No. 12-416

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

WATSON PHARMACEUTICALS, INC., 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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As the government's certiorari petition explains, the question presented in this case implicates an untenable circuit conflict on a well-defined legal issue of exceptional importance to the national economy. The need for this Court's review is reinforced by the pending petitions in *Merck & Co.* v. *Louisiana Wholesale Drug Co.*, No. 12-245 (filed Aug. 24, 2012), and *Upsher-Smith Laboratories Inc.* v. *Louisiana Wholesale Drug Co.*, No. 12-265 (filed Aug. 29, 2012) (collectively, the *K-Dur* petitions). The petitioners in those cases are pharmaceutical companies that disagree with the government's position on the merits but agree that a square circuit conflict exists and that the question presented requires nationwide resolution.

Two of the respondents in this case (Watson Pharmaceuticals, Inc. and Solvay Pharmaceuticals, Inc.)—who are the only parties to one of the reverse-payment

agreements that the Federal Trade Commission (FTC) challenges here—agree that the FTC's petition should be granted. Respondents Par Pharmaceutical Cos. and Paddock Holdings, Inc. (collectively, Par) oppose further review and contend that the Court should deny the FTC's petition outright even if it grants the *K-Dur* petitions on the same question presented. Par identifies no sound basis for denying review here.

A. Par Offers No Substantial Reason To Deny All The Certiorari Petitions

The *K-Dur* respondents suggest that this Court may benefit from "await[ing] a final judgment and a complete record in a reverse payment case." Br. in Opp. at 10, *K-Dur*, *supra* (No. 12-245). The FTC's petition seeks review of a final judgment affirming the dismissal of the FTC's complaint. The FTC's allegations in this case reflect its extensive investigation of the AndroGel® reverse-payment agreements; they are not the sort of half-informed speculation that might, in another case, caution this Court to await confirmation of a dispute's true factual contours. The Eleventh Circuit held that a reverse-payment agreement is lawful unless it imposes greater restrictions on generic competition than would a judicial ruling that the brand-name manufacturer's patent is valid and infringed. Because the FTC has not alleged that the agreements at issue in this case are illegal under that standard, no further factual development would assist this Court in determining whether the Eleventh Circuit's approach is correct. To the contrary, the existence of a final judgment on a motion to dismiss makes this case a particularly suitable vehicle for resolving the question presented. See Pet. 30.

Par contends (Br. in Opp. 17-20) that the question presented is unimportant because reverse-payment

agreements are declining when measured as a fraction of all settlements of Hatch-Waxman paragraph IV litigation. The leading brand-name and generic pharmaceutical industry trade groups do not share that perspective, and have filed amicus briefs supporting the *K-Dur* petitions. See Pharm. Research & Mfrs. Amicus Br., *K-Dur*, *supra* (No. 12-245); Generic Pharm. Amicus Ass'n Br., *K-Dur*, *supra* (No. 12-265). And the statistics on which Par relies demonstrate that, although reverse-payment agreements have in some years declined as a *percentage* of overall Hatch-Waxman settlements, the *absolute number* of reverse-payment agreements was twice as great in 2011 as in 2007. See Par Br. in Opp. 19 n.4.

Par posits that this trend is linked to revisions made to the Hatch-Waxman Amendments (see Pet. 3) in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), Pub. L. No. 108-173, 117 Stat. 2066. Par states that, under the MMA, the "incentives for reverse-payments are diminished" (Br. in Opp. 24). Par also points out (*id.* at 23-24) that, in briefs filed at this Court's invitation in prior cases, the United States noted the possibility that the MMA might reduce the prevalence of reverse-payment settlements and thereby lessen the continuing practical importance of questions concerning the legality of such agreements.

Since those briefs were filed, however, a clear circuit conflict has developed, and the yearly number of reverse-payment agreements has increased substantially. Par offers no reason to suppose (and no party to either this case or *K-Dur* contends) that the legal standard governing antitrust review of agreements like the ones at issue here and in *K-Dur* should vary depending on whether a generic manufacturer's original abbreviat-

ed new drug application (ANDA) or its paragraph IV certification (see Pet. 4) was submitted before or after the MMA became effective. Absent any impact on the governing legal standard, there is no basis for Par's prediction that "[t]he merits briefs and any ensuing decision in this case would be strewn with digressions about how things used to be pre-MMA." Br. in Opp. 24.

Finally, any marginal benefit that might be achieved by awaiting a case involving an ANDA or paragraph IV certification subject to the MMA is far outweighed by the practical costs associated with deferring review. The existing circuit conflict will create substantial incentives for forum-shopping by all parties until the split is resolved. See Pet. 15. Substantial resources will be wasted litigating under the wrong standard in one circuit or another. If the Eleventh Circuit is correct, brand-name and generic drug manufacturers will be improperly deterred from settling infringement litigation on terms that couple monetary payments from the brand-name to the generic manufacturer with a promise of delayed generic entry. And if the Third Circuit is correct, consumers will continue to suffer serious harm from current and future reverse-payment agreements. Because the MMA amendments affect neither the legal analysis of agreements like the ones at issue here and in *K-Dur* nor whether those agreements are profitable, there is no reason to allow such uncertainty to persist.

B. There Is No Plausible Reason To Deny The FTC's Petition If The *K-Dur* Petitions Are Granted

Par suggests (Br. in Opp. 15) that the FTC's petition should be denied outright even if the *K-Dur* petitions are granted. Absent a jurisdictional or other threshold reason not to entertain the petition—and Par points to none—there is no basis in this Court's certiorari prac-

tice for denying the FTC's petition outright. As a leading treatise explains, "a petition for certiorari may be held * * * until a decision is reached by the Court in a pending case raising identical or similar issues"; "the certiorari papers are held by the Court pending its plenary ruling, following which [a] summary reconsideration order [directed to the court below] is entered." Eugene Gressman et al., *Supreme Court Practice* 339, 346 (9th ed. 2007).

There is, in particular, no merit to Par's suggestion (Br. in Opp. 15, 26-27) that the FTC's petition should be denied simply because the Eleventh Circuit panel issued the decision below before the Third Circuit issued its conflicting decision in *K-Dur*.[1] In the relatively rare situation presented here, where certiorari petitions seeking review of two conflicting court of appeals decisions are simultaneously pending before the Court, nothing in this Court's Rule 10 suggests a preference for reviewing either the earlier or the later of the two decisions. As support for its argument, Par identifies cases in which the Court *granted* review of a decision to resolve a split that developed after the decision under review had been rendered. See *id.* at 26-27 & n.6. Par offers no precedent for what it seeks here—denial of a certiorari petition despite the simultaneous grant of another petition on the same question presented, simply because of the order in which the decisions below were rendered.

Par also suggests (Br. in Opp. 15-16, 26 & n.5) that there was something wrongful about the development of

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[1] The Eleventh Circuit denied rehearing in this case *after* the Third Circuit's issued its decision in *K-Dur*, which the FTC had provided to the Eleventh Circuit under Federal Rule of Appellate Procedure 28(j) while its petition for rehearing was pending.

the circuit conflict here because the FTC and the United States offered amicus presentations that the Third Circuit found persuasive. But the government is not required to accede to the first unfavorable adjudication of an issue in a court of appeals. To the contrary, the government's usual practice—as a party and, *a fortiori*, as an amicus curiae—of relitigating "questions of substantial public importance" in multiple fora ensures that more than one court of appeals can "explore a difficult question before this Court grants certiorari." *United States* v. *Mendoza*, 464 U.S. 154, 160 (1984).[2]

Par also expresses concern (Br. in Opp. 27) that reversal of the Eleventh Circuit's decision would upset expectations that this Court should regard as legitimate. Under our hierarchical judicial system, however, decisions rendered by a lower court are by their nature subject to review and possible reversal by this Court. Par's asserted interest in "repose" (*id.* at 26) is further undermined by the fact that the FTC seeks only declaratory and injunctive relief, rather than damages for the period of time during which the pertinent reverse-payment agreements have been in effect. See Pet. 31-32. If (as the government contends) the Eleventh Circuit erred in treating those agreements as lawful, then Par has already enjoyed the windfall of years of sharing unjust monopoly profits with Solvay. Par's purported reliance interests provide no justification for allowing

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[2] Par speculates that Justice Kagan may be recused from this case by virtue of the FTC's decision to appeal to the Eleventh Circuit during her tenure as Solicitor General. Br. in Opp. 3 n.1. There is no basis for that speculation. The FTC had exclusive authority to commence and supervise the appeal below, 15 U.S.C. 56(a)(2), and it neither requested nor received authorization from the Solicitor General to appeal from the district court's adverse ruling.

those windfall benefits to continue until the agreements expire in 2015.

Par further explains (Br. in Opp. 14) that, during the eight years since the United States first addressed the issue in this Court, the government has refined its position regarding the legal standards that should govern antitrust review of reverse-payment agreements. Of course, private plaintiffs, pharmaceutical-company defendants, and the courts of appeals have done the same. That opportunity for refinement is a signal virtue of this Court's preference for allowing issues to percolate in lower courts, and the culmination of that process is a reason to grant the FTC's petition, not to deny it.

In addition, Par overstates the differences between the government's current legal theory and the positions taken by the United States in prior briefs in this Court. Par emphasizes (Br. in Opp. 14) that the United States urged this Court to deny certiorari in *FTC* v. *Schering-Plough Corp.*, 548 U.S. 919 (2006). The United States' brief in that case, however, did not endorse the scope-of-the-patent rule that Par advocates and that the court below applied. Rather, the United States argued that the Eleventh Circuit's decision in *Schering-Plough* did not foreclose consideration, as part of the antitrust inquiry, of the strength of the underlying infringement suit. See U.S. Br. at 17-19, *Schering-Plough*, *supra* (No. 05-273). The United States further contended that "the interests in consumer welfare protected by the antitrust laws militate against adoption of a legal standard that would facilitate patent holders' efforts to preserve weak patents by dividing their monopoly profits with settling challengers." *Id.* at 10. The following year, in its amicus brief in *Joblove* v. *Barr Labs, Inc.*, 551 U.S. 1144 (2007), the United States criticized the

scope-of-the-patent approach as "insufficiently stringent" and "erroneous," and it stated that "a court reviewing an antitrust challenge to a settlement of a patent infringement claim that includes a reverse payment should apply the rule of reason." U.S. Br. at 8, 12, 13, *Joblove*, *supra* (No. 06-830); see Pet. 21-22 n.6.

C. This Case Is A Superior Vehicle To *K-Dur*

As explained in the FTC's petition (at 29-32), this case is a superior vehicle to *K*-Dur for addressing the question presented. Respondents Watson and Solvay agree. See Watson Br. 28; Solvay Br. 29-31.

1. Par's contrary arguments are insubstantial. First, Par asserts that a "patent surprise" (Br. in Opp. 8-9, 24-25) during Paddock's development of generic AndroGel® makes this antitrust suit atypical. But the fact that Paddock's development efforts were nearly complete when Solvay received its patent is irrelevant to the antitrust question presented. What matters is that once the patent in question issued, the generic manufacturers made paragraph IV certifications to that patent and then entered into reverse-payment agreements with the brand-name manufacturer. In those respects, this case is entirely typical of suits in which reverse-payment agreements have been challenged as anticompetitive.

Second, Par contends that its own situation is unusual because, at the time it settled its litigation against Solvay, existing Eleventh Circuit precedent indicated that the parties' reverse-payment agreement was lawful. Br. in Opp. 14, 26. Nothing in this Court's decisions suggests, however, that an otherwise-impermissible agreement among competitors can be treated as lawful simply because it accords with circuit precedent in effect at the time and place the agreement was made. Par's argu-

ment is particularly misconceived in this civil action for injunctive relief. In such a suit, there is generally neither a scienter element to establishing a violation of the antitrust laws nor a good faith defense to their enforcement. See generally 2 Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 303 (3d ed. 2007) (discussing differences among various modes of antitrust enforcement).

Third, Par points out that the district court hearing the patent infringement action against it entered a consent decree in connection with the Par/Solvay settlement agreement (but not in connection with the Watson/Solvay agreement). Br. in Opp. 28-30. Par also makes an intricate argument about the competitive consequences of its status as a second filer (as compared to Watson's status as a first filer). *Id.* at 30-33. Those issues were not addressed by the court of appeals below, and this Court "do[es] not ordinarily address for the first time * * * an issue which the Court of Appeals has not addressed," *J. Truett Payne Co.* v. *Chrysler Motors Corp.*, 451 U.S. 557, 568 (1981).

In any event, those arguments provide no reason to deny the FTC's petition. At the very most, they suggest that Par may have grounds for resisting liability even if the agreement between respondents Watson and Solvay (both of which have urged the Court to grant the FTC's petition) is ultimately found to violate the antitrust laws. If Par is genuinely confident that its agreement is lawful irrespective of the resolution of the question presented, it can inform the Court that it is no longer interested in the case in this Court. Cf. Sup. Ct. R. 12.6.

2. The Court therefore should grant the FTC's petition for a writ of certiorari. The *K-Dur* petitions could then be held pending resolution of this case. In the

alternative, if the Court believes it would benefit from additional briefing focused on *K-Dur*, it could grant all the pending petitions and consolidate the cases. The *K-Dur* respondents advocate the latter course. Br. in Opp. at 17, *K-Dur*, *supra* (No. 12-245). We concur in their view that, if the Court grants all the pending petitions and consolidates the cases, it should substantially expand the time allotted for oral argument in view of the importance and complexity of the legal issues and the factual intricacy of the *K-Dur* record.

The *K-Dur* respondents further "suggest that the Court realign the parties for purposes of briefing" if all the pending petitions are granted. Br. in Opp. at 17, *K-Dur*, *supra* (No. 12-245). We disagree. There may be some force to the *K-Dur* respondents' concern that, if all three pending petitions are granted and the cases are briefed on the standard schedule, "*amicus* participation may be multiplied unnecessarily," *ibid.* (or some amici may strategically delay the filing of their briefs). But if this Court concludes that the two cases are so similar that a single entity's amicus participation in both would be duplicative, it can obviate that concern by granting certiorari in only one case.

On the few recent occasions that we have identified when this Court has granted petitions from opposite sides of a circuit split and consolidated the cases (or ordered them argued in tandem), it has not realigned the parties, but has simply allowed briefing in the normal course. See, *e.g.*, *Hanlon* v. *Berger*, 525 U.S. 981 (1998) (No. 97-1927), consolidated with *Wilson* v. *Layne*, 525 U.S. 981 (1998) (No. 98-83). The *K-Dur* respondents have not advanced a compelling reason to depart from that practice here.

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

Respectfully submitted.

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NOVEMBER 2012