. *Id*. at 199-200 (White, J., concurring). As he further observed, "[t]he patent laws do not authorize, and the Sherman Act does not permit, such agreements between business rivals to encroach upon the public domain and usurp it to themselves." *Id*. at 200.[2]

The Commission's holding was not only compelled by antitrust principles, but is also essential to fulfill the policies of the Hatch-Waxman Act. As we have explained, that statute was enacted to encourage the early resolution of disputed pharmaceutical patent claims, and Congress amended it in 2003 to provide specifically for antitrust review of settlements like the present one by the Commission and the Department of Justice. See Pet. 20-22; Waxman Br. 2-10. The opinion below is overtly hostile to those statutory goals. The court bemoans the "caustic environment" of patent litigation and finds shocking the prospect that a statutory scheme designed to promote chal-

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[2] See also *Blonder-Tongue Labs., Inc.* v. *Univ. of Illinois Found.*, 402 U.S. 313, 343 (1971) ("The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope") (quoting *Precision Instrument Mfg. Co.* v. *Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945)).

lenges to patent claims might actually "cost Schering its patent." Pet. App. 33a, 31a.

c. Respondents distort the Commission's ruling by contending that it amounts to a "*per se*" rule based on a "theory that payments [by the patentee] render settlements anticompetitive." Resp. Br. 11, 19-20. In fact, the Commission looked to the existence of these payments not as an evil in itself or as *per se* improper, but as a reflection of the parties' own assessment of their respective prospects in patent litigation. ESI, for example, was *not* willing to trade off its chance of success in litigation for guaranteed entry in January 2004, but it *was* willing to accept that entry date plus $15 million (including $5 million purportedly for attorneys' fees). Pet. 7. As the Commission recognized, the parties are in a better position to understand the strengths and weaknesses of their patent claims, and such actions – if unexplained – provide a far more reliable gauge of the real strength of the patent claims than second-guessing by an antitrust tribunal.[3] See Pet. App. 80a-87a. The Commission declined respondents' invitation to adjudicate the patent merits as part of the antitrust analysis, because contemporaneous actions are far more probative than *post hoc* rationalizations.[4]

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[3] In any event, respondents are wrong in asserting that their evidence regarding the strength of Schering's patent claim was unrebutted, and that generics "would have been excluded" for the full patent term in the absence of settlement. Resp. Br. 5. The issue was contested at trial, and the ALJ determined it was not possible to predict the outcome of the patent litigations reliably. Pet. App. 264a-265a. Moreover, as shown previously, contemporaneous projections by respondents themselves presumed that generic entry would in fact occur well in advance of patent expiration. Pet. 8 n.4.

[4] The Commission also pointed out additional reasons why an *ex post* inquiry into the patent merits was neither necessary nor helpful, including the inherent unreliability of such inquiries and the prospect that such inquiries could "ultimately have a chilling effect on the efficient settlement of patent litigation." Pet. App. 81a; see *id.* at 80a-87a.

The Commission made clear, however, that its rule of reason analysis would permit a patent holder to justify settlements with payments that would promote efficiencies or other procompetitive effects. Pet. App. 61a-62a, 87a-91a. Respondents made no such showing, *ibid*., and are understandably silent on this issue in their brief in opposition.

Amicus Bayer Corporation attacks the strawman of a "'better settlement' theory," Bayer Br. 9-13, on which the Commission did not rely. While the Commission used a hypothetical cashless settlement as a benchmark for the expected outcome of litigation, Pet. App. 75a-76a (see Pet. 18-19), the ultimate focus of its inquiry was simply whether Schering's payments "resulted in a greater delay than would otherwise have occurred," Pet. App. 75a, whether the "otherwise" was an alternative settlement or the expected value of continued litigation. The failure of the court of appeals to discuss these principles, Bayer Br. 15, simply reflects the court's misunderstanding of the antitrust and patent principles at stake in this case.

2. Respondents attempt to forestall this Court's review of the important substantive issues presented by arguing that the analysis of the Upsher agreement turns on factual issues not worthy of this Court's attention and that the ESI agreement can be dismissed as unimportant. Resp. Br. 1-2, 12-16. Neither assertion bears scrutiny.

a. Respondents ignore the most salient aspect of the standard of review issue posed in Question 2 – *i.e.*, that it is the Commission's findings, not the administrative law judge's, that are to be tested against the record and, if supported by substantial evidence, accorded due deference by the court of appeals. *Consolo* v. *Federal Maritime Comm'n*, 383 U.S. 607, 618-620 (1966) (that substantial evidence may support a conclusion contrary to the commission's is no basis for overturning the latter); *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, 496 (1951) (the substantial evidence "standard is not modified in any way when the [agency] and its examiner disagree"). The

court of appeals' improper reliance on the ALJ's findings is pivotal to its analysis. See Pet. App. 25a-26a.

In an apparent effort to lend more weight to the ALJ's findings and diminish those of the Commission, respondents claim that the factual issue reduces to a simple arithmetic comparison of projected sales and money paid for patent licences. Resp. Br. 6-8. The relevant question, however, which the Commission analyzed in 40 pages of findings, was whether the totality of the evidence indicated that Schering's unconditional, up-front payment *really was* a royalty payment, or was instead in large part a payment for the exclusion of competition. See Pet. App. 92a-141a.[5] To the extent there was a "credibility" issue here, it was "not solely a function of the witness's demeanor but also of that testimony's inherent plausibility," in light of the context. See Breyer, Stewart, Sunstein & Spitzer, *Administrative Law and Regulatory Policy* (4th ed. 1999), at 222. The Commission had the responsibility and prerogative to make that assessment.

We recognize that the Court is generally reluctant to correct errors in the application of the substantial evidence test, but the error here is so blatant and the consequences so serious that review is warranted. See *Universal Camera,* 340 U.S. at 491 (Court will intervene where court of appeals has "grossly misapplied" test); accord *FTC* v. *Indiana Federation of*

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[5] There is, therefore, no inconsistency between the Commission's opinion and the statements elsewhere of its author, Commissioner Thomas B. Leary, regarding the difficulty of evaluating intellectual property. See Resp. Br. 10-11 n.7, 16 n.9. In fact, in both the article and the opinion, Commissioner Leary listed exactly the same factors as relevant when assessing whether a side deal amounts to an exclusion payment, including negotiation history, other offers for the intellectual property at issue or property with similar attributes, evidence based on subsequent events, and the structure of the payment terms. See Pet. App. 93a-139a; Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II* (May 17, 2001), at 6, available at: http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm.

Dentists, 476 U.S. 447, 454 (1986). 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.

b. In any event, no such factual dispute exists with regard to the ESI agreement, which the Commission assessed under the same principles as those it applied to the Upsher agreement. As respondents concede, Schering's $10 million payment that was contingent on FDA approval of ESI's competitive generic product had no purpose other than to induce ESI to enter into the agreement in which its market entry was precluded until 2004. Resp. Br. 6. Even assuming that Schering was responding to the pressures of the magistrate-supervised mediation, that does not change the fact that the settlement was a private agreement, entered into by sophisticated business parties for their mutual and substantial benefit, and was *not* approved by any court.

3. Finally, respondents make no serious effort to dispute the showings of the Commission and several *amici* about the staggering economic importance of the availability of generic drugs. Indeed, they acknowledge that "generic entry will bring lower prices." Resp. Br. 17 n.10; *cf.* Pet. 24-25; States Br. 11-14; AARP Br. 9-14; Waxman Br. 2-3; NACDS Br. 4-6. Respondents' attempts to minimize the impact of the present case, Resp. Br. 20-23, ignore the basic fact that whatever "*in terrorem*" effect on anticompetitive settlements the Commission's enforcement program may have had is vitiated by the ruling below. Respondents suggest enforcement under Section 5(m) of the FTC Act, 15 U.S.C. 45(m), but actions under that provision require an existing final Commission order, such as the one vacated here. Equally quixotic is respondents' supposition that a Commission order against an exclusionary settlement could pass muster in the Eleventh Circuit – to which any pharmaceutical company that does business there could appeal.

See 15 U.S.C. 45(c). As explained above, the combined effect of the court of appeals' decisions here and in *Valley Drug* precludes meaningful Commission review of patent settlements. See Pet. 21.[6]

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

Respectfully submitted.

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[6] That court's recent ruling in *Andrx Pharms., Inc.* v. *Elan Corp., PLC*, 421 F.3d 1227 (11th Cir. 2005), does nothing to ameliorate the effects of its prior rulings, for it is premised on the acceptance (at the dismissal stage) of allegations that the patentee and generic entrant conspired to use the generic's 180-day exclusivity period to block other competitors "from ever marketing a generic" version of the drug in question. 421 F.3d at 1235.