No. 03-779

In the Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC., PETITIONER

v.

KROGER COMPANY, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether the court of appeals erred in holding that an interim agreement between the parties to patent infringement litigation constituted a per se violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

TABLE OF CONTENTS

Miscellaneous—Continued: Page

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This brief is filed in response to the Court's invitation to the Solicitor General to express the views of the United States. The position of the United States is that this Court's review is unnecessary at this time. The decision below may not conflict with any other court of appeals' decision, this case arises in a somewhat atypical factual setting, and statutory changes post-dating the events at issue here may affect the frequency with which similar questions will arise in the future.

STATEMENT

1. Respondents, Kroger Co. and other pharmaceutical purchasers, contend that an agreement among parties to a patent infringement suit violated the federal antitrust laws. The patent suit arose in the statutory context created by the Drug Price Competition and Patent Term Restoration Act of

tected by U.S. Patent No. 5,470,584 (the '584 patent). Pet. App. 6a-7a. On September 22, 1995, petitioner, Andrx Pharmaceuticals, Inc., filed an ANDA with the FDA seeking approval to market a generic version of Cardizem CD. Petitioner thereafter filed a paragraph IV certification stating that its generic product did not infringe any of the patents listed with the FDA covering Cardizem CD. Because petitioner was the first to file an ANDA and paragraph IV certification with the FDA, it was eligible for the 180-day exclusivity period under 21 U.S.C. 355(j)(5)(B)(iv). Pet. App. 6a.

In January 1996, Carderm Capital, L.P., the owner of the '584 patent, and Hoechst Marion Roussel, Inc. (HMR), Carderm's licensee and the manufacturer of Cardizem CD, filed a patent infringement suit against petitioner, which triggered the 30-month stay of FDA approval under 21 U.S.C. 355(j)(5)(B)(iii). Pet. App. 7a. Petitioner counterclaimed against HMR, alleging antitrust violations and unfair competition. *Ibid.*

In September 1997, shortly after the FDA announced that it would approve petitioner's ANDA, effective upon termination of the automatic 30-month stay, petitioner and HMR entered into an agreement that settled petitioner's antitrust and unfair competition counterclaims and provided for interim arrangements relating to the patent infringement claims (the Agreement). The Agreement provided that (a) petitioner "would not market a bioequivalent or generic version of Cardizem CD in the United States" until it obtained "a favorable, final and unappealable determination" in the patent case or HMR licensed petitioner or a third party; (b) petitioner would continue to prosecute its ANDA and not relinquish its 180-day exclusivity rights; and (c) HMR would make quarterly payments to petitioner from the date that FDA approval of the ANDA became effective until entry of a final and unappealable judgment in the patent case (or

3. Respondents and other purchasers of pharmaceuticals filed suit[2] against petitioner and HMR, alleging that the Agreement was an unlawful restraint of trade under Section 1 of the Sherman Act, 15 U.S.C. 1. The core allegation was that the Agreement not only delayed the marketing of petitioner's generic product but also, because petitioner's exclusivity period would not expire until 180 days after petitioner entered the market, effectively precluded anyone else from bringing a generic form of Cardizem CD to market. Pet. App. 10a-11a.

4. The district court granted partial summary judgment in favor of the plaintiffs, holding that the defendants had entered into an "agreement between horizontal competitors that allocates the entire United States market for Cardizem CD and its bioequivalents to [HMR], and thus constitutes a restraint of trade that has long been held illegal *per se* under established Supreme Court precedent." Pet. App. 35a (citing *Palmer* v. *BRG of Ga., Inc.*, 498 U.S. 46 (1990), and *United States* v. *Topco Assocs., Inc.*, 405 U.S. 596 (1972)). The court construed the Agreement "[o]n its face" to restrain petitioner from marketing not only "its generic version of Cardizem CD in July 1998 when FDA approval was expected and obtained," but also "other bioequivalent or generic versions of Cardizem CD which were not at issue in the pending [HMR]/Andrx patent case, including the reformulated generic drug described in its September 11, 1998 prior approval supplement to its ANDA." *Id.* at 65a; see also *id.* at 59a-60a, 61a. Thus, the court concluded, the Agreement "restrained [petitioner] from marketing non-infringing or potentially non-infringing versions of Cardizem CD." *Id.*

or otherwise compromising its right to the 180-day period of exclusivity," *ibid.*, the court found that the Agreement "allocated the entire United States market for Cardizem CD and its bioequivalents to [HMR] during the life of that Agreement." *Id.* at 66a. The court distinguished the Agreement from a patent license with territorial restrictions, such as that held not to offend the antitrust laws in *Dunlop Co.* v. *Kelsey-Hayes Co.*, 484 F.2d 407 (6th Cir. 1973), cert. denied, 415 U.S. 917 (1974), noting that the Agreement extended beyond allegedly infringing formulations. Pet. App. 74a-75a.

Two months after granting partial summary judgment, the district court certified the question of the per se status of the Agreement for interlocutory appeal pursuant to 28 U.S.C. 1292(b), along with an issue relating to defendants' motion to dismiss the plaintiffs' antitrust claims for failure to plead antitrust injury. C.A. App. 606 (Order No. 16). The court of appeals granted leave to appeal. Pet. App. 83a-85a.

5. The court of appeals held that the district court properly granted partial summary judgment for the plaintiffs as to the illegality of the Agreement, concluding that "[t]he Agreement whereby HMR paid Andrx $40 million per year not to enter the United States market for Cardizem CD and its generic equivalents is a horizontal market allocation agreement and, as such, is *per se* illegal under the Sherman Act." Pet. App. 4a. The Agreement, the court of appeals explained, "was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade." *Id.* at 18a. The court rejected the defendants' reliance on the fact that the Agreement arose in the context of patent infringment litigation, concluding that "the Agreement cannot be fairly characterized as merely an

attempt to enforce patent rights or an interim settlement of the patent litigation." *Id.* at 19a.[3]

I. Patent Infringement Settlements Precluding Entry By the Alleged Infringer In Exchange For Reverse Payments May Raise Antitrust Concerns, But Such Agreements Are Not Automatically Subject To Per Se Condemnation

Although "public policy wisely encourages settlements" of legal disputes, *McDermott, Inc.* v. *AmClyde*, 511 U.S. 202, 215 (1994), it does not follow that all settlements are consistent with the public interest. Settlements of patent infringement claims are often predicated on an agreement that the alleged infringer will not make and sell the allegedly infringing product in competition with the patentee and its licensees, or that it will do so only pursuant to the terms of a license agreement. Were it not for the existence of the patent and the allegation of infringement, a court would likely treat such an agreement as an unreasonable restraint of trade in violation of Section 1 of the Sherman Act. Indeed, trade in v rade in v rad- Twn147 Tc0.. Indeed,

other possible "legitimate justifications" for reverse payments, such as a "'cash starved' generic" drug firm that could productively use "some up-front support from the pioneer manufacturer," a "generic challenger [that] is more optimistic about the litigation outcome than the pioneer," "widely differing risk preferences," and a "judgment-proof generic manufacturer [whose] downside risks of damage exposure are small." *In re Schering-Plough Corp.* (*Schering*), No. 9297 (FTC Dec. 18, 2003), slip op. 37-38 (<http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf>), appeal docketed, No. 04-10688-AA (11th Cir. filed Feb. 13, 2004); see also Shapiro, *supra*, 34 RAND J. Econ. at 408 & n.29 (citing risk aversion and asymmetric information about market conditions).

At the same time, a rule of reason analysis permits antitrust liability to attach to patent settlements involving reverse payments in appropriate circumstances. Applying a rule of reason analysis and based on a fully litigated factual record, the FTC condemned the settlements in the *Schering* decision, finding that the patentee paid the generic firms to defer their entry; that the entry of those lower-cost generics would be a "direct consumer benefit" (*Schering*, slip op. 20); that the payments were not ancillary to a pro-competitive

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Schering-Plough, No. 9297 (FTC Apr. 3, 2002) (consent order as to American Home Products Corp.), <http://www.ftc.gov/os/2002/04/scheringplough_do.htm>. Commentators generally take this position as well. See, *e.g.*, Hovenkamp, *supra*, 87 Minn. L. Rev. at 1759; Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 Minn. L. Rev. 1789, 1802 (2003); Shapiro, *supra*, 34 RAND J. Econ. at 407-408; Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis and Lemley*, 87 Minn. L. Rev. 1767, 1782, 1787 (2003) (distinguishing expected litigation costs from other collateral costs and from considerations of patent validity).

settlement; and accordingly that such agreements were anticompetitive. *Id.* at 25, 26, 31. As the FTC observed, in a settlement without a reverse payment, it is reasonable to infer that the settlement reflects the parties' expectations about the outcome of the patent litigation. As a result, any restraint upon entry by the generic applicant results from its views of the patent's strength. By contrast, a reverse payment can enable competitors to share the profits created by the generic firm's non-entry into the market. The FTC has thus concluded that, unless there are offsetting pro-competitive considerations, an agreement involving a payment from the patentee to an alleged infringer logically results in a later generic entry date and less competition than would be expected absent the payment. *Id.* at 26.

II. The Sixth Circuit's Decision Involves An Agreement That Has Been Construed To Exclude Non-Infringing and Potentially Non-Infringing Products And Does Not Squarely Conflict With The Eleventh Circuit's Decision In

The petition seeks (Pet. 7, 9-18) to have this Court resolve an alleged conflict between the decision below and the subsequent decision in *Valley Drug Co.* v. *Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), petition for cert. pending, No. 03-1178 (filed Feb. 13, 2004), conditional petition for cert. pending sub nomTD0.0072 Tc0bn5o-Wb02 Twuc1The Tf9.1338a 4(5ihat Ha

were also alleged to prohibit the marketing of *non-infringing* products and to prohibit the waiving of the ANDA filer's 180-day exclusivity period. With respect to those allegations, however, the court stated that "th[o]se prohibitions may be beyond the scope of [the patent's holder's] lawful right to exclude and, if so, would expose appellants to antitrust liability for any actual exclusionary effects resulting from these provisions." *Id.* at 1306 n.18; cf. *Ethyl Gasoline Corp.* v. *United States*, 309 U.S. 436, 456 (1940). The Eleventh Circuit's rejection of a per se rule was thus addressed to "the failure * * * to market *admittedly infringing* products." 344 F.3d at 1306 n.18 (emphasis added).

It is less than clear that the Sixth Circuit's decision departs from the holding in *Valley Drug.* The better reading of the Sixth Circuit's opinion is that it does not deem illegal per se every settlement agreement that includes a reverse payment in exchange for the exclusion from the market of an allegedly infringing product. To be sure, petitioner and its amici point to seemingly broad language in the Sixth Circuit's opinion that they construe to require application of a per se rule in such circumstances. See, *e.g.*, Pet. 10 (citing Pet. App. 18a); Am. Intell. Prop. Law Ass'n Amicus Br. (AIPLA Br.) at 2-3. If construed in that manner, the court of appeals' decision would be erroneous. As discussed, a per se rule is reserved for the limited instance in which an exclusion from the market has "such predictable and pernicious anticompetitive effect" that "experience with [that] particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it." *State Oil Co.*, 522 U.S. at 10 (citation omitted). Certain settlements of patent litigation may benefit consumers and the public, regardless of the presence of a payment to the alleged infringer, and thus application of a per se rule would be inappropriate.

construed, it constituted a per se violation of the antitrust laws. Whether or not the district court's conclusions as to ancillarity and the applicability of the Agreement to non-infringing products are correct, it is hardly novel to condemn as illegal per se an agreement between an incumbent and a potential competitor that is not ancillary to any lawful agreement and that precludes the potential competitor from entering the market with a product that does not infringe any patent owned by the incumbent. See Hovenkamp, *supra*, 87 Minn. L. Rev. at 1764-1765 ("While the language in the [district court's] opinion is a little opaque, if it meant that Andrx promised not to sell products that Cardizem did not claim in its patent to begin with, then that portion of the agreement was per se unlawful notwithstanding the presence of a patent dispute.").

The court of appeals gave no indication that it departed

of its opinion (*id.* at 19a n.13), the court cited to a discussion in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188, 241 (E.D.N.Y. 2003), that specifically referenced the district court's reliance in this case on the Agreement's coverage of two products that were not at issue in the pending patent litigation.

In *Valley Drug*, the Eleventh Circuit was properly hesitant to recognize a square conflict between the two decisions. The Eleventh Circuit thus noted that the Sixth Circuit may have been influenced not only by the Agreement's provisions for reverse payments but also "by other provisions of the agreement which might more readily seem to exceed the potential exclusionary power of the patent." 344 F.3d at 1311 n.26.[7] Given the uncertainty over the scope and impact of the Sixth Circuit's decision, review at this time may be premature.

III. The Sixth Circuit's Decision Involves An Unusual Context—An Interim Patent Settlement Agreement—That Has Not Occurred With Significant Frequency

Petitioner also argues (Pet. 19-27) that the Court's review of the question whether interim agreements are unlawful per se is warranted because the issue is one of great and recurring importance. Settlements with reverse payments in an amount far exceeding litigation costs (such as the agree-

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[7] To be sure, the Eleventh Circuit also criticized the Sixth Circuit for failing "to measure the several provisions [of the Agreement] against the exclusionary power of the patents, or differentiate between provisions that fell within the scope of the patent's protection and those which did not." 344 F.3d at 1311 n.26. But the Sixth Circuit did not expressly preclude such an inquiry, and indeed, to the extent the court's approval of per se treatment rests on the Agreement's coverage of non-infringing or potentially non-infringing products, that reasoning would suggest a need for precisely such an inquiry to be conducted on remand. In any event, there is as yet no clear conflict on this issue.

ment in this case), however, appear to be rare outside the

patent holder that timely files an infringement action. Under 21 U.S.C. 355(j)(5)(B)(iii), the FDA is barred from approving the alleged infringer's ANDA for 30 months, thus blocking the generic drug's entry, unless the patent on the pioneer drug is judicially declared invalid or not infringed. 21 U.S.C. 355(j)(5)(B)(iii).[8] In contrast to the agreements in this case and in *Valley Drug*, all of the decisions pending in the lower courts cited by petitioner (Pet. 13-16) involve final settlements that conclusively resolve the parties' patent dispute. The distinction is important because the calculus of competitive costs and benefits is substantially different for interim settlements and final settlements. While final settlements of infringement claims may have anticompetitive effects, they may "facilitate innovation and investment in the patented technology by eliminating litigation risks and providing certainty over patent rights." AIPLA Br. at 14. The type of interim agreement at issue in this case, on the other hand, may have none of those effects, because it leaves questions of patent validity and infringement to be litigated. Consequently, this Court's consideration of the question presented might be of limited practical importance and would

[8] The interim agreements at issue in this case and in *Valley Drug* arose from peculiar circumstances in which the automatic 30-month stay that is ordinarily available to the patent holder was not in place. In the present case, HMR did not sue a later ANDA filer, Biovail, for infringement, *Andrx Pharmaceuticals, Inc.* v. *Biovail Corp.*, 256 F.3d at 803, and thus the automatic 30-month stay on FDA approval that an infringement suit would have triggered did not arise against Biovail's ANDA. Petitioner's 180-day exclusivity rights, however, could still block Biovail's entry into the market, and the Agreement was entered just a few months after Biovail filed its ANDA. In

not necessarily offer guidance regarding the antitrust liability that may attach to final patent infringement settlements.

IV. Subsequent Amendments To The Hatch-Waxman Act Militate Against This Court's Review Of The Sixth Circuit's Decision At This Time

This Court's review also may be unwarranted in light of certain amendments to the Hatch-Waxman Act that were enacted by Congress in 2003, after the parties entered into the agreements at issue in this case and in *Valley Drug*. Those amendments provide that the Act's 180-day exclusivity will be awarded on a product basis, rather than a patent-by-patent basis, Pub. L. No. 108-173, § 1102, 117 Stat. 2458 (to be codified at 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)), and permit all ANDA applicants that filed on the first day that an ANDA could be filed to be eligible for the 180-day exclusivity period, 117 Stat. 2457 (to be codified at 21 U.S.C. 355(j)(5)(B)(iv)(II)(bb)). The former change may reduce the number of times that the FDA may grant the 180-day exclusivity to a company that has filed the first ANDA containing a paragraph IV certification. The latter change, by allowing multiple ANDA applicants to obtain the 180-day exclusivity period, may increase the transaction costs for pioneer drug companies that seek to enter into agreements with those applicants. On balance, therefore, the 2003 amendments may reduce the number of agreements containing reverse payments.

Congress also amended the Act to require pioneer drug companies and generic applicants to file all patent settlement agreements and certain other agreements with the U.S. Department of Justice and the FTC within 10 days of execution. §§ 1111-1117, 117 Stat. 2461-2463. Because the amendments are complex and relatively new, it is not yet clear how they will affect competitive concerns relating to interim agree-

ments between pioneer and generic drug manufacturers. Accordingly, review by the Court of the question presented may be premature.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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