In the Supreme Court of the United States

MERCK & Co., INC.

v.

LOUISIANA WHOLESALE DRUG COMPANY, INC., ET AL.

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

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA) AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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TABLE OF CONTENTS

Interest of amicus1
Summary of the argument3
Argument:
The Third Circuit's unwarranted presumption
of illegality for Hatch-Waxman settlements
including payments to prospective generic
manufacturers creates a direct circuit conflict
with immediate detrimental consequences for
the pharmaceutical industry6
A. The courts of appeals had upheld the
lawfulness of settlements that the Third
Circuit—to the detriment of competition
and consumers—alone now condemns6
B. The Third Circuit's new limitations on
settlements will harm the pharmaceutical
industry and consumers nationwide13
Conclusion

TABLE OF AUTHORITIES

Page(s) Cases:
Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986 (N.D. Ill. 2003)
In re, 261 F. Supp. 2d 188 (E.D.N.Y. 2003)
FTC v. Watson Pharm., Inc., 677 F.3d 1298 (11th Cir. 2012)
370 (S.D.N.Y. 1999)
U.S. 939 (2004)7, 12, 16

Statutes:

Federal Food, Drug, and Cosmetic Act, 21	
U.S.C. 355 et seq.:	
21 U.S.C. 355(j)(2)(A)(vii)(IV)	9
21 U.S.C. 355(j)(5)(B)(iii)	
21 U.S.C. 355(j)(5)(B)(iv)	
21 U.S.C. 355(j)(5)(D)7	
35 U.S.C. 271(e)(5)	
Hatch-Waxman Act, Pub. L. No. 98-417, 98	0
Stat. 1585 (1984)	7
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Miscellaneous:	
Kent S. Bernard & Willard K. Tom, Antitrust	
Treatment of Pharmaceutical Patent	
Settlements: The Need for Context and	
Fidelity to First Principles, 15 Fed. Cir.	
B.J. 617(2006)	. 12
Daniel A. Crane, Ease Over Accuracy in	,
Assessing Patent Settlements, 88 Minn. L.	
Rev. 698 (2004)11, 12	, 16
J.A. DiMasi & H.G. Grabowski, The Cost of	•
Biopharmaceutical R&D: Is Biotech	
Different?, 28 Managerial & Decision Econ.	
469 (2007)	2
J.A. DiMasi et al., The Price of Innovation,	
New Estimates of Drug Development Costs,	
22 J. Health Econ. 151 (2003)	2

Miscellaneous—continued

INTEREST OF AMICUS¹

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies.² PhRMA's mission is to advocate in support of public policies that encourage the discovery of life-saving and life-enhancing new medicines by pharmaceutical and biotechnology research companies. During 2011 alone, PhRMA members invested an estimated \$49.5 billion in discovering and developing new medicines.³ PhRMA closely monitors legal issues that affect the pharmaceutical industry and has frequently participated in cases before this Court.

The issue presented by the instant petition—whether innovator companies can lawfully settle Hatch-Waxman patent litigation on terms that restrict

¹ Petitioner Merck & Co., Inc. has consented to the filing of amicus curiae briefs in support of either party or of neither party, in a letter on file with the Clerk. Respondents' counsel was given timely notice pursuant to Rule 37.2(a) and consented to the filing of this brief. No counsel for any party authored this brief in whole or in part, and no person or entity, other than PhRMA and its counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

² A list of PhRMA's member companies can be found at www.phrma.org/about/member-companies (last visited Sept. 23, 2012). Petitioner Merck & Co., Inc. is a member of PhRMA but did not participate in the preparation of this brief.

³ See PhRMA, *Pharmaceutical Industry 2012 Profile 28* fig. 10 (2012), http://www.phrma.org/sites/default/files/159/phrma_industry_profile.pdf (last visited Sept. 23, 2012).

the alleged infringer's activities within the scope of the patent and also include a payment (or other consideration) to the alleged infringer—is extremely important to the pharmaceutical industry. In practice, in many Hatch-Waxman cases, no reasonable settlement would be possible without some bargained-for consideration flowing to the generic applicant other than a license. And, until the Third Circuit's decision in the present case, the courts of appeals had uniformly refused to declare settlements that include some form of consideration to the generic applicant presumptively suspect, as long as any exclusion of competitors remained within the scope of the patent.

By erecting a significant barrier to the settlement of patent disputes, the Third Circuit's rule threatens to lock parties into protracted litigation and, in some instances, delay the introduction of generic medicines. Ultimately, by restricting the ability of innovator companies to manage risk and avoid the costs and uncertainty of litigation, the Third Circuit's rule dramatically diminishes incentives for innovation and product development. Creating a new medicine takes, on average, an investment of ten to fifteen years with costs estimated at approximately \$1.3 billion, when the costs associated with failed drugs are taken into account. J.A. DiMasi & H.G. Grabowski, The Cost of Biopharmaceutical R&D: Is Biotech Different?, 28 Managerial & Decision Econ. 469, 475-476 (2007); J.A. DiMasi et al., The Price of Innovation, New Estimates of Drug Development Costs, 22 J. Health Econ. 151, 181-182 (2003). PhRMA's innovator members rely on strong patent protection when they make these extraordinary investments in research and development. At the same time, companies are aware of the vagaries of litigation, including jury trials. If companies confronted the prospect that the protection patents afford must be litigated to conclusion, the incentive to innovate and bring new products to market would be undermined, harming not only PhRMA's members, but also the public, which has a vital interest in ensuring that promising research for new life-saving and life-enhancing treatments continues.

SUMMARY OF THE ARGUMENT

This issue presented in this case is tremendously important to the pharmaceutical industry. The decision below has upended Congress's carefully balanced regulatory regime under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), which established a framework for premarketing litigation of patent disputes between innovator drug manufacturers and would-be generic manufacturers. Congress intended that the Hatch-Waxman Act would encourage the entrance of generics, but also preserve innovators' incentives to pour the tremendous resources into discovery development of new life-saving and life-enhancing drugs.

Congress chose to incentivize generics' entry by encouraging litigation of innovators' patent infringement claims prior to marketing by generics. Such preentry litigation poses risks to innovator companies, who may—through the uncertainties of litigation—lose their patents and thus lose their means of recovering drugs' development costs, as well as the resources to fund the discovery and development of new drugs. And,

because by Congress's design this litigation occurs before generics have incurred any liability for causing damages, innovators cannot bargain with would-be generic infringers by offering to reduce the amount of damages to be paid the innovator by the infringer; rather, the threatened harm is all in the future, after the generic's entry. Accordingly, to reach reasonable settlements of such litigation, innovators at times must compensate would-be generic infringers for *not* infringing during some or all of the remaining life of the disputed patent. That is, the innovator offers a payment or other form of consideration to would-be infringers in order to settle the dispute before trial.

Until now, the courts of appeals had reached a consensus that settlements containing payments or other forms of consideration were lawful, as long as they did not exclude competitors beyond the scope of the patent. With its holding that payments from the innovator to the generic are *prima facie* evidence of unreasonable restraints of trade, the Third Circuit has now parted ways with this consensus. (Indeed, the court even declined to follow the Eleventh Circuit's ruling on precisely the same settlement agreement, creating an undeniable conflict among the circuits on whether the very same conduct is lawful.)

The Third Circuit's rule will in many cases prevent or severely hamper innovator companies from settling Hatch-Waxman patent disputes. The consequences for innovators, generic drug manufacturers, and the public will be grave. Deterring patent settlements and encouraging protracted litigation will increase costs and consume judicial resources, prolong uncertainty, deter innovation, delay activities to invent around patents, and, ultimately, harm consumers.

Because the Third Circuit's outlier ruling will have outsized impact, this Court's immediate review is warranted. The Third Circuit is a significant locus of Hatch-Waxman litigation due to the number of pharmaceutical companies headquartered or with their principal place of operations within the Circuit. Consumer antitrust challenges to Hatch-Waxman settlements can nearly always be (and often are) venued in district courts within the Third Circuit. Moreover, the FTC is now taking the broadest possible view of the Third Circuit's opinion—disregarding the Eleventh Circuit's opinion directly to the contrary with respect to the very same agreements—and claims it imposes a blanket prohibition on settlements containing any consideration whatsoever flowing from innovators to alleged patent infringers. Thus, if left intact, the Third Circuit's decision will force innovator and generic manufacturers across the country to litigate cases that would otherwise settle, will delay the introduction of generic medicines in many cases, and ultimately will reduce the incentives for innovator companies to develop, introduce, and improve new and innovative medicines.

ARGUMENT

THE THIRD CIRCUIT'S UNWARRANTED PRESUMPTION OF ILLEGALITY FOR HATCH-WAXMAN SETTLEMENTS INCLUDING PAYMENTS TO PROSPECTIVE GENERIC MANUFACTURERS CREATES A DIRECT CIRCUIT CONFLICT WITH IMMEDIATE DETRIMENTAL CONSEQUENCES FOR THE PHARMACEUTICAL INDUSTRY

A. The Courts Of Appeals Had Upheld The Lawfulness Of Settlements That The Third Circuit—To The Detriment Of Competition And Consumers—Alone Now Condemns

Until the decision below, the courts of appeals had reached a consensus that settlements of Hatch-Waxman litigation that include a payment or some form of consideration from the innovator company to the alleged generic infringer are not presumptively invalid and comport with the antitrust laws as long as the settlements' terms do not exclude competition beyond the scope of the patent. See In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1336 (Fed. Cir. 2008), cert. denied, 557 U.S. 920 (2009) (describing consensus of Second, Eleventh, and Federal Circuits and holding it "to be completely consistent with Supreme Court precedent"); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212-213 (2d Cir. 2006), cert denied, 551 U.S. 1144 (2007) (as amended). As the Eleventh Circuit has explained, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312 n.9 (2012);

Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006).

Because patent infringement litigation under the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), occurs in a pre-market context, a payment (or other compensation) to an alleged generic infringer may provide the only reasonable terms on which a settlement can be achieved. Not surprisingly, many Hatch-Waxman settlements contain such terms. "Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement." Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1310 (11th Cir. 2003), cert denied, 543 U.S. 939 (2004). Such is to be expected in "the

⁴ Although the Sixth Circuit in *In re Cardizem CD Antitrust* Litigation, 332 F.3d 896 (2003), cert denied, 543 U.S. 939 (2004), imposed per se liability for a Hatch-Waxman settlement, the agreement in that case—unlike the instant case and unlike the mine run of Hatch-Waxman settlements—was a non-final settlement that "clearly had anticompetitive effects outside the exclusion zone of the patent," because the generic manufacturer agreed not to market even non-infringing formulations of the generic drug. In re Ciprofloxacin, 544 F.3d at 1335 (distinguishing In re Cardizem). The agreement, which the parties struck after the FDA had tentatively approved the generic manufacturer's ANDA, also delayed market entry by other generic manufacturers because, in exchange for a series of payments during the pendency of the litigation, the generic manufacturer agreed not to market its allegedly infringing drug or transfer its 180-day exclusivity period. See In re Cardizem, 332 F.3d at 902-903, 907. Congress has since amended the statute to prevent such bottlenecks; a first-filer forfeits its 180-day exclusivity period if it fails to market a generic drug within a certain time period. See 21 U.S.C. 355(j)(5)(D); Watson, 677 F.3d at 1312 n.9.

infamously costly and notoriously unpredictable process of patent litigation." Watson, 677 F.3d at 1300; see also Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J.) ("No one can be certain that he will prevail in a patent suit."); TM Patents, L.P. v. IBM Corp., 72 F. Supp. 2d 370, 378 (S.D.N.Y. 1999) ("[N]early 40 percent of claims constructions are changed or overturned by the Federal Circuit."). Even when an innovator company firmly believes its patents are valid and infringed, it may also believe it untenable to leave the ultimate determination of the soundness of its substantial investment to the uncertainties of a jury trial.

Until now, the courts of appeals have understood that this flow of consideration from the innovator to the alleged infringer is "a natural by-product of the Hatch-Waxman process," a process which "essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude." Schering-Plough, 402 F.3d at 1074 (quoting In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003)); accord In re Tamoxifen, 466 F.3d at 207; In re Ciprofloxacin, 544 F.3d at 1333 n.11.

Prior to the Third Circuit's decision, courts understood that, in contrast with ordinary infringement litigation, the Hatch-Waxman Act redistributes the risks because would-be generic manufacturers have "standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from infringing commercial sales." In re Ciprofloxacin, 261 F. Supp. 2d at 251. Would-be generics have the further incentive provided by the

statutory 180-day exclusivity period for the first challenger to a patent. See 21 U.S.C. 355(j)(5)(B)(iv). The patent holder, however, has no corresponding upside, as there are no infringement damages to collect, but has an enormous downside—losing its patent. *In re Ciprofloxacin*, 261 F. Supp. 2d at 251.

the courts had heretofore recognized, settlement of Hatch-Waxman litigation can benefit competition and consumers. Many such settlements permit entry of generic competitors prior to the expiration of innovators' patents, producing benefits for consumers. See, e.g., In re Ciprofloxacin, 261 F. Supp. 2d at 252 (noting that settlement had "permit[ed] generic entry of one of the most widely prescribed and best-selling antibiotics"); see also Kent S. Bernard & Willard Tom. Antitrust *Treatment* K. Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles, 15 Fed. Cir.

As described in the Petition, upon filing an Abbreviated New Drug Application (ANDA), a would-be generic manufacturer seeking to market a generic during the life of the innovator company's listed patent must certify for each such patent that "such patent is invalid or will not be infringed by" the generic drug. 21 U.S.C. 355(j)(2)(A)(vii)(IV). Congress has deemed the very filing of this "Paragraph IV" certification by a would-be generic manufacturer an act of infringement, in response to which the innovator has standing to file an infringement suit. See 35 U.S.C. 271(e)(2); 21 U.S.C. 355(j)(5)(B)(iii). To encourage generic manufacturers to attempt entry in this fashion, Congress has provided that the first generic applicant to make such a certification receives a 180-day period, starting from the date on which the applicant begins marketing the generic drug, within which the FDA will not approve additional ANDAs making such a certification. 21 U.S.C. 355(j)(5)(B)(iv).

B.J. 617, 630-631 (2006) (describing study suggesting that allowing so-called reverse payment Hatch-Waxman settlements has an overall effect of facilitating earlier generic entry than under more restrictive rules). "Similarly, Hatch-Waxman settlements, like[] the ones at issue here, which result in the patentee's purchase of a license for some of the alleged infringer's other products, may benefit the public by introducing a new rival into the market, facilitating competitive production, and encouraging further innovation." Schering-Plough, 402 F.3d at 1075 (approving same settlement agreements at issue in this litigation).

Indeed, the prospect of early entry or other compensation that covers start-up and litigation costs may provide the necessary incentive for some generics to challenge an innovator's patent in the first place especially because patent litigation may be very expensive for small firms. Judge Posner has observed that a "ban on reverse-payment settlements," such as that imposed by the Third Circuit, "might well be thought anticompetitive" because it "would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement." Asahi Glass, 289 F. Supp. 2d at 994 (emphasis added). See In re Ciprofloxacin, 261 F. Supp. 2d at 256 ("[A] generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it. Otherwise, the incentives to mount an ANDA IV challenge could be reduced."). By encouraging generics to bring paragraph IV challenges, the prospect of so-called "reverse-payment" settlements benefits consumers

because those settlements often bring generics to market prior to patent expiry.⁶

In addition to lowering consumers' costs, Hatch-Waxman settlements also foster innovation. Settlements may fuel research or development that would otherwise be in limbo due to uncertainty during the pendency of litigation. See Daniel A. Crane, Ease Over Accuracy in Assessing Patent Settlements, 88 Minn. L. Rev. 698, 706 (2004) ("Prolonged litigation may * * * freeze inventive activity for years because of the uncertainty over whether the alleged infringer will be allowed to participate in the market with its current technology or will be required to invent around the patent and to find an alternative, noninfringing way of entering."); accord Schering-Plough, 402 F.3d at 1075. "An early settlement eliminates the uncertainty over the scope and validity of the patent and may lead the defendant to invent around the patent earlier than if it had awaited the outcome of the patent lawsuit." Crane, 88 Minn, L. Rev. at 706.7

The prospect of a reverse-payment settlement also can encourage paragraph IV challenges by mitigating the risk that the generic company would incur vast liability for damages when launching its product after the automatic 30-month stay expires, should litigation extend beyond expiration. A first-filer must launch its generic product following FDA approval after the expiration of the stay, or lose its 180-day exclusivity period. See 21 U.S.C. 355(j)(5)(D).

⁷ Settlement also reduces the many direct and indirect costs of litigation—costs which in many cases amount to far greater sums than the attorney fees alone, and which may pose barriers to entry or be passed on to consumers. Such costs include the time spent by firm employees "preparing the case, producing

Significantly, in some circumstances, the grant of consideration from the innovator to the would-be generic is the *only* means by which a Hatch-Waxman case can reasonably be settled. This may be the case, for example, where a cash-strapped generic company lacks the means to delay entry; where the parties have asymmetric expectations about the likelihood of success in the litigation; or where they have asymmetric risk See Marc G. Schildkraut, Patent-Splitting Settlements and the Reverse Payment Fallacy, 71 Antitrust L.J. 1033, 1034, 1058-1061 (2004) (describing "many circumstances where a reverse payment is necessary to resolve a patent litigation and that resolution is better for consumers than continued litigation"); Bernard & Tom, 15 Fed. Cir. B.J. at 629-631. In such circumstances, the Third Circuit's restriction on "reverse-payment" settlements would

documents, working with lawyers on litigation strategy, being deposed, traveling for lawsuit-related events, testifying at trial, and observing legal proceedings"; the necessity of seeking discovery "from suppliers or customers or engaging in other public conduct that may embarrass the litigants or damage relationships with third parties"; and loss of control over sensitive competitive information. Crane, 88 Minn. L. Rev. at 703-704. Furthermore, "[t]he length of patent litigation may * * * mak[e] marketing, research and development, and other business planning difficult while the outcome of the case remains uncertain." Id. at 704; see also Schering-Plough, 402 F.3d at 1075-1076 (recognizing that "[p]atent litigation breeds a litany of direct and indirect costs" and noting also the "public problems associated with overcrowded court dockets"); Valley Drug, 344 F.3d at 1309 ("The failure to produce the competing * * * drug, rather than the payment of money, is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.").

force the parties to incur and inflict all the costs of litigating the case through trial and to completion. The generic might not undertake the challenge to the patent in the first place under such a rule, or the innovator, for fear that an unpredictable jury might declare even a strong patent invalid, might never develop the new drug in the first place. Both innovators and generics, and ultimately consumers, lose under the Third Circuit's rule. This Court should grant the petition in order to set the law aright again.

B. The Third Circuit's New Limitations On Settlements Will Harm The Pharmaceutical Industry And Consumers Nationwide

Notwithstanding the consensus among other circuits permitting so-called reverse-payment settlements, the Third Circuit's newly-minted contrary rule will act as an effective ban on Hatch-Waxman settlements nationwide. Hatch-Waxman litigation is heavily concentrated in the Third Circuit. As of the writing of this brief, a nationwide docket search indicated that 80 Hatch-Waxman suits had been filed in district courts within the Third Circuit since January 1, 2012, and only five in all other circuits combined.8 These cases are so frequently litigated within the Third Circuit because more than a third of PhRMA's 28 full members are headquartered within the Third Circuit.

⁸ A nationwide search in the LexisNexis CourtLink database of federal district court documents and docket sheets for the period January 1, 2012 to September 12, 2012 using the search term "patent" together with "ANDA," "Hatch," "Waxman," or "generic" (if used within five words of "drug") turned up 85 Hatch-Waxman cases, of which 80 were within the Third Circuit.

PhRMA, Member Companies, http://www.phrma.org/about/member-companies (last visited Sept. 23, 2012); see also Remarks of FTC Chairman Jon Leibowitz, Sixth Ann. Georgetown L. Global Antitrust Enforcement Symposium 4 (Sept. 19, 2012), http://ftc.gov/speeches/leibowitz/120919jdlgeorgetownspeech.pdf (last visited Sept. 23, 2012) ("Leibowitz Remarks") (stating 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"). The Third Circuit's upsetting of the settled consensus as to the permissibility of Hatch-Waxman settlements within the scope of the patent will, therefore, have major consequences for Hatch-Waxman litigation as a whole.

Moreover, the Third Circuit's decision may multiply class actions challenging settlements within that Circuit. As a result, even in Hatch-Waxman litigation outside the Third Circuit, including in those circuits that have upheld so-called reverse-payment settlements, pharmaceutical companies will be deterred from entering into such agreements. Although the settlement would be legal within the circuit where it was entered, the settling companies could be subject to a private antitrust suit within the Third Circuit challenging the legality of the settlement, as occurred here. The favorable rulings of the Second, Eleventh, and Federal Circuits cannot save such a settlement if it is challenged in the Third Circuit, and thus, this Court should correct the Third Circuit's error.

The FTC's aggressive interpretation of the Third Circuit's opinion, and its Chairman's vow to challenge further settlements, further demonstrate the need for this Court's immediate intervention. The FTC has taken the position that nearly any form of settlement can be characterized as a verboten "payment" constituting "prima facie evidence of an unreasonable restraint of trade" under the Third Circuit's decision. See FTC Brief as Amicus Curiae, In re Effexor XR Antitrust Litig., No. 3:11-cv-05479, 1-2 (D.N.J. Aug. 10, 2012) (quoting In re K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012)). In the *Effexor* case, the FTC contends that an agreement by an innovator company not to issue its own "authorized generic" version of Effexor XR during the alleged generic infringer's 180day exclusivity period alone constitutes an anticompetitive "payment," see ibid., notwithstanding the fact that the innovator company will in any case be competing with the new generic entrant with its own branded drug during the period in question. The FTC's brief accordingly has put pharmaceutical companies nationwide on notice that the FTC regards any consideration to the alleged infringer as a potentially illicit reverse payment. And the FTC can (and already bring enforcement actions challenging settlements in district court, including within the Third Circuit. See, e.g., FTC v. Cephalon, No. 2:08-cv-02141-MSG (E.D. Pa. May 8, 2008). Indeed, the Chairman of the FTC has recently suggested that, should this Court decline certiorari in petitions raising this circuit split, "we'll simply be forced to bring pay-for-delay cases in the Third Circuit for years to come." Leibowitz Remarks at 2.

The Third Circuit's settlement-deterring rule poses "grave consequences for R & D and, in turn, severe consequences for consumers." *In re Ciprofloxacin*, 261

F. Supp. 2d at 256. From 2005 to 2010, nearly 100 Hatch-Waxman cases settled on terms the FTC considers "pay-for delay," because the settlements contain either monetary payments to would-be generic infringers or "implicit compensation." See FTC Bureau of Competition, Agreements Filed with the FTC Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 1-2 (2010), http://www. ftc.gov/os/2011/05/1105mmaagreements.pdf (last visited Sept. 23, 2012). Forced instead to litigate such cases to their end, innovators will be subject to burdensome costs as well as the prospect of uncorrected litigation error that may decrease the value of their intellectual property, decrease expected returns on research and development, and thereby decrease innovation. See In re Ciprofloxacin, 261 F. Supp. 2d at 256; Crane, 88 Minn. L. Rev. at 706 ("[R]estricting patent settlements will have the effect of increasing the anticipated costs of litigation for any firm considering entering a patentintensive market."). "The results will be fewer new drugs that have led in the past to healthier and more productive lives for U.S. customers and large gains to the U.S. economy." In re Ciprofloxacin, 261 F. Supp. 2d at 256; see also *Valley Drug*, 344 F.3d at 1309 ("To hold that an ostensibly reasonable settlement of patent litigation gives rise to per se antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally."); James Langenfeld & Wenqing Li, Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers, 70 Antitrust L.J. 777, 788 (2003)

(arguing that it is "particularly likely in the pharmaceutical industry" that limitations on settlements designed to protect intellectual property would in the long run harm consumer welfare by reducing the introduction of new products).

The stakes are too high for the Third Circuit's rogue decision to go uncorrected.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted.

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