Nos. 12-245, 12-265

In the

Supreme Court of the United States

MERCK & CO., INC.,
Petitioner,
v.
LOUISIANA WHOLESALE DRUG CO., INC., *et al.*,
Respondents.

UPSHER-SMITH LABORATORIES, INC.,
Petitioner,
v.
LOUISIANA WHOLESALE DRUG CO., INC., *et al.*,
Respondents.

On Petitions For Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF FOR WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF THE PETITIONS FOR WRIT OF CERTIORARI

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INTEREST OF *AMICUS CURIAE*[1]

Washington Legal Foundation ("WLF") is a non-profit public interest law and policy center with supporters in all 50 States. WLF regularly participates as *amicus curiae* in federal and state court proceedings to promote economic liberty, free enterprise, and a limited and accountable government and, to that end, has appeared in numerous cases related to patent rights and antitrust law. In particular, WLF participated as an *amicus* before the Third Circuit in the proceedings below, *see* Pet. App. 1a-44a,[2] and before the Eleventh Circuit in connection with a 2005 decision in which the Eleventh Circuit addressed the very same patent settlements at issue here and reached a conclusion opposite from the Third Circuit's, *see Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006).

WLF files this brief because the decision below creates an intolerable conflict among the courts of appeals that leaves the holders of drug patents who are subject to suit in the Third Circuit with substantially diminished legal rights relative to other similar patent holders. WLF is also concerned that the Third Circuit's decision will stifle the incentives of generic drug

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[1] All parties received timely notice of the intent to file this brief and have consented to its filing in letters on file with the Clerk of the Court. No counsel for a party has authored this brief in whole or in part, and no person other than *amicus* and its counsel has made a monetary contribution to the preparation or submission of this brief. *See* Sup. Ct. R. 37.2(a), 37.6.

[2] "Pet. App.," as used herein, refers to the appendix to the petition for a writ of certiorari filed by Merck & Co., Inc., in Case No. 12-245.

makers to compete with brand-name drug companies in direct contravention of the goals of the antitrust laws and the intent of Congress.

BACKGROUND

At issue in this case is the legal standard for antitrust review of patent settlement agreements between brand-name drug manufacturers and generic drug makers. Schering-Plough Corporation ("Schering") (now owned by petitioner Merck & Co., Inc.) held a formulation patent for a potassium chloride supplement marketed under the brand name K-Dur. Upsher-Smith Laboratories, Inc. ("Upsher-Smith") and ESI Lederle ("ESI") each sought abbreviated regulatory approval to market generic versions of K-Dur, pursuant to the procedures set forth in the Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585. As contemplated in the Hatch-Waxman Act, Schering filed patent infringement actions against Upsher-Smith and ESI to protect its patent. These patent infringement actions ultimately settled, with agreements that expressly permitted the generic manufacturers to begin marketing generic versions of K-Dur before the expiration of the patent's term of exclusivity. Both settlements also included the payment of money from Schering to the generic drug makers (sometimes referred to as a "reverse payment").

In 2001, the Federal Trade Commission ("FTC") issued an administrative complaint charging that these settlements constituted unreasonable restraints of trade in violation of section 1 of the Sherman Act, 15 U.S.C. § 1, and unfair methods of competition in

violation of section 5 of the FTC Act, 15 U.S.C. § 45. An administrative law judge initially ruled against the agency's complaint after a nine-week trial, but on appeal, the FTC reversed and issued a final order condemning the settlement agreements. That final order was in turn rejected by the Eleventh Circuit in *Schering-Plough Corp. v. FTC*, *supra*, which followed an earlier decision of the Eleventh Circuit adopting the so-called "scope of the patent" rule, *see Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004).

The "scope of the patent" rule holds that settlement agreements between brand-name and generic drug manufacturers do not violate the antitrust laws provided they do not purport to expand the potential exclusionary scope of the drug patent beyond its term of years or beyond the claims covered by the patent, absent a showing by those challenging the settlement that the patent was procured by fraud or that the underlying patent infringement action was a sham (in other words, objectively baseless). *See, e.g.*, *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1306-15 (11th Cir. 2012) (reviewing the rule and adhering to it); *Schering-Plough*, *supra*; *Valley Drug*, *supra*. The Second Circuit and the Federal Circuit have followed the Eleventh Circuit in adopting the same "scope of the patent" rule. *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212-13 (2d Cir. 2005) (adopting same rule as Eleventh Circuit), *cert. denied*, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) (expressly following rule adopted by Eleventh and Second Circuits), *cert. denied*, 557 U.S. 920 (2009).

On a separate track from the FTC action against Schering, various private parties (including companies that were direct purchasers of K-Dur) brought parallel antitrust claims challenging the very same K-Dur settlement agreements under section 1 of the Sherman Act. These are the actions at issue here. Initially, the private claims were rejected by the district court on the basis of the "scope of the patent" rule. *See* Pet. App. 45a-46a (adopting special master's report and recommendation, reprinted at Pet. App. 47a-110a, and granting summary judgment to defendants). On appeal, however, the Third Circuit reversed, holding that reverse-payment settlement agreements between brand-name and generic drug companies are presumptively unlawful under section 1. Pet. App. 1a-44a.

The Third Circuit expressly disagreed with the "scope of the patent" rule applied by the Eleventh, Second, and Federal Circuits and refused to follow it. *Id.* at 25a ("[W]e cannot agree with those courts that apply the scope of the patent test."). The Third Circuit concluded that the "scope of the patent" rule is contrary to the Hatch-Waxman Act, which, the court found, evidences an intent by Congress to subject reverse-payment settlements involving pharmaceutical patents to heightened antitrust scrutiny. *See id.* at 25a-33a.

In lieu of the approach taken by other courts of appeals, the Third Circuit adopted a rule under which "the finder of fact must treat any payment from a [brand-name drug] patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade," and must then shift the burden of proof to the

patent holder to show "that the payment (1) was for a purpose other than delayed entry or (2) offers some procompetitive benefit." *Id.* at 32a. The Third Circuit agreed with the FTC's position that "there is no need to consider the merits of the underlying patent suit because '[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the [reverse] payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.'" *Id.* at 33a (quoting FTC's final order in *Schering-Plough*).

SUMMARY OF ARGUMENT

This Court should grant certiorari because the approach adopted by the court of appeals in this case deprives the holders of drug patents of critically important legal rights that are core attributes of any patent and, in so doing, creates an untenable conflict among the circuits. Brand-name drug manufacturers who are subject to suit in the Third Circuit (which is likely to be the great majority of such companies in the U.S.) have substantially reduced rights to settle with generic drug makers than do other identically situated patent holders. Indeed, the FTC has now vowed to bring all of its "reverse payment" antitrust actions in the Third Circuit whenever possible. This status quo will distort innovation in the drug industry, is grossly unfair, and is incompatible with the national procedural scheme for resolution of generic drug entry enacted by Congress in the Hatch-Waxman Act. The present case, moreover, provides the best vehicle for the Court to take up this important issue because it is the Third Circuit's decision below that created the circuit split and because all sides of the issue, including

the FTC's, were thoroughly represented in this case.

This case also presents a vitally important issue worthy of this Court's review because the Third Circuit's misguided decision threatens to dampen significantly the incentives that generic drug makers would otherwise have to challenge pioneer patents and compete with brand-name drug companies by stifling the generic makers' prospects for winning advantageous settlements. This anticompetitive impact is starkly at odds with the antitrust laws and with the purposes of the Hatch-Waxman Act. The pivotal nature of the Third Circuit's decision is demonstrated by the fact that the FTC has begun to use this decision to argue for an even broader rule that would condemn any settlements between brand-name and generic drug makers that defer generic entry and that involve any transfer of value from the brand-name manufacturer, even without a payment of money.

ARGUMENT

I. THE COURT SHOULD GRANT REVIEW TO RESOLVE A CIRCUIT SPLIT THAT DEPRIVES MOST PHARMACEUTICAL PATENT HOLDERS OF IMPORTANT LEGAL RIGHTS.

The circuit split created by the court of appeals decision in this case leaves pharmaceutical patent holders with dramatically unequal legal rights depending upon the circuit in which they are subject to suit. This Court should grant review to eliminate this intolerable disparity.

A. Patent Holders Ordinarily Enjoy Broad Legal Rights to Settle Disputes Over the Validity or Infringement of Their Patents Without Risk of Antitrust Liability.

The Constitution gives Congress the authority "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries," U.S. Const. Art. I, § 8, cl. 8, and Congress has exercised this power by enacting the patent laws. As the constitutional text declares, the purpose of these laws is to stimulate innovation and risk taking by rewarding inventors with the exclusive right to exploit the economic potential of their inventions for a finite period of time.

By statute, patents "have the attributes of personal property," 35 U.S.C. § 261, and the grant of a patent, like title to other property, carries with it important legal rights. These include the core right to the exclusive control and use of the patented technology during the term of the patent, *id.* § 154(a)(1), and the right to license the technology to others on terms and conditions agreeable to the patent holder (or to refuse to license, subject to rare exception), *see id.* §§ 261, 271(d)(4)-(5). The bundle of rights possessed by the patent holder also includes the right to bring a civil action in court to enforce the grant of exclusivity against those who would infringe the patent, including by injunction or through the award of damages. *Id.* §§ 281, 283, 284. Once issued, moreover, a patent is "presumed valid," and in any legal action respecting the patent, "[t]he burden of establishing

invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." *Id.* § 282.

As these attributes make evident, "[t]he grant of a patent is the grant of a statutory monopoly," *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964), and "the essence of a patent grant is the right to exclude others from profiting by the patented invention," *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). Within the exclusionary zone of a patent, therefore, the patent holder has a lawful right to exclude, restrain, or condition competition in the patented technology without risk of liability under the antitrust laws.

Necessarily implied in these statutory rights is the discretion to settle any objectively colorable legal claim regarding the validity or infringement of the patent on terms acceptable to the patent holder. *See Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 992-93 (N.D. Ill. 2003) (Posner, J., sitting by designation) (citations omitted) (emphasis in original):

> A firm that has received a patent from the patent office (and not by fraud . . .), and thus enjoys the presumption of validity that attaches to an issued patent, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to

> be found not to have infringed it, if the suit went to judgment. It is not 'bad faith' to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights. No one can be *certain* that he will prevail in a patent suit.

Unless the underlying infringement claim is frivolous or the patent clearly invalid, settlement terms that fall within the lawful exclusionary zone of the patent are not properly subjected to "the hot coals of antitrust litigation," *id.* at 992. Thus, this Court has held that "[w]here there are legitimately conflicting claims or threatened interferences [involving patents], a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act." *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931). This principle finds support by analogy in the *Noerr/Pennington* doctrine, under which this Court has held that the First Amendment right to pursue litigation to protect and vindicate legal interests (either by competitors acting jointly or by a single firm with monopoly power) is exempt from antitrust liability under the Sherman Act unless the legal claim is a sham—in other words, objectively baseless. *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993). The subjective motivation behind the legal action is irrelevant to the antitrust exemption. *See id.* at 56 & n.4; *see also Asahi Glass*, 289 F. Supp. 2d at 993.

That the settlement includes a payment from the patent holder to the alleged infringer should not in any

way undermine the patent holder's right to settle a dispute so long as the settlement does not exceed the exclusionary potential of the patent (again, provided the patent was not procured by fraud on the Patent and Trademark Office and provided the infringement claim is not objectively baseless). That judgment underlies the "scope of the patent" rule adopted by the Eleventh, Second, and Federal Circuits in the context of settlement agreements between brand-name and generic drug makers. *See supra* at 2.

B. Courts Applying the "Scope of the Patent" Rule Have Concluded that the Hatch-Waxman Act Does Not Take Away the Ordinary Settlement Rights for Holders of Drug Patents.

The courts of appeals that have adopted the "scope of the patent" rule have held that the Hatch-Waxman Act preserves for the holders of pharmaceutical patents all the same legal rights enjoyed by other patent holders, including the right to settle disputes relating to the validity or infringement of the patent. These courts have recognized that Hatch-Waxman is designed to expedite the approval process for generic versions of established drugs *while leaving intact the substantive rights of patent holders*.

Under the statute, a generic drug maker may file an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") for the bioequivalent form of a drug already approved for safety and effectiveness. 21 U.S.C. § 355(j). If a patent for the listed drug has not expired and the generic drug manufacturer desires to market its drug before the

patent expires, the generic maker must file a so-called "Paragraph IV certification," asserting that the patent is invalid or would not be infringed by the manufacture, use, or sale of the generic equivalent. *Id.* § 355(j)(2)(A) (vii)(IV). In that event, the Hatch Waxman Act further provides that the patent owner *must* bring a patent infringement suit against the ANDA filer within 45 days of receiving notice of the Paragraph IV certification in order to obtain a 30-month stay of FDA approval of the generic's ANDA. *Id.* § 355(j)(5)(B)(iii). In that way, the Hatch-Waxman framework pushes the parties to resolve their patent disputes promptly through legal action. Because of the expense and risks involved in litigation, this resolution frequently takes the form of a compromise and settlement.

What is more, as courts have repeatedly recognized, "reverse payments are particularly to be expected [as part of such settlements] in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them." *In re Tamoxifen*, 466 F.3d at 206 (citation omitted); *see also Schering-Plough*, 402 F.3d at 1074 (stressing that the Hatch-Waxman Act redistributed the relative risk assessments of parties involved in patent litigation in a manner that "explains the flows of settlement funds and their magnitude"). As the Second Circuit explained in *Tamoxifen*, in a "typical patent infringement case" (*i.e.*, outside the framework of Hatch-Waxman), "the alleged infringer enters the market with its drug after the investment of substantial sums of money for manufacturing, marketing, legal fees, and the like." 466 F.3d at 206. If the patent holder sues for damages, including lost

profits, and prevails in that suit, it stands to receive not only the continued preservation of its patent but also considerable money damages. *Id.* On the other hand, the losing infringer not only must pay the judgment, but also faces the loss of its entire initial investment in the product. *Id.* In such a case, "[i]t makes sense . . . for the alleged infringer to enter into a settlement in which it pays a significant amount to the patent holder to rid itself of the risk of losing the litigation." *Id.*

In the Hatch-Waxman Act context, however, the relative risks are precisely reversed. The statute intentionally creates a powerful incentive for the patent holder to sue *before* the generic drug manufacturer has invested substantial funds in manufacturing, marketing, or selling the drug. "The prospective drug manufacturer therefore has relatively little to lose in the litigation." *Id.* at 206-07. The patent holder, on the other hand, has much to lose and little to gain from continuing the litigation—should it lose, it will be stripped of its patent, and by winning it gains nothing but the continued protection of its lawful monopoly. *Id.* at 207 (noting that the patent holder has "little reason . . . to pursue the litigation beyond the point at which it can assure itself that no infringement will occur in the first place").

For these reasons, the Hatch-Waxman framework effectively compels the patent holder to settle in most cases—even if it must make a considerable payment to the generic drug manufacturer to achieve the settlement. Because any litigant must consider the risk of losing—no matter how confident it is in the merits of its position—and because of how

devastating a loss of patent protection can be, the patent holder may determine that making a substantial payment to the generic drug manufacturer to settle the case is in its economic self-interest.

The "scope of the patent" rule adopted by the Second, Eleventh, and Federal Circuits takes account of this dynamic and the reversal of incentives created by the Hatch-Waxman Act while preserving the substantive rights of patent holders. The rule presumes that as long as the settlement agreement does not suppress competition beyond the exclusionary potential of the patent—and as long as the patent was not procured by fraud and the infringement suit is not a baseless sham—such a settlement agreement, particularly in the Hatch-Waxman framework, should be free from antitrust risk.

C. As a Result of the Contrary Decision Below, Pharmaceutical Patent Holders Subject to Suit in the Third Circuit Now Have Substantially Reduced Settlement Rights Relative to Other Similar Patent Holders.

In contrast with the other courts of appeals, the Third Circuit below read the Hatch-Waxman Act to diminish dramatically the substantive legal rights of pharmaceutical patent holders. While all patents are entitled to a *presumption of validity under the patent laws*, the Third Circuit has held that reverse-payment patent settlements between brand-name and generic drug manufacturers, as distinct from all other patent settlements, are *presumptively unlawful under the antitrust laws*.

By shifting the burden to the patent holder to prove that any payment from the patent holder to the generic maker has a purpose other than delaying generic entry or that it has some separate procompetitive benefit, Pet. App. 32a, the Third Circuit, unlike its sister circuits, refuses to recognize that a patent holder—any patent holder—*has the lawful right to delay entry* within the exclusionary scope of the patent. *See Dawson*, 448 U.S. at 215 (noting that the "*essence* of a patent grant is the right to exclude others from profiting by the patented invention" during the term of the patent) (emphasis added). Furthermore, the Third Circuit's rule effectively imposes *per se* antitrust liability on the parties to the settlement, since the court held that "there is no need to consider the merits of the underlying patent suit." Pet. App. 33a. If the fact finder is precluded from considering the merits of the underlying litigation, the patentee cannot prove that in the absence of the reverse-payment settlement, it would likely have prevailed in enforcing its patent and that the overall settlement agreement is therefore *more* procompetitive than what would have resulted from the litigation.

Fundamentally, the Third Circuit's decision is driven by the notion that there is something inherently suspicious about a settlement that involves the payment of consideration from the brand-name patent holder to the alleged generic infringer. Nearly every settlement, however, involves some sort of consideration to the defendant, whether in the form of monetary payment or other benefit. Otherwise, the defendant would have little or no reason to settle. Moreover, as discussed above, the incentive structure

built into the Hatch-Waxman Act actually makes it even more likely that the settlement of patent infringement suits would include a reverse payment. Ultimately, "[n]o one can be *certain* that he will prevail in a patent suit." *Asahi Glass*, 289 F. Supp. 2d at 993. And unless the circumstances of the settlement are objectively baseless or the competition-suppressing effects of the agreement exceed the exclusionary scope of the patent, the settlement should be free from antitrust scrutiny.[3]

The inequality of rights available to pharmaceutical patent holders who are sued in the Third Circuit versus other similarly situated patent holders is unjust and unacceptable, and for that reason alone, this Court should grant certiorari to put an end

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[3] Notably, in *Tamoxifen*, the Second Circuit upheld the lawfulness of a reverse-payment settlement even though the district court found the patent at issue invalid in the underlying patent litigation. *See* 466 F.3d at 193. The appeal of the district court's judgment was pending at the time the parties settled, and recognizing that the appellate court might have overturned the district court's judgment, the Second Circuit concluded that the settling parties' legal positions were not objectively baseless. *Id.* at 203-05. Because the settlement agreement fell within the scope of the underlying patent, it was not subject to antitrust scrutiny. *Id.* at 213-15 ("The fact that the settlement here occurred after the district court ruled against [the patent holder] seems to us to be of little moment. There is a risk of loss in all appeals that may give rise to a desire on the part of both the appellant and the appellee to settle before the appeal is decided."*); see also Asahi Glass*, 289 F. Supp. 2d at 991, 993 (concluding that a patent settlement was not subject to antitrust scrutiny even though the court had previously ruled that the generic drug maker did not infringe the patent at issue because the earlier ruling was on appeal at the time of the parties' settlement—and thus at risk for reversal).

to this disparity. Moreover, the courts in the Third Circuit will now be magnets for "reverse payment" antitrust suits against drug makers, and, if undisturbed, the Third Circuit's rule has the potential to affect the vast majority of the U.S. pharmaceutical industry. Indeed, the Chairman of the FTC has acknowledged the conflict among the courts of appeals and has candidly stated that until the circuit split is resolved by this Court, the FTC will "simply be forced to bring pay-for-delay cases in the Third Circuit for years to come," and, he added, "After checking, it turns out that 95 percent of the pay-for-delay settlements filed with the FTC over the last eight years involved pharmaceutical companies that are headquartered or incorporated in the Third Circuit."[4]

The likely result will be that brand-name pharmaceutical companies will put less money into research and development of innovative new drugs because the diminished ability to protect their pioneer patents from generic challenge through advantageous settlement agreements will increase the costs and uncertainties of litigation and will render those patents less valuable. *See Schering-Plough*, 402 F.3d at 1075 ("[T]he caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product. The intensified guesswork involved with lengthy litigation cuts against

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[4] Jon Leibowitz, Chairman, FTC, Remarks at the Sixth Annual Georgetown Law Global Antitrust Enforcement Symposium (Sept. 19, 2012), at 4, available at http://www.ftc.gov/speeches/leibowitz/120919jdlgeorgetownspeech.pdf.

the benefits proposed by a rule that forecloses a patentee's ability to settle its infringement claim." (citation omitted)); *Tamoxifen*, 466 F.3d at 203 ("Rules severely restricting patent settlement might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation.").

D. The Third Circuit's Decision Provides the Best Vehicle for Resolving this Disparity Among the Circuits.

The Court should resolve this untenable conflict among the courts of appeals by granting the present petitions and taking up the Third Circuit's decision for review.

It is the Third Circuit's outlier reasoning that has created the legal conflict, and it is that reasoning that calls out for review by this Court. The various perspectives of all relevant parties were fully aired and thoroughly presented in the proceedings below, including the perspectives of sophisticated brand-name drug companies and generic drug manufacturers, the perspectives of numerous plaintiffs who are direct purchasers of the affected drug products, and the perspective of the most relevant federal agency, the FTC, which has actively pursued and advocated for years for the legal position now embraced by the Third Circuit. All of these perspectives will be well-developed and well-represented before this Court.

Moreover, the FTC has previously conducted its

own administrative challenge to the very same settlement agreements at issue before the Third Circuit, with a full administrative record developed by the agency. *See* Pet. App. 70a (special master's report) (detailing the nine-week agency trial record, including testimony of 41 witnesses, thousands of exhibits, and 8,629 pages of transcript, and the comprehensive decision of the administrative law judge, who made 431 findings of fact); *see also Schering-Plough*, 402 F.3d at 1061 (summarizing the procedural history before the FTC concerning the K-Dur settlements).

These petitions therefore present the ideal vehicle for resolution of the important questions raised by the circuit split.

II. UNLESS CERTIORARI IS GRANTED, THE THIRD CIRCUIT'S DECISION WILL LESSEN COMPETITION IN DRUG MARKETS IN CONTRAVENTION OF THE GOALS OF THE ANTITRUST LAWS AND THE HATCH-WAXMAN ACT.

The Third Circuit's decision also raises an exceptionally important issue worthy of certiorari because, if left unreviewed, this decision will have the perverse result of dampening the incentives of generic drug makers to compete against brand-name drug companies, and that outcome would plainly be contrary to the purposes of the very antitrust laws asserted by the Third Circuit and the goals of the Hatch-Waxman framework enacted by Congress.

The Third Circuit acknowledged that its holding ran against the important policy goal of promoting

settlement. *See* Pet. App. 31a. The court justified this result by purporting to advance the "countervailing public policy objective[]" of encouraging parties to litigate their patent challenges "to protect consumers from unjustified monopolies by name brand drug manufacturers." *Id.* at 31a-32a. One of the purposes of the Hatch-Waxman Act is, indeed, to encourage generic manufacturers to compete more assertively with brand-name companies and thereby increase the availability of low-cost drugs.

What the Third Circuit failed to recognize, however, is that by significantly constraining the rights of the settling manufacturers and thereby discouraging patent settlements, its decision will inevitably create a disincentive for generic makers to compete by challenging pharmaceutical patents in the first place and will thus ultimately *decrease* the availability of low-cost drugs. Generic drug makers will be less inclined to file ANDAs that challenge the patents held by brand-name companies if they are effectively foreclosed from obtaining settlement agreements that establish a date certain for early generic entry and involve the payment of value from the patent holder. This outcome is antithetical to Congress's goals in Hatch-Waxman and is arguably anticompetitive. *See Asahi Glass*, 289 F. Supp. 2d at 994 ("A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive."); *see also Schering Plough*, 402 F.3d at 1075 (recognizing that "reverse-payment" settlements can "benefit the public by introducing a new rival into the market, facilitating competitive production, and encouraging

further innovation").

In this very case, for example, the settlements at issue resulted in generic competition years before the date on which Schering's patent was set to expire. If Schering would have pursued the litigation and won—or if the generic manufacturers never attempted to challenge the patent in the first place—consumers would have lost the benefit of years of early competition. Thus, this Court has long recognized that the "interchange of patent rights and the division of royalties . . . is frequently necessary if technical advancement is not to be blocked by threatened litigation," and "such interchange may promote rather than restrain competition." *Standard Oil Co.*, 283 U.S. at 170-71.

The Third Circuit suggests that the impact of its decision will be limited because its holding applies only to settlements involving "reverse payments." Nearly *any* settlement, however, will involve some benefit to the defendant, and therefore many patent settlements would be potentially subject to antitrust scrutiny to some degree under the Third Circuit's rationale. *See Asahi Glass*, 289 F. Supp. 2d at 994 (emphasizing that "*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements."). This premise has also been recognized by other courts of appeals. *See, e.g.*, *Tamoxifen*, 466 F.3d at 207 n.20 ("A blanket rule that all settlements involving reverse payments are unlawful could thus conceivably

endanger any ordinary settlements of patent litigation."); *Schering-Plough*, 402 F.3d at 1074 (agreeing with Judge Posner's observation in *Asahi*).

Significantly, the far-reaching implications of the Third Circuit's decision are not merely theoretical. Less than a month after the Third Circuit handed down its opinion below, the FTC filed an *amicus* brief in a case pending in the district court in New Jersey arguing that the use of the term "payment" in the Third Circuit's opinion includes nonmonetary benefits flowing from the brand-name drug company to the generic manufacturer. Brief for FTC as *Amicus Curiae*, *In re Effexor XR Antitrust Litig.*, No. 3.11-cv-05479 (D.N.J. filed Aug. 10, 2012) (arguing that a nonmonetary benefit to the generic drug manufacturer should be deemed the equivalent of a "reverse payment" for delayed entry and constitutes *prima facie* evidence of an unreasonable restraint of trade). Based on that argument, any settlement agreement in which the generic drug manufacturer agrees to delay entry could be subjected to antitrust scrutiny, because presumably the generic company would not have agreed to the delay unless it thought it was receiving some benefit in return.

That reality means that the Third Circuit's holding will likely have a very harmful effect on competition in the pharmaceutical industry that is exactly the opposite of what the court intended. This outcome will ultimately have an enormous impact on the welfare of consumers who benefit from such competition, and the issue presented in the petitions for certiorari therefore clearly merits review by this Court.

CONCLUSION

For the foregoing reasons, *amicus curiae* Washington Legal Foundation urges the Court to grant the petitions for writ of certiorari.

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