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.

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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

1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585. The Hatch-Waxman Act establishes procedures designed to facilitate the entry of lower-priced generic drugs while maintaining incentives to invest in new drug development.

Under the Act, a company seeking approval from the Food and Drug Administration (FDA) to market a new drug must file a New Drug Application (NDA) demonstrating the safety and efficacy of its product. 21 U.S.C. 355(b). Once an NDA has been approved, another company seeking to market a generic version of the drug may file an Abbreviated New Drug Application (ANDA) demonstrating that its product is bioequivalent to the brand-name counterpart. 21 U.S.C. 355(j). The FDA may approve the marketing of a generic drug prior to the expiration of a patent relating to the brand name drug if the applicant makes a "paragraph IV certification" that certifies that the patent in question is invalid or is not infringed by the generic product. 21 U.S.C. 355(j)(2)(A)(vii). If the patent holder files a patent infringement suit within 45 days after receiving notification of such a certification, the FDA's approval is automatically stayed for 30 months, unless the patent expires or is judicially determined to be invalid or not infringed before that time. 21 U.S.C. 355(j)(5)(B)(iii). The first company to file an ANDA with a paragraph IV certification relating to a particular brand name drug is granted the exclusive right to market a generic version for 180 days after it begins commercial marketing or a court holds the patent invalid or not infringed. 21 U.S.C. 355 (j)(5)(B)(iv).[1]

2. Cardizem CD is a brand-name prescription drug which contains a controlled-release formulation of diltiazem hydrochloride. The formulation's dissolution profile—0%-45% of the total diltiazem to be released within 18 hours—is pro-

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[1] In 2003, Congress amended the Hatch-Waxman Act in various respects. See pp. 18-19, *infra*.

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

certain other events). Pet. App. 8a. HMR began making payments to petitioner under the Agreement in July 1998.

In September 1998, petitioner supplemented its ANDA to seek approval for a reformulated generic version of Cardizem CD that permitted not less than 65% of total diltiazem to be released within 18 hours. Pet. App. 40a-41a. The FDA approved the supplemented ANDA on June 9, 1999. *Id.* at 9a. HMR, apparently conceding that the reformulated product did not infringe the '584 patent, immediately stipulated that it would not bring an infringement claim as to the reformulated product. In addition, the two firms settled the pending patent case (neither abandoning its position regarding infringement) and terminated the Agreement, although petitioner agreed not to market the generic versions of Cardizem CD at issue in the patent case without a license from HMR. *Id.* at 44a-45a. By that time, HMR's payments to petitioner pursuant to the Agreement totaled $89.83 million. *Id.* at 18a. Two weeks later, petitioner began marketing its generic version of Cardizem CD at a price below that of HMR's brand-name product. *Id.* at 45a.

The Federal Trade Commission (FTC) investigated the Agreement, and in March 2000, issued an administrative complaint against petitioner, HMR, and Carderm, alleging that the Agreement was anticompetitive in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45. *In re Hoechst Marion Roussel, Inc., Carderm Capital L.P., & Andrx Corp. (In re HMR)*, No. 9293, Compl. (FTC Mar. 16, 2000) <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>. The matter was settled with a consent order providing prospective relief. Decision and Order (FTC May 11, 2001) <http://www.ftc.gov/os/2001/05/hoechstdo.htm>. A subsequent ANDA filer also challenged the Agreement on antitrust grounds. *Andrx Pharm., Inc.* v. *Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001), cert. denied, 533 U.S. 931 (2002).

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.* at 65a. Moreover, by restraining petitioner from "relinquishing

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[2] The actions were consolidated for pretrial proceedings in the Eastern District of Michigan. Apparently, all parties other than petitioner and respondents here have reached settlements. Pet. App. 14a n.9; Pet. ii.

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]

DISCUSSION

Agreements settling patent infringement cases can raise difficult, important, and unsettled issues at the intersection of intellectual property law and antitrust law. A rule treating as a per se violation of the antitrust laws every patent infringement settlement agreement that precludes the marketing of allegedly infringing products in exchange for payments from the patentee to the alleged infringer (so called "reverse payments") would conflict with the well-established principle that per se treatment is reserved for conduct that has a predictable and pernicious anticompetitive effect.

This case, however, is not an appropriate vehicle for the Court to provide guidance as to the application of the antitrust laws to settlements in patent infringement cases involving reverse payments. The district court construed the Agreement at issue in this case to cover petitioner's marketing not only of allegedly infringing products but also of non-infringing or potentially non-infringing products that were not at issue in the patent litigation. Moreover, this case involves the relatively rare situation in which the parties entered into an *interim* agreement that did not resolve the parties' underlying patent dispute. These atypical aspects of the case militate against further review, particularly at this interlocutory stage.

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[3] After observing that the court's determination that the Agreement was illegal per se did "not resolve the issues of causation and damages," Pet. App. 21a, the court of appeals further held that the district court properly denied the defendants' motion to dismiss the complaint for failure to allege an antitrust injury. *Id.* at 4a, 21a-33a. Petitioner has not sought review of that holding.

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, but for the patent and the alleged infringement, the hypothetical settlement agreement would likely be seen as "a naked restrain[t] of trade with no purpose except stifling of competition," *Broadcast Music, Inc.* v. *CBS*, 441 U.S. 1, 20 (1979) (citation and internal quotation marks omitted), and therefore treated as unlawful per se based on its "predictable and pernicious anticompetitive effect" and its "limited potential for procompetitive benefit." *State Oil Co.* v. *Khan*, 522 U.S. 3, 10 (1997).

In the patent context, however, a settlement involving restrictions on the sale of allegedly infringing products is not necessarily anticompetitive. A patent grants the patent holder the lawful "right to exclude others from profiting by the patented invention." *Dawson Chem. Co.* v. *Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). Thus, patent holders can lawfully refuse to license competitors to produce the patented article, or can grant exclusive territorial or other limited licenses to one or more chosen licensees. *Ibid.*; 35

U.S.C. 261, 271(d)(4); *In re Independent Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000), cert. denied, 531 U.S. 1143 (2001).

At the same time, a restrictive agreement that occurs in connection with a patent litigation settlement is subject to antitrust scrutiny if the patent holder obtains "protection from competition which the patent law, unaided by restrictive agreements, does not afford," *United States* v. *Masonite Corp.*, 316 U.S. 265, 279 (1942). There may be particular reason for concern about the competitive consequences of a settlement that includes payments from the patent holder to the alleged infringer. Such reverse payments can be a device for the sharing of monopoly rents made possible by the alleged infringer's exclusion from the market and can result in less competition than would likely have prevailed in the absence of the payment. Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1749 (2003); Carl Shapiro, *Antitrust limits to patent settlements*, 34 RAND J. Econ. 391, 408 (2003).

There is insufficient basis, however, for per se condemnation of all settlement agreements in patent infringement cases that preclude marketing of allegedly infringing products in exchange for payments from the patentee to the alleged infringer. Reverse payments may have the salutary effect of facilitating efficient settlements that advance consumer welfare. For example, reverse payments may reflect a savings in the patent holder's expected litigation costs. Thus, consent orders entered into by the FTC reflect the view that payments to the alleged infringer up to the value of the patent holder's expected litigation costs in enforcing the patent are not anticompetitive.[4] The FTC has identified

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[4] *Bristol-Myers Squibb Co.*, No. C-4076 (FTC Apr. 14, 2003) (consent order), <http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf>;

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 *Valley Drug*

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 nom. *Walgreen Co.* v. *Abbott Laboratories*, No. 03-1175 (filed Feb. 16, 2004). The two decisions, however, do not present a square conflict that necessitates this Court's review at this time. The Eleventh Circuit in *Valley Drug* rejected the characterization of interim patent settlement agreements as per se illegal, but relied on the fact that the parties agreed that the ANDAs that were the subjects of the infringement suits *admittedly infringed* a patent. 344 F.3d at 1304-1306 & n.18. The Eleventh Circuit recognized that the agreements before it

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.

The Sixth Circuit's opinion is better read, however, as limited to the particular agreement before the court, which had been construed by the district court to restrain petitioner "from marketing *non-infringing* or *potentially non-infringing* versions of Cardizem CD," thus reaching versions "not at issue in the * * * patent case, including" the non-infringing reformulated generic drug that the FDA approved and petitioner eventually marketed. Pet. App. 65a (emphasis added); accord *id.* at 59a-61a. The FTC's complaint similarly had construed the agreement to restrain petitioner "from selling any other bioequivalent or generic version of Cardizem CD, regardless of whether such product would infringe Hoechst MRI's or Carderm's patents." *In re HMR*, *supra*, Compl. at ¶ 23. The district court moreover found that the Agreement restrained Andrx from "relinquishing or otherwise compromising its right to the 180-day period of exclusivity," thereby possibly delaying entry by other generic firms. Pet. App. 65a. Both of those restraints extended beyond the legitimate scope of the patent claims by reaching non-infringing products and conduct by petitioner that the patent conferred no right to exclude or demand.[5]

The district court rejected petitioner's arguments that the challenged provisions should be treated as ancillary to a lawful agreement, Pet. App. 75a-81a,[6] and concluded that, as

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[5] In its *Schering* decision, the FTC observed that the Sixth Circuit "found that it was *per se* illegal for a pioneer drug company to pay money to a generic manufacturer in return for a commitment to delay entry," whereas the Eleventh Circuit in *Valley Drug* "expressly considered contrary authority and declined to apply the *per se* label." *Schering*, slip op. 12-13. The FTC noted, however, that the Sixth Circuit's decision "can be distinguished on its facts" because "there were additional potentially anticompetitive commitments by the generic." *Id.* at 13 n.26.

[6] An agreement not to compete that is ancillary to a lawful agreement is properly analyzed under the rule of reason, rather than the per se rule. Federal Trade Comm'n & U.S. Dep't of Justice, *Antitrust Guidelines for*

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 from the district court's analysis, and its opinion suggests that it relied on the district court's construction of the Agreement. Thus, in rejecting petitioner's "attempts to avoid *per se* treatment," the court of appeals stated that "the Agreement cannot be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation," "*[a]s explained in greater detail in the district court's opinion*." Pet. App. 18a-19a (emphasis added). The court then cited a portion of the district court's opinion (*id.* at 19a, citing *id.* at 67a-80a) that included the district court's determinations that the Agreement extended to non-infringing versions, *id.* at 77a, 79a, and in effect excluded other competitors, *id.* at 77a, 80a. Moreover, in footnote 13

Collaborations Among Competitors § 3.2 (Apr. 2000) <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>; U.S. Dep't of Justice & Federal Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* § 3.4 (Apr. 1995) <http://www.usdoj.gov/atr/public/guidelines/ipguide.pdf>.

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 Hatch-Waxman context. 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, 1797-1798, 1800 (2003). A variety of factors unique to the pharmaceutical industry, including the effects of state laws and various policies of health care institutions that accelerate and magnify the economic impact of generic entry and the contours of the Hatch-Waxman regulatory scheme, have created incentives for the use of reverse payment provisions in pharmaceutical patent litigation. For example, reverse payment settlements may be attractive to the patentee in this context because they may forestall entry not only by the alleged infringer, but by other generic firms as well. Hovenkamp, *supra*, 87 Minn. L. Rev. at 1757.

More significantly, the question presented by petitioner appears to have limited significance even in the Hatch-Waxman context because this case involves an *interim* settlement agreement that did not finally resolve the parties' underlying patent dispute. After undertaking an exhaustive study of litigation agreements over an eight-year period relating to drug products for which paragraph IV certifications have been filed, the FTC has found such interim agreements to be rare. Aside from the agreements challenged here and in *Valley Drug*, the FTC study found only one other interim agreement between a patentee and an alleged infringer, and no such agreements entered into after the FTC's investigations in this area became public in April 1999. Federal Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 34 (July 2002) <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

Such interim settlement agreements are particularly unlikely given that the Hatch-Waxman Act effectively grants an automatic 30-month preliminary injunction in favor of a

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 *Valley Drug*, the patent holder, Abbott, failed to file an infringement suit with respect to one ANDA within the statutory period necessary to trigger the 30-month stay on FDA approval. The parties entered into their interim agreements shortly after the generic firm received final approval by the FDA with respect to the product not subject to the 30-month stay. 344 F.3d at 1299.

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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