No. ___

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether 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.

2. Whether the court of appeals grossly misapplied the pertinent "substantial evidence" standard of review, by summarily rejecting the extensive factual findings of an expert federal agency regarding matters within its purview.

PARTIES TO THE PROCEEDING

Petitioner is the Federal Trade Commission. Respondents, who were petitioners in the court of appeals below, are Schering-Plough Corporation, and Upsher-Smith Laboratories, Inc.

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The Federal Trade Commission, pursuant to the authority of 15 U.S.C. 56(a)(3)(A), respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this case.[1]

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[1] The Commission has exercised its authority to represent itself before this Court only twice previously, in the 30 years that it has had that authority. See Pub. L. No. 93-637, § 204(a), 88 Stat. 2183, 2199-2200 (1975); *FTC* v. *Indiana Federation of Dentists*, 476 U.S. 447 (1986) ("*IFD*"); *FTC* v. *Superior Ct. Trial Lawyers Ass'n*, 493 U.S. 411 (1990). The Commission takes this step now not only to seek correction of a ruling that conflicts with fundamental antitrust and administrative law principles, but because of the great urgency of the matter, in light of the billions of dollars of consumer savings on prescription drugs that the ruling below jeopardizes. See *infra* at 24-26.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-35a) is reported at 402 F.3d 1056. The order of the court of appeals denying rehearing and rehearing *en banc* (Pet. App. 341a-342a) is unreported. The Opinion of the Commission and Final Order (Pet App. 36a-153a) will be reported at 136 F.T.C. ___. The Initial Decision of the Administrative Law Judge (Pet. App. 154a-340a) will be reported at 136 F.T.C. ___.

JURISDICTION

The judgment of the court of appeals was entered on March 8, 2005. A petition for rehearing was denied on May 31, 2005. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant portions of the Sherman Act, 15 U.S.C. 1; the Federal Trade Commission Act, 15 U.S.C. 45; the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman Act"); and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003) ("2003 Medicare Amendments") are set out in an appendix to this petition. Pet. App. 343a-363a.

STATEMENT

In the Hatch-Waxman Act, Congress sought to speed the entry of low-cost generic drugs into the market by encouraging challenges to patent claims that stand impermissibly in the way of entry. The Act has been remarkably successful; generic challengers have prevailed in most cases in which courts have

ruled on arguments that drug patents were either invalid or not infringed by the challengers, and American consumers have saved billions of dollars as a result.

The present case involves a stratagem that a number of pharmaceutical companies have used to frustrate Congress's resolve to subject drug patents to scrutiny, by entering into agreements that allow them to delay the entry of generic drugs and share the profits derived from maintaining high drug prices. In the two agreements at issue here, the generic manufacturers agreed to delay sale of their products until specified future dates in exchange for cash payments from the patentee. Because the parties anticipated that the patentee's enhanced profits from delayed generic competition would far exceed the generic competitors' lost profits, the parties could share a windfall, at the expense of consumers. Petitioner Federal Trade Commission ("Commission") applied well settled antitrust principles to rule that those agreements unreasonably restrained trade by foreclosing the possibility of earlier generic entry, but the court of appeals set aside the Commission's decision on the ground that any competition forgone was within the "exclusionary potential" of the patent claims, regardless of the purpose or effect of the agreements. Pet. App. 17a. By protecting agreements in which patentees buy off potential challengers from effective antitrust challenge, the ruling below conflicts with fundamental antitrust principles and threatens to vitiate an important statute designed to promote the health and economic well-being of American consumers. The ruling comes at a crucial point. Of the twenty top-selling prescription drugs in the United States today, eleven, with annual sales of nearly $25 billion, are currently subject to litigation by generics seeking to enter the market. See note 23, *infra*.

1. Congress intended that the Hatch-Waxman Act would "make available more low cost generic drugs," while fully protecting legitimate patent claims. H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1, at 14 (1984). The Act allows for

accelerated FDA approval of a drug through an Abbreviated New Drug Application ("ANDA"), upon showing that the new drug is "bioequivalent" to an approved drug. 21 U.S.C. 355(j). It also encourages the development of generic drugs by declaring various research and development activities non-infringing. 35 U.S.C. 271(e)(1); see *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, No. 03-1237, 125 S. Ct. 2372 (June 13, 2005).

The Act's incentive structure to accelerate the introduction of generic drugs begins with the requirement that the branded firm submit to the FDA a list of all patents that the firm claims cover its drug. 21 U.S.C. 355(b)(1). A generic firm submitting an ANDA must make a certification regarding the application of any listed patent to its product. Most pertinent here, a so-called "Paragraph IV certification" states that the patent is invalid or not infringed, and thus clearly identifies a patent dispute. 21 U.S.C. 355(j)(2)(A)(vii)(IV). Congress sought to encourage patent challenges by providing that the first generic applicant filing a Paragraph IV certification would obtain 180 days of marketing exclusivity. 21 U.S.C. 355(j)(5)(B)(iv). No parallel economic incentive is provided for ANDA filings that do not challenge the branded drug's patent. Congress likewise created an economic incentive for the patent holder to commence suit upon receiving a Paragraph IV notification. Upon receipt of notice from an ANDA filer, the patent holder receives an automatic 30-month stay prohibiting generic entry into the market, if it sues the generic for infringement within 45 days. 21 U.S.C. 355(j)(5)(B)(iii). If such litigation is not commenced within 45 days, however, the FDA approval process may proceed, and the FDA may approve the ANDA as soon as regulatory requirements are fulfilled. *Ibid*.

As reflected in the instant case, the parties to such litigation can use settlements to carve up the market between them to avoid the risks of competition. There is no indication, however, that Congress meant to pre-empt the application of settled

antitrust principles to such settlements. Indeed, prompted in substantial part by congressional concern over the competitive effects of agreements such as those at issue here, Congress amended the Hatch-Waxman Act as part of the 2003 Medicare Amendments, *supra*. Those amendments sought in part to stamp out the "abuse of the Hatch-Waxman law" resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market." S. Rep. No. 167, 107th Cong., 2nd Sess., at 4 (2002). In the words of Rep. Waxman, "[t]he law has been turned on its head. * * * We were trying to encourage more generics and through different business arrangements, the reverse has happened." Cheryl Gay Stolberg et al., *Keeping Down the Competition; How Companies Stall Generics and Keep Themselves Healthy*, The New York Times, July 23, 2000, at A11 (quoting Rep. Waxman). Among the various corrective measures to address such abuses, the amendments require pioneer drug companies and generic applicants who enter into patent litigation settlements to file those settlement agreements with the Commission and the Department of Justice for antitrust review. Pub. L. No. 108-173, §§ 1111-1118 (Pet. App. 360a-363a). In the event that such an agreement is found to violate the antitrust laws, the amendments provide that the generic party will forfeit any 180-day marketing exclusivity period it may have. 21 U.S.C. 355(j)(5)(D)(i)(V).

Experience has borne out the efficacy of this congressional scheme and the correctness of its premises – *i.e.*, that many patents will not stand in the way of generic entry if challenged, and that successful challenges can yield enormous benefits to consumers. The Commission studied all patent litigations initiated between 1992 and 2000 between branded drug manufacturers and Paragraph IV generic challengers, and found that the generics prevailed in cases involving 73 percent of the challenged drug products. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at 19-20

(July 2002), <www.ftc.gov/os/2002/07/genericdrugstudy.pdf> ("*FTC Generic Drug Study*"). Generic competition following successful patent challenges to Prozac, Zantac, Taxol, and Plantinol alone is estimated to have saved consumers more than $9 billion.[2] These savings result from the pricing policies of generic sellers, which generally price at a substantial discount from branded drugs. As a result of such price competition, as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, branded drugs lose an average of 44 percent of their sales within the first full year after launch of a lower-priced generic product.[3]

2. Respondent Schering-Plough Corp. ("Schering") markets "K-Dur 20," a potassium supplement generally taken in conjunction with drugs for high blood pressure or congestive heart disease. See Pet. App. 2a-4a, 48a-52a. At the time of the subject agreements, K-Dur 20 was the most frequently prescribed potassium supplement, with annual sales reaching $170 million by 1997. The active ingredient in K-Dur 20, potassium chloride, is in common use and is unpatentable. Schering owns a formulation patent ("the '743 patent") that relates to the material that coats the potassium chloride crystals, providing an extended-release mechanism. The '743 patent expires in 2006. Thus, a generic manufacturer can use the active ingredient in K-Dur 20 without infringing Schering's patent, so long as it uses a coating material not covered by the '743 patent.

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[2] *Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm.*, 107th Cong. (April 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12, <http://commerce.senate.gov/hearings/042302jaegar.pdf>.

[3] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, xiii (July 1998) ("*CBO Study*").

In 1995, two generic drug makers, ESI Lederle Inc. ("ESI") and respondent Upsher-Smith Laboratories, Inc. ("Upsher"), filed ANDAs for approval of generic versions of K-Dur 20, both with Paragraph IV certifications that the products they intended to market in direct competition with K-Dur 20 were non-infringing generic substitutes. Schering brought separate patent actions against ESI and Upsher, each within the respective 45-day period so as to trigger the 30-month automatic stay of FDA approval.

In late 1996, Schering and ESI began settlement negotiations. In March 1997, ESI proposed that Schering make a payment to ESI, in return for which ESI would delay its market entry. Pet. App. 251a-252a. The parties eventually reached such a settlement. *Id*. at 52a. A portion of the settlement covered a side deal for various product licenses, but it is undisputed that, separately, Schering agreed to pay ESI $15 million not to market any generic version of Schering's K-Dur 20 before January 2004. *Id*. at 142a n.101. Of that amount, $10 million had no proffered rationale other than warding off competition by ESI; ESI would receive it only if FDA approved ESI's application to sell its generic drug. *Ibid.* ESI ultimately obtained FDA approval, and Schering made the additional $10 million payment *Ibid*.

Two months after it began its settlement negotiations with ESI, Schering entered into settlement negotiations with Upsher. *Id*. at 97a. From the very first negotiating meeting, Upsher made a demand of $60-70 million from Schering to stay off the market. *Ibid.* On the eve of trial, Schering and Upsher entered into an agreement that settled their patent litigation. *Id*. at 50a. Schering agreed to make the unconditional, up-front $60 million payment Upsher had demanded, and Upsher agreed to forego marketing its generic product until September 2001. *Ibid.* Upsher also agreed to grant Schering a license to market six Upsher products in prescribed territories, with conventional royalties tied to the actual sales of those products. *Ibid.* The

$60 million unconditional payments were justified to Schering's board of directors as a "prerequisite of any deal" and as dictated by Upsher's desire for a guaranteed income stream to compensate it for lost revenue it otherwise would have earned from the generic potassium product. *Id.* at 97a n.78.

As a result of these agreements, Upsher and ESI remained off the market until 2001 and 2004, respectively, contrary to the parties' own prior expectations.[4] Market changes that occurred upon entry reflect the impact of the delayed entry. Upsher entered the market at a price approximately 50 percent of the price of K-Dur 20. Total branded Schering prescriptions fell from roughly 1,150,000 to approximately 390,000 within twelve months, and the lost 760,000 prescriptions were almost completely offset by sales of approximately 700,000 prescriptions of generic K-Dur. Pet. App. 72a-73a. Consumers thus saved many tens of millions of dollars in lower drug prices the first year after generic entry.

3. The Commission issued its administrative complaint in March 2001, charging that Schering's agreements with Upsher and ESI violated section 5 of the FTC Act, 15 U.S.C. 45. ESI entered into a consent agreement in April 2002, but respondents proceeded to trial; Schering sought to defend both agreements. An administrative law judge ("ALJ") dismissed the complaint in June 2002. Pet. App. 160a. The Commission reversed in December 2003, concluding on *de novo* review that the ALJ erred in several key factual findings and in his legal analysis.

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[4] Pre-settlement Schering documents showed that Schering had expected that generic entry would substantially erode its K-Dur 20 sales in 1998 and 1999. Pet. App. 69a. Upsher had similarly projected generic entry and lower prices starting in 1997, *id.* at 70a, and had informed the patent court in March 1997, after receiving tentative FDA approval, that the statutory stay on final approval was the only impediment to its immediate entry. *Id.* at 86a.

The Commission first determined that per se condemnation was not warranted, given the complexities of the patent litigation context in which the agreements arose. Pet. App. 60a-62a. Nevertheless, it concluded that the issue of market power could be addressed by direct proof of the effects of the introduction of generic K-Dur 20. *Id.* at 65a-67a (citing *IFD*, 476 U.S. at 460-461). The Commission found that there was abundant evidence that generic entry here was a "uniquely significant market event" that lowered prices and took substantial sales away from Schering, and therefore that delaying such entry had actual anticompetitive effects. *Id.* at 68a-75a.

The Commission then considered the exclusionary impact of the agreements in relation to that of the patent itself. It began with the observation that the strength of a patent does not depend simply on its expiration date, but on the probability that litigation will or will not prove the patent to be valid or, in this case, infringed. *Id*. at 81a-82a. Therefore, a hypothetical settlement in which the parties compromised on a time of entry without cash payments would reflect the strength of the patent as viewed by the parties. *Id.* at 75a-76a. The Commission further recognized, however, that Schering would not have made the large cash payments in this case without some *quid pro quo* and, in the absence of other consideration, it is logical to conclude that Schering was buying protection from the competition that could have resulted from the litigation. *Id.* at 76a-77a. The Commission found further support for this conclusion in the language of the settlement agreement and in the bargaining history – which, as noted above, began with Upsher's demand for a large cash payment. *Id.* at 77a. The Commission also considered whether a direct examination of the patent issues would be a better way to take account of the patent dispute in antitrust analysis, but concluded that such an inquiry was neither necessary nor appropriate here. *Id*. at 80a-

87a.[5] As the final step in its analysis, the Commission acknowledged that certain procompetitive effects of the agreements were "theoretically possible," *id*. at 61a, but found no evidence that those theories applied. *Id.* at 87a-92a.

With respect to the Upsher agreement, the Commission addressed in detail and rejected respondents' contention that the $60 million payment was entirely for side licenses conveyed under the agreement and not for Upsher's promise to delay its entry. Pet. App. 92a-141a. It found that the evidence demonstrated that the amount and unconditional nature of Schering's payment were based on Upsher's demand that it be compensated for its anticipated lost revenues during its absence from the market. *Id*. at 94a-107a. The Commission also rejected Schering's argument that one of the Upsher licences itself warranted the $60 million payment, finding that Schering's purported assessment of the Upsher product was belied by its own contemporaneous assessment of a similar product offered by a company that did not threaten it with generic competition.[6]

Schering's agreement with ESI evidenced on its face a promise to defer entry in exchange for cash payments. *Id.* at 142a. On those undisputed facts, and following the same

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[5] Although FTC staff argued that a post hoc adjudication of the underlying patent cases was unwarranted, it nonetheless also introduced evidence in support of the proposition that Schering faced a substantial risk that Upsher and ESI would be found not to infringe. Contrary to the court's assertion, however, the ALJ did not "evaluate[] the strength of the patent" (Pet. App. 15a), concluding that "the likely outcome of the patent disputes cannot be reliably predicted." *Id*. at 312a. He relied instead on an erroneous presumption of infringement. See *Id*. at 81a n.60.

[6] The Commission found Schering's product review perfunctory and not consistent with what Schering required in the past to evaluate a similar commercial opportunity. Pet. App. 108a-130a. Moreover, a more thorough and contemporaneous Schering analysis of a comparable product demonstrated that Schering in fact thought that those products did not justify a substantial, non-contingent payment. *Id*. at 111a-117a.

analytical approach it applied to the Upsher agreement, the Commission concluded that this agreement was an unreasonable restraint of trade. *Id*. at 142a-145a.

4. On Schering's and Upsher's petitions for review, the court of appeals set aside the Commission's decision. *Id.* at 2a. The court began with the startling premise that "neither the rule of reason nor the *per se* analysis is appropriate" in an antitrust case involving patents, and that the analysis must instead focus on the "exclusionary potential" of the patent, and whether the agreements had exceeded that potential. *Id*. at 16a-17a (citing *Valley Drug Co.* v. *Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied sub nom. Walgreen Co.* v. *Abbott Labs.*, No. 03-1178 (Oct. 12, 2004)). In assessing the exclusionary potential of the '743 patent, the court relied on the incorrect supposition that the patent provided Schering with "the legal right to exclude Upsher and ESI from the market until they proved either that the * * * patent was invalid or that their products * * * did not infringe Schering's patent," *id.* at 18a, and noted that there was no allegation that the patent claim was a "sham." *Id.* at 20a.

In particular, the court ruled that a payment by the patentee, accompanied by an agreement by the challenger to defer entry, could not support an inference that the challenger must have agreed to a later date in return for such payment, even if there was no other plausible explanation for the payment. In the case of the ESI agreement, for example, the court held that the $10 million payment that was directly linked to regulatory approval of the generic drug and for which no other consideration was attributed was lawful because it was "within the patent's exclusionary power." *Id.* at 28a. The court also cited, as to both agreements, the presumed public policy benefits of the settlement of litigation. *Id.* at 28a-29a. The court concluded that the existence or size of such a payment cannot be used to show that the patent holder has obtained a greater degree of market exclusion than its patent justified. *Id.* at 35a.

Despite these legal holdings, the court of appeals nevertheless reviewed and rejected the Commission's extensive factual findings in support of its conclusion that Schering had paid Upsher for delayed entry. *Id*. at 21a-26a. The court was particularly critical of the Commission's decision not to accept the "credibility" determinations of the ALJ (*id.* at 25a-26a), but declined to address the Commission's stated reasons for reaching its conclusions. *Cf. id.* at 94a-96a. The court of appeals criticized the Commission for taking the economic incentives of the parties into account in assessing the plausibility of their claims that the side deal itself warranted the $60 million payment. *Id.* at 23a-25a. The court referred to "overwhelming" evidence in support of the ALJ's findings (*id.* at 25a, 26a), but did not identify any such evidence.

REASONS FOR GRANTING THE PETITION

This case merits review by this Court to correct fundamental legal errors by the court of appeals that not only depart from settled antitrust and administrative law principles, but also dramatically alter Congress's intended balance between the patent and antitrust laws as applied to generic drugs. Contrary to this Court's teachings, the court of appeals' ruling essentially imposes a rule that a patentee is presumptively entitled to buy protection from all competition for the full patent term, even if such payments effectively augment the patent's actual exclusionary power. To fashion this rule, the court candidly stated that, to resolve this antitrust case, it would apply "neither the rule of reason nor the per se analysis" but would reach a result that "reflects policy." Whatever the source of that policy, it cannot be found in the Patent Act, which recognizes that infringement is not to be presumed but proven by the patentee; the Hatch-Waxman Act, which seeks to stimulate generic challenges to branded drugs; or the antitrust laws, which

prevent monopolists from buying off would-be rivals by the simple device of sharing monopoly profits with them.

Review of this error is urgently needed because the ruling below could seriously impede the Commission's law enforcement efforts on behalf of consumers nationwide. In light of the large number of leading drugs that are the subject of patent challenges, the economic stakes for the American consumer in this issue are staggering.

The court of appeals' reversal of the Commission's factual findings regarding the Upsher agreement also warrants review, because it departs so drastically from the established standard of appellate review. This issue does not, however, affect the court of appeals' analysis of the ESI agreement, which independently warrants the grant of *certiorari* on Question 1.

I. THE COURT OF APPEALS ERRED IN RULING THAT AGREEMENTS BETWEEN COMPETITORS ARE LAWFUL IF WITHIN THE "POTENTIAL" REACH OF A PATENT CLAIM.

1. The starting point for this case, as the court of appeals recognized, is that an agreement between competitors in which one pays the other to stay out of a market is "clearly anticompetitive," and hence unlawful unless excused by the lawful exercise of patent rights. Pet. App. 13a. This Court has repeatedly dealt with analogous situations. See, *e.g.*, *United States* v. *Masonite Corp.*, 316 U.S. 265, 274 (1942); *Ethyl Gasoline Corp.* v. *United States*, 309 U.S. 436, 455 (1940). In such cases, the overarching principle is clearly established: that "[t]he owner of a patent cannot extend his statutory grant by contract or agreement." *Masonite*, 316 U.S. at 277; *Ethyl*, 309 U.S. at 456; *United States* v. *Line Material Co.*, 333 U.S. 287, 308 (1948), even if the agreement takes the form of a litigation settlement. See *United States* v. *Singer Mfg. Co.*, 374 U.S. 174, 197-200 (1963) (White, J., concurring) (competitors' collusive

termination of a patent interference proceeding to help broaden the patent's scope runs afoul of the Sherman Act). Although the court of appeals acknowledged this principle, Pet. App. 18a, it failed to appreciate that parties settling litigation deal in uncertainties, and that the elimination of the prospect of competition, even if uncertain, harms consumers. The standard the court set down gives patentees free rein to "buy off" potential competitors, even in the context of generic drugs, where Congress has specifically sought to promote patent challenges to facilitate non-infringing generic entry.

The sweeping nature of the court of appeals' rule derives from its approach to assessing the "exclusionary potential of the patent." Pet App. 17a. The court based its reasoning upon the statutory presumption of patent validity, 35 U.S.C. 282, and upon a demonstrably *incorrect* extension of that presumption to the patent infringement issues most relevant here,[7] and ruled that the "exclusionary power" of the patent at issue here encompassed a right to exclude both Upsher and ESI from the market "until they proved either that the '743 patent was invalid or that their products * * * did not infringe Schering's patent." Pet. App. 18a. Although the court appeared to acknowledge that the presumptions it relied upon could be overcome by "evidence to the contrary," *id*. at 20a, the only circumstance in which it indicated the parties would exceed the exclusionary potential of the patent was that of "sham" infringement claims. *Ibid*. Furthermore, in light of the same court's earlier ruling that an exclusionary settlement could not be condemned "merely because the patent is subsequently declared invalid," in the absence of a showing such as that the

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[7] The Federal Circuit has consistently held that the patent holder has the burden of proving infringement by a preponderance of the evidence. See, *e.g.*, *Kegel Co., Inc.* v. *AMF Bowling, Inc.*, 127 F.3d 1420, 1425 (Fed. Cir. 1997); *Wolverine World Wide, Inc.* v. *Nike, Inc.*, 38 F.3d 1192, 1196 (Fed. Cir. 1994).

patentee "knew" that the patent was invalid or not infringed, *Valley Drug*, 344 F.3d at 1306, 1308-1309, it appears that the court below would recognize only limited exceptions to its rule that settlements within the outer, nominal bounds of patent claims are presumed lawful.

The court of appeals' formalistic approach to the issue of the "exclusionary potential" of the patent ignores the most salient factor that gives rise to patent litigation and settlements, the existence of *uncertainty* regarding whether a patent is valid, or (as was the focus here) infringed by particular products. Upsher and ESI stood as potential competitors to Schering's K-Dur; they could offer competing products unless Schering demonstrated that their products infringed. It is a fundamental principle of antitrust law, however, that it is unlawful to enter into an agreement in which potential competitors (even those whose successful entry is uncertain) agree to stay out of a market. See *Palmer* v. *BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (per curiam).[8] "[T]he anti-trust laws are as much violated by the prevention of competition as by its destruction." *United States* v. *Griffith*, 334 U.S. 100, 107 (1948) (citation omitted); see also *United States* v. *Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) ("it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash

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[8] In that case, the court of appeals had accepted the view that the agreement of one party (BRG) not to enter into the bar review business outside of the state of Georgia could not be condemned as a market allocation agreement, because "BRG had never done business outside the state of Georgia, [and] nothing in the record suggested that it ever intended to do so * * * ." 874 F.2d 1417, 1424 (11th Cir. 1989). This Court rejected that reasoning, holding that "[s]uch agreements are anticompetitive regardless of whether the parties split a market within which both do business * * * ." 498 U.S. at 49-50. As one leading commentator has put it, citing *Palmer*, "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." XII Herbert Hovenkamp, *Antitrust Law*, ¶ 2030b, at 175 (1999).

nascent, albeit unproven, competitors at will"). Had Schering paid substantial sums of money to a potential generic to delay entry, where the only impediment to entry was uncertainty about the generic's ability to obtain FDA approval, there would be no question that such an agreement was anticompetitive. See *Andrx Pharms., Inc.* v. *Biovail Corp. Int'l*, 256 F.3d 799, 806-809 (D.C. Cir. 2001) (uncertainty of FDA approval does not preclude antitrust claim). There is no reason why uncertainty regarding patent litigation should be treated differently.

Although all property rights are subject to legal uncertainties, the "probabilistic" nature of the property interest created by the patent laws[9] makes it especially important to take such uncertainty into account. Unlike forms of property that are defined in terms of title to tangible items with clearly defined boundaries, the exercise of rights conferred even by a valid patent requires that the boundaries of the patent's coverage be delimited in relation to an accused infringing product. "The heart of [a patentee's] legal monopoly is *the right to invoke the State's power* to prevent others from utilizing his discovery without his consent." *Zenith Radio Corp.* v. *Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) (emphasis added). When it asserts its patent and threatens a lawsuit, the patentee can hope that the strength of its patent will either convince the accused infringer to accede or convince a court to issue an injunction, but neither path guarantees success. As both economists and legal scholars have remarked, "a patent is not a right to exclude, but rather a right to *try* to exclude."[10]

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[9] See Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. Econ. Perspectives 75 (2005); Carl Shapiro, *Antitrust limits to patent settlements*, 34 RAND J. Econ. 391, 395 (2003).

[10] Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1761 (2003) (emphasis added); see Shapiro, *supra* note 9, at 395.

Available empirical data reinforce the importance of taking such uncertainties into account in any practical assessment of the "exclusionary potential" of a patent claim. A study examining nearly all written, final validity decisions by the district courts and the Federal Circuit from 1989 through 1996 found that 46 percent of patents challenged in litigation were invalidated. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-206 (1998). As discussed above, the percentage of vulnerable patent claims appears to be even greater in the Hatch-Waxman context, in which branded companies have often aggressively made multiple patent claims for drugs facing generic challenge. See *FTC Generic Drug Study* at 19-20.

2. Accordingly, a realistic assessment of whether a patentee settling a disputed claim has "extend[ed] his statutory grant by contract or agreement," *Masonite*, 316 U.S. at 277, must consider whether the patentee has eliminated the possibility of competition by paying off rivals to give up their claims. Suppose, for example, that there is a 50-50 chance that a patent-holder will prevail in litigation to keep a particular product off the market, and thus a 50 percent chance of entry yielding immediate benefits to consumers (assuming the patent conveys market power).[11] If the patent holder and challenger enter into a settlement in which the challenger gives up the right to enter,

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[11] The Commission found, based on the special circumstances surrounding the entry of generic drugs and on the specific experience upon the introduction of a generic version of Schering's K-Dur, that delay in that introduction had substantial adverse effects on consumers, and that, under this Court's teachings in *California Dental Ass'n* v. *FTC*, 526 U.S. 756 (1999), and in *IFD, supra*, the presence of such effects obviates any more extensive market inquiry. Pet. App. 64a-75a. Although the court of appeals made critical reference to this portion of the Commission's opinion in passing, Pet. App. 15a-16a, it did not base its ruling on this point. Its own discussion of "competitive effects," Pet. App. 28a-35a, focused entirely on the ostensible competitive justifications for the restraints.

for the remaining term of the patent, in return for a cash payment from the patentee, consumers would lose the 50 percent chance they had of enjoying the benefits of competition. As the Commission recognized, settlements that are beneficial or neutral to consumers are certainly possible. For example, if the parties simply compromise on an entry date prior to the patent's expiration, without cash payments, the resulting settlement presumably would reflect the parties' own assessment of the strength of the patent. Pet. App. 75a-76a.

If, however, the patent holder makes a substantial payment to the challenger as part of the deal, "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). The court of appeals rejected this reasoning as a matter of law, dismissing out of hand the notion that "the size of the payment [by the patentee], or the mere presence of a payment" should have any bearing on the antitrust analysis of an agreement of this sort. Pet. App. 34a. The court of appeals' reasoning ignores the fact that a firm "certain that a patent was valid * * * would have no incentive whatsoever to pay another firm to stay out of the market." Herbert Hovenkamp, *Antitrust Law*, ¶ 2046, at 339 (2004 Supp).

Moreover, contrary to the court of appeals' assumption, 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. App. 17a n.15. The Commission's analysis never assumed that different settlements between the parties would necessarily have replaced those under investigation. Rather, the Commission used a *hypothetical* no-payment compromise as a benchmark to assess "'the difference between the amount of competition [resulting from the actual settlements] * * * versus the amount of competition that was likely to occur had it not been

for the payment to delay * * *.'" Pet. App. 76a (quoting expert witness). Where a patent holder makes a payment to a challenger in order to induce it to agree to a later entry than it would otherwise agree to, consumers are harmed *either* because a settlement with an earlier entry date might have been reached, *or* because continuation of the litigation without settlement would yield a greater prospect of competition.[12]

The court of appeals' treatment of the settlement between Schering and ESI clearly illustrates its error. As to that agreement, the Commission assumed that Schering had paid $15 million for a purported side deal and $5 million to defray litigation costs, and did not rely on those payments. See Pet. App. 144a. The Commission pointed out, however, that there was no proffered justification for the $10 million payment – which was expressly contingent on ESI's obtaining the FDA approval that would allow it to enter the market – other than ESI's "adaman[cy]" that such a payment was necessary "to get ESI's agreement on settlement terms that delayed generic entry until 2004." *Ibid*. The court of appeals refused to consider the relationship between the payment and the increased likely level of exclusion, instead opining that the agreement was necessarily lawful because the patent issue remained subject to "fierce" dispute, and the settlement was "within the patent's exclusionary power," as incorrectly defined by the court. Pet. App. 28a.

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[12] For example, to return to the hypothetical patent claim with a 50 percent chance of success, if there are 10 years remaining in the patent term, continued litigation between the parties affords consumers an overall expected value of 5 years' competition, taking into account the likelihood of the two possible outcomes. If the parties instead reach a settlement in which the patent holder makes a payment to the challenger, and the challenger agrees to enter only one year prior to the expiration date, consumers are worse off, on average, than had the litigation gone forward. The court of appeals' approach, by contrast, would automatically endorse such a settlement because it is within the outer, nominal bounds of the patentee's claims.

3. The legal environment in which the parties entered into these restrictive agreements makes the court of appeals' error all the plainer. To establish the governing national policy in this area, Congress has twice addressed the matter of patent rights regarding branded and generic drugs, first in the Hatch-Waxman Act and then in the 2003 Medicare Amendments. In those enactments, it went to great lengths to encourage challenges to vulnerable patent claims, for the purpose of promoting early non-infringing generic entry. For example, Congress encouraged the early commencement of patent litigation – and linked it to the regulatory process – by defining the filing of an ANDA with a Paragraph IV certification as a "new (and somewhat artificial) act of infringement" that allows the patentee to bring suit without waiting for the generic company to enter the market. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676 (1990); 35 U.S.C. 271(e)(2).[13] The statute also affords the first ANDA applicant a period of exclusivity, as a further incentive to encouraging patent challenges. 21 U.S.C. 355(j)(5)(B)(iv). These provisions reflect Congress's recognition that many infringement claims are indeed vulnerable, and that consumers will benefit through successful challenges. Moreover, the pertinent provisions of the 2003 Medicare Amendments, which were prompted in part by the very antitrust concerns raised in this case,[14] further these congressional policies by requiring that

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[13] Furthermore, Congress gave patent holders a strong incentive to bring such patent litigation promptly, by affording them an automatic 30-month stay of FDA approval for the ANDA if (but only if) they commence suit within 45 days. 21 U.S.C. 355(j)(5)(B)(iii).

[14] See, *e.g.*, S. Rep. No. 167, *supra*, at 4 ("the industry has recently witnessed the creation of pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market. Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law that was intended to promote generic alternatives").

parties entering into the settlement of patent litigation involving pharmaceuticals file such settlements with the Commission and the Department of Justice for review, and by imposing the added sanction of loss of any marketing exclusivity period for a generic manufacturer found to have violated the antitrust laws. See Pub. L. No. 108-173, § 1112 (Pet. App. 360a-361a); 21 U.S.C. 355(j)(5)(D)(i)(V).

The court of appeals' approach to antitrust analysis of patent settlements in the Hatch-Waxman context will vitiate these congressional enactments. Pharmaceutical companies have strong economic incentives to enter into the sort of anticompetitive agreements the court of appeals condoned in this case. In nearly any case in which a generic contemplates market entry, the profit that the generic anticipates will be well under the profit that the branded manufacturer would make from the same volume of sales.[15] Accordingly, absent antitrust constraints, it will almost always be profitable for the branded manufacturer to buy off generics by offering them as much or more than they would make by entering, thus securing continued exclusivity and the continued ability to charge monopoly prices.[16] Furthermore, by setting such a high bar for a showing that a patentee has exceeded the exclusionary power of the patent, the court of appeals' ruling would make Congress's recent directive that drug patent settlements be reported to the antitrust enforcement agencies for review a pointless gesture.

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[15] See *CBO Study,* at xiii (generic versions cost on average 25 percent less than original brand-name drugs at retail prices); *id.* at 28 (wholesale price of generic drugs about half that of brand-name drugs in the first year after generic entry).

[16] In the majority of past instances of such agreements, competition was barred for the *entire* nominal duration of the patents. See *FTC Generic Drug Study* at 31.

The inconsistency between the court of appeals' ruling and congressional policy is especially clear in the court's treatment of the ostensible competitive benefits of patent settlements. See Pet. App. 29a-35a. The court invoked the general public policy preference for the settlement of litigation, citing the prospect of cost savings and the achievement of "certainty" regarding patent rights. *E.g., id.* at 29a, 30a, 33a. The court noted that the Hatch-Waxman Act altered the bargaining positions of the respective parties, and may make a conventional settlement more difficult to reach in some cases. *Id.* at 31a. In fact, the court's dire warnings that the Commission's approach would impede settlements (*id.* at 34a) are entirely unwarranted. As the Commission recently reported, pursuant to Congress's directive in the 2003 Medicare Amendments, legitimate patent settlements continue to occur without hindrance from the Commission decision, using means other than payments by the patent holders to reach a compromise.[17]

More important, the court of appeals drew entirely the wrong lesson from Congress's modification of the respective rights of patent holders and challengers in the pharmaceutical context. Congress made those changes for the very purpose of benefitting consumers by fostering successful challenges and permitting early entry of non-infringing generics. The court of appeals' ruling nullifies this congressional choice, for no discernible public gain, by excusing otherwise unlawful collusive actions in order to allow the patent holder to "realize[] the full potential of its infringement suit." *Ibid.* The court of appeals' ruling, avowedly "reflect[ing] policy," *id.* at 35a, flatly contradicts the policies of Congress.

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

II. REVIEW IS NEEDED TO ENSURE UNIFORMITY ON AN ISSUE OF EXCEPTIONAL NATIONAL IMPORTANCE.

Review of the foregoing issue is needed not only because of disarray among the lower courts on this issue, but because of the dramatic impact the present ruling could have on U.S. consumers. Another court of appeals appears to have taken a strikingly different approach, 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." *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) (footnote omitted), *cert. denied sub nom. Andrx Pharms., Inc.* v. *Kroger Co.*, No. 03-779 (Oct. 12, 2004). Although a number of circumstances made that interlocutory case a poor vehicle for plenary consideration of the issue,[18] the present case comes to the Court on a full record. Moreover, the ruling below has sharpened the tension between the Sixth and Eleventh Circuits. See *supra*, at 14-16.

Practical considerations magnify the impact of the ruling below on law enforcement in this area. The Commission has brought a number of administrative cases challenging pharmaceutical patent settlements, all of which except the present one

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[18] As the United States pointed out in an amicus brief in which the Commission joined, the *Cardizem* ruling was not only interlocutory but involved an unusual fact pattern involving an "interim" settlement that precluded entry during patent litigation but did not bring that litigation to an end. See Brief for the United States As Amicus Curiae, at 7, 15-18, *Andrx Pharms., Inc.* v. *Kroger Co.*, No. 03-779 (*certiorari denied* Oct. 12 2004). Moreover, the *Cardizem* court's reference to the possibility that the agreement there extended to non-infringing products, 332 F.3d at 908 n.13, cast doubt on the reach of its per se rule.

led to the entry of consent orders.[19] Yet, because the Commission's administrative decisions are reviewable in any circuit in which the respondent resides or does business, 15 U.S.C. 45(c), any substantial pharmaceutical company involved in a future case of this sort could presumably obtain review in the Eleventh Circuit to take advantage of the ruling below without running the risk of a conflicting ruling from another circuit.

The economic implications of the court of appeals' ruling, which invites collusive arrangements between branded drug companies and generic challengers, are staggering. American consumers and health plans spend over a hundred billion dollars on prescription drugs each year.[20] In recent years, facilitated by the incentive structure of the Hatch-Waxman Act, numerous generic manufacturers have successfully challenged listed patents and entered prior to the expiration dates of those patents. See *FTC Generic Drug Study,* at 19-20 (generics prevailed in cases involving 73 percent of challenged drug products). Successful challenges have included a number of "blockbuster" drugs with annual sales in the billions of

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[19] *Bristol-Myers Squibb Co.*, FTC Dkt. No. C-4076 (April 14, 2003); *Hoechst Marion Roussel, Inc.*, FTC Dkt. No. 9293 (May 8, 2001); *Geneva Pharms., Inc.*, FTC Dkt. No. C-3946 (May 22, 2000); *Abbott Labs.*, FTC Dkt. No. C-3945 (May 22, 2000).

[20] In 2002 alone, for example, Americans spent over $160 billion for prescription drugs. See The Henry J. Kaiser Family Foundation, *Prescription Drug Trends*, at 1 (Oct. 2004). Retail prescription prices have increased an average of 7.4 percent annually from 1993-2003, almost triple the average inflation rate of 2.5 percent during that same period. *Ibid.*; see also Centers for Medicare & Medicaid Services, *Highlights – National Health Expenditures, 2003*, at 1 (January 11, 2005) (prescription drug spending rose 14.9 percent in 2002 and 10.7 percent in 2003). They are projected to increase at an even higher average rate over the next decade (10.7 percent annually between 2004 and 2013). *Prescription Drug Trends* at 2. For the past two decades, spending for prescription drugs has been the fastest growing component of the national healthcare spending. *Id.* at 1.

dollars.[21] The entry of generic drugs into such markets invariably results in dramatically lower prices for consumers and health care payors.[22] There is every indication, moreover, that this process has the potential to continue to provide consumer benefits. Of the twenty top-selling prescription drugs in the United States today, eleven, with annual sales of nearly $25 billion, currently are the subject of litigation by generic firms seeking to enter the market under the terms of the Hatch-Waxman Act.[23] The prospect of consumer benefit from such challenges is enormous, to the extent that they lead to early, non-infringing generic entry. Under the court of appeals' ruling, however, the parties in such cases will have the strong economic incentive discussed above to enter into settlements that share the benefits of continued monopoly prices and

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[21] See, *e.g., SmithKline Beecham Corp.* v. *Apotex Corp.,* 247 F. Supp.2d 1011 (N.D. Ill. 2003), *aff'd on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005) (patent claiming the antidepressant Paxil held invalid); *Astra Aktiebolag* v. *Andrx Pharms., Inc.*, 222 F. Supp.2d 423 (S.D.N.Y. 2002), *aff'd sub nom. In re Omeprazole Patent Litig.,* 84 Fed. App. 76 (Fed. Cir. Dec. 11, 2003) (generic manufacturer did not infringe patents claiming anti-ulcer drug Prilosec); *Eli Lilly & Co.* v. *Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (patent claiming antidepressant Prozac held invalid).

[22] See *CBO Study,* at ix (consumers saved roughly $8-10 billion by purchasing generic equivalents of brand-name drugs in 1994 alone); Food and Drug Administration, *Savings from Generic Drugs Purchased at Retail Pharmacies* (May 3, 2004) (patients can save up to 52 percent in prescription drug costs by purchasing generic versions of brand-name drugs).

[23] See Drug Topics, *Top 200 Brand-Name Drugs by Retail Dollars in 2004* (Feb. 21, 2005), <http://www.drugtopics.com> (listing top-selling drugs). SEC filings and public statements by the manufacturers of the twenty top-selling drugs indicate that the following eleven drugs are subject to litigation by generic rivals: Lipitor, Effexor-XR, Plavix, Celebrex, Neurontin, Protonix, Norvasc, Zyprexa, OxyContin, Fosamax, and Risperdal. See, *e.g.*, Pfizer Inc., *Form 10-Q* (Aug. 8, 2005); Wyeth, *Form 10-Q* (Aug. 5, 2005); Purdue Pharma, L.P., *Press Release* (June 8, 2005).

deprive consumers of the benefit of low-cost, non-infringing generic drugs.

III. THE COURT OF APPEALS GROSSLY MISAPPLIED THE SUBSTANTIAL EVIDENCE STANDARD.[24]

This case is also one of the rare instances in which the Court should intervene to correct a gross misapplication of the "substantial evidence" standard of review. Although the task of determining whether substantial evidence supports agency findings is ordinarily left to the courts of appeals, see *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, 491 (1951), this Court has not hesitated to intervene when a court's misapprehension or, as in this case, gross misapplication of the standard threatened the effective application of the antitrust laws. See, *e.g., IFD*, *supra*.

Section 5 of the Federal Trade Commission Act provides that "[t]he findings of the Commission as to the facts, if supported by evidence, shall be conclusive." 15 U.S.C. 45(c). This language has long been understood to apply the "substantial evidence" test of the Administrative Procedure Act, 5 U.S.C. 706(2)(E). See *IFD*, 476 U.S. at 454. The test is whether the Commission's findings are supported by "such relevant evidence as a reasonable mind might accept as adequate," *ibid.* (quoting *Universal Camera*, 340 U.S. at 477), not whether the reviewing court, "'mak[ing] its own appraisal of the testimony, picking and choosing for itself among uncertain and conflicting inferences,'" would reach the same conclusion.

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[24] Question 2 of the Petition, addressed in this part, applies only to the agreement between Schering and Upsher. No such factual dispute exists with respect to the agreement between Schering and ESI. Accordingly, regardless of whether review is granted on this question, review of Question 1 is nevertheless appropriate in light of the gravity of the court of appeals' error and the great importance of the issue.

IFD, 476 U.S. at 454 (quoting *FTC* v. *Algoma Lumber Co.*, 291 U.S. 67, 73 (1934)).

As explained above, the pivotal factual issue regarding the Upsher agreement was whether the $60 million payment was, in substantial part, a *quid pro quo* for Upsher's agreement not to compete until 2001, rather than an up-front, unconditional "royalty" for the product licenses that Schering obtained. The Commission examined this issue in great detail, Pet. App. 92a-141a, focusing on a license for a niacin product that the parties acknowledged was the primary item of supposed value. See *id.* at 108a n.83. The court of appeals' discussion reflects a consistent refusal to accord any weight to the reasoned conclusions of the agency entrusted with adjudicating these matters. See 15 U.S.C. 45(b). The court begins, for example, by impugning expert testimony on which the Commission did *not* rely, on the premise that the Commission's conclusions were "curiously" similar. Pet. App. 22a-24a. Then, the court dismisses the evidence upon which the Commission did rely, but entirely ignores the Commission's own explication of the record. For example, the court chastises the Commission's "non-expert opinion that Schering should have done more due diligence" in its evaluation of the niacin product. *Id.* at 24a. But the Commission's conclusions were based on no such second-guessing, but rather on the *inconsistency* between Schering's actions here and its own actions in assessing a similar commercial opportunity presented by a company that did not threaten it with generic competition. *Id.* at 108a-111a, 122a-130a.[25] Moreover, the court of appeals simply ignored the

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[25] The other product was clinically similar, and evidence showed that it presented a less risky opportunity, having already received clinical approval by the FDA. See Pet. App. 111a-116a. Schering declined to offer any up-front payment for that product, after detailed investigation. *Id.* at 116a-117a. By contrast, Schering purported to assign a high value to Upsher's unapproved product, following a more cursory investigation, and despite the

most damning, contemporaneous, and documentary evidence on which the Commission relied.[26] And, although the court of appeals made the conclusory holding that the evidence supporting its view was "overwhelming," *id*. at 25a, 26a, it cited to no such evidence.

Two aspects of the court of appeals' analysis are particularly troubling, and plainly at odds with this Court's teachings regarding appellate review of agency findings. First, the court below criticized the Commission's recognition of the economic motivations facing Schering and Upsher in drawing inferences about the $60 million payment. See *id*. at 23a-24a. But agencies are allowed to draw on their familiarity with the subject matter entrusted to them by Congress. See generally *Dickinson* v. *Zurko*, 527 U.S. 150, 160-161 (1999) (discussing reasons for deference to agency factfinding). Business practices and the economic incentives facing businesses are at the heart of the FTC's institutional expertise, and, as this Court has recognized, the Commission is entitled to rely on "common sense and economic theory" in its administrative adjudications. *IFD,* 476 U.S. at 456. Second, the court of appeals erred in deferring to the "credibility" determinations of the ALJ, rather than to the Commission's findings. Pet. App. 25a. This Court has instructed that the substantial evidence "standard is not modified in any way when the [agency] and its examiner disagree," *Universal Camera*, 340 U.S. at 496. The present circumstances underscore the wisdom of that principle. The finding at issue was not a simple fact such as who had said

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fact that the contract contained no commitment by Upsher to carry through in obtaining approval. *Id*. at 122a-130a.

[26] The Commission had relied, for example, on the terms of the agreements themselves, Pet. App. 93a-94a, and on Schering's presentation to its board of directors, which explained that the payments represented lost revenue for the period Upsher stayed off the market, *id*. at 97a n.78.

what at a particular meeting, but the broader question whether Schering and Upsher had entered into the side licensing agreement as an end in itself or in order to facilitate (and perhaps mask) large payments intended to keep Upsher out of the market. While the testimony of Schering executives is relevant to the inquiry, as the Commission acknowledged, Pet App. 96a n.77, its plausibility must be weighed against the entire record. The Commission is the body entrusted by Congress with making such determinations. On *de novo* review, the Commission unanimously disagreed with the ALJ's factual determination, and its final ruling was entitled to deference. The court of appeals' analysis shows that it failed to afford such deference.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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