Nos. 12-245 and 12-265

IN THE

Supreme Court of the United States

MERCK & CO., INC.,

Petitioner,

and

UPSHER-SMITH LABORATORIES INC.,

Petitioner,

v.

LOUISIANA WHOLESALE DRUG CO., INC., ET AL.,

Respondents.

ON PETITIONS FOR WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF OF *AMICUS CURIAE* NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF PETITIONERS

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September 24, 2012

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QUESTIONS PRESENTED

Petitioners' alternative formulations of their Questions Presented accurately and fairly characterize the ultimate issue upon which this Court should grant certiorari. In No. 12-245 Merck & Co., Inc. ("Merck") defines the issue as follows:

> Whether the federal antitrust laws permit a brand-name manufacturer that holds the patent for a drug to enter into a settlement of patent litigation with a prospective generic manufacturer, where the settlement includes a payment from the brand manufacturer to the generic manufacturer but does not exclude competition beyond the scope of the patent.

The formulation by *Upsher-Smith Laboratories, Inc.* ("Upsher-Smith") in No. 12-265 is similar:

> Whether the Third Circuit erred by holding, contrary to the Second, Eleventh and Federal Circuits, that an agreement settling patent litigation that does not restrict competition outside the scope of the exclusionary right granted by the patent itself may presumptively violate the antitrust laws.

Nonetheless, petitioners' briefs completely fail to address four important subsidiary questions, two legal and two economic, resolution of any one of which in petitioners' favor would mandate affirmative responses to both of the foregoing formulations of the ultimate issue:

Subsidiary Question 1. Whether the Third Circuit erred in presuming, in a private Clayton Act antitrust action alleging a Sherman Act Section 1 violation, that a potential seller of generic pharmaceuticals would have entered the market "at risk" absent an earlier settlement of a Hatch-Waxman patent infringement suit which included a "reverse payment" provision;

Subsidiary Question 2. In the absence of proof that a patent infringement suit brought under the Hatch-Waxman Act was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits", and after an entry date for a generic manufacturer is specified in a settlement agreement that also contains a reverse payment term, whether the Third Circuit erred in determining hypothetically that some earlier alternative entry date would have represented "an otherwise logical litigation compromise" in the absence of the reverse payment term.

Subsidiary Question 3. In a private Clayton Act antitrust action alleging a Sherman Act Section 1 violation, did the Third Circuit err by applying a "quick look" rule of presumptive illegality to a complicated fact pattern presenting both patent-antitrust interface and Hatch-Waxman issues extremely similar if not identical to those presented in eight previous federal appellate court cases in which, as properly interpreted, a full-blown rule of reason inquiry was required; and

Subsidiary Question 4. Would application of the Third Circuit panel's decision interfere directly with the ability of the generic manufacturers to effectively manage their Hatch-Waxman litigation dockets and eventually frustrate the Congressional objective of maximizing patent challenges.

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

This brief *amicus curiae* is respectfully submitted on behalf of the New York Intellectual Property Law Association ("NYIPLA" or "Association") in support of both petitioners.[1]

The separate petitions Nos. 12-245 of Merck and 12-265 of Upsher-Smith, docketed respectively on August 24, 2012 and August 30, 2012, seek review by this Court on a writ of certiorari of the panel decision and judgment of the United States Court of Appeals for the Third Circuit in *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3rd Cir. 2012) ("*K-Dur*").

The arguments set forth in this brief *amicus curiae* were approved on September 21, 2012 by an absolute majority of the officers and members of the Board of Directors of the NYIPLA, including any officers or directors who did not vote for any reason including recusal, but do not necessarily reflect the views of a majority of the members of the Association, or of the law or corporate firms with which those members are associated. After reasonable investigation, the NYIPLA believes that no officer or director or member of the Amicus Briefs Committee who voted in favor of filing this brief, nor any attorney associated with any such officer,

1. Pursuant to Spm. Ct. R. 37.6, the NYIPLA and its counsel represent that they have authored the entirety of this brief, and that no person or entity other than the *amicus curiae* or its counsel have made a monetary contribution to the preparation or submission of this brief. Pursuant to Spm. Ct. R. 37.2(a), copies of the written consents to the filing of this brief from all parties are submitted herewith.

director or committee member in any law or corporate firm, represents a party in this litigation. Some officers, directors, committee members or associated attorneys may represent entities, including other *amici curiae*, which have an interest in other matters that may be affected by the outcome of this litigation.

The NYIPLA

The NYIPLA is a professional association of more than 1,300 attorneys whose interests and practices lie in the area of patent, copyright, trademark, trade secret and other intellectual property ("IP") law. The NYIPLA is one of the largest regional IP bar associations in the United States. The Association's members include in-house counsel serving businesses and other organizations that deal with IP rights in all technologies and disciplines, as well as attorneys in private practice who represent both IP owners and their adversaries (many of whom are also IP owners). The entities served by the NYIPLA's members include inventors, entrepreneurs, venture capitalists, businesses, universities, and industry and trade associations.

Many of the Association's members represent and counsel their clients as plaintiffs and defendants in patent litigations, including patent infringement litigation arising under the Drug Price Competition and Patent Term Restoration Act of 1984 as amended (the "Hatch-Waxman Act").[2] Most notably, for purposes of this litigation, the

2. Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271 and 282 (2000), as amended by Title XI of the Medicare Prescription Drug,

NYIPLA's members represent both branded and generic pharmaceutical manufacturers in such litigations.

The NYIPLA's Previous Involvement With These Important Issues

As will be developed below, this is the eighth occasion upon which this Court has been asked to grant a writ of certiorari to review a decision of a United States court of appeals construing the antitrust legality of a "reverse payment" term in an agreement settling a patent infringement action brought under the Hatch-Waxman Act as amended. Certiorari was properly denied on each of the prior seven occasions when guidance for the federal appellate courts (and for the antitrust enforcement agencies) regarding reverse payments was sought from this Court.[3]

A little less than nine years ago now, on December 29, 2003, the NYIPLA filed a brief *amicus curiae* with

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Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended at 21 U.S.C. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C. § 271(e)(5) (West Supp. 2004).

3. On September 20, 2012, the Federal Trade Commission (the "FTC" or "the Commission") announced that a ninth petition for certiorari will be filed seeking review of the Eleventh Circuit's decision in *Fed. Trade Comm'n v. Watson Pharms., Inc.*, 677 F3d 1298 (11th Cir. 2012) ("*Watson*"). *See* Lipman, "*FTC Sets Sights on High Court Pay-For-Delay Fight*," IP Law360 (September 20, 2012), available online at: http://www.law360.com/ip/articles/380240?nl_pk=2591e73c-b284-4f8f-8e68-a867a1492f13&utm_source=newsletter&utm_medium=email&utm_campaign=ip (last accessed September 21, 2012).

this Court supporting the grant of certiorari to the generic petitioner seeking review of the Sixth Circuit's *Cardizem* decision,[4] the second of the eight decisions as to which review has been sought in this Court by way of certiorari. In *Andrx v. Kroger*, the Association supported the grant of certiorari primarily for the reason that counseling clients who participated in Hatch-Waxman patent litigation by the members of the Association had become highly problematic. The NYIPLA argued that certiorari should be granted because of what it initially viewed as an irreconcilable conflict between the apparent application of a rule of *per se* illegality by the Sixth Circuit in the *Cardizem* decision and a seemingly antithetical finding of antitrust legality premised upon a nuanced rule of reason inquiry by the Eleventh Circuit in *Valley Drug.*[5]

The brief *amicus curiae* filed by the NYIPLA in late 2003 also argued that this Court's guidance as to the legality of reverse payment terms in the settlement of Hatch-Waxman patent infringement litigations would prove useful for the FTC. That assertion was premised upon the then recent decision of the Commission in *Schering-Plough.*[6]

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4. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) ("*Cardizem*"), *cert denied sub nom. Andrx Pharms., Inc. v. Kroger Co.*, 539 U.S. 939 (2004) ("*Andrx v. Kroger*").

5. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert denied*, 543 U.S. 939 (2004) ("*Valley Drug*").

6. *In re Schering-Plough Corp.*, 136 FTC 956 (2003), *vacated sub nom. Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied sub nom. Fed. Trade Comm'n v. Schering-Plough Corp.*, 548 U.S. 919 (2006) ("*Schering-Plough*").

Certiorari was denied in *Andrx v. Kroger* after, in response to an SVSG order entered by this Court, the Solicitor General (sometimes "SG") opined that *Valley Drug* and *Cardizem* could be harmonized – by treating the latter not as a holding of *per se* illegality but rather as a holding that the settlement agreement "has been construed to exclude non-infringing and potentially non-infringing products" from the market and thus unlawfully expand the scope of the patent at issue.[7]

Two other aspects of the SG's *Cardizem* Brief are worthy of note. First, the FTC through its General Counsel joined in that brief, thereby endorsing the positions adopted by the Department Of Justice ("DOJ"). Second, the settlement agreements in *Cardizem* as construed by the Solicitor General are the same agreements considered by the D.C. Circuit in *Biovail*,[8] the first of the reverse payment litigations which this Court has been asked to review via certiorari.

I. INTRODUCTION

As will be developed below, when the SG's *Cardizem* brief is taken into account, the NYIPLA believes that certiorari was correctly denied by the Court in each of the first seven occasions upon which it was sought. The conflict we perceived in 2003 was illusory, but the conflict the Third Circuit has now created is quite real and this Court should grant certiorari to resolve that conflict.

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7. "Brief For The United States As Amicus Curiae" (July 2004) ("SG's *Cardizem* Brief") at 3-4, 11-15.

8. *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001), *cert. denied*, 235 U.S. 931 (2002).

In *K-Dur*, the Third Circuit panel first rejected what it termed the "scope of the patent" test for determining the antitrust legality of Hatch-Waxman settlement agreements which contain reverse payment terms. Instead, the Court reasoned (1) that it was free to employ a "quick look" test to find the agreements presumptively unlawful (686 F.3d at 218);[9] and (2) that it was free under *Biovail* and the Commission's opinion in *Schering-Plough* to presume 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 logical litigation compromise" (*id.*).

Development Of The Consensus Rule

The "scope of the patent" test sometimes has been referred to elsewhere as the "consensus" or "*Tamoxifen*" rule.[10] The test has three parts and can be summarized as follows:

> An agreement settling a Hatch-Waxman patent infringement litigation cannot be found to violate Section 1 of the Sherman Act, 15 U.S.C. §1 on the ground that it contains a "reverse payment" term unless:

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9. Since the summer of 2009, both the DOJ and the FTC have been arguing for the adoption of a rule of presumptive illegality for Hatch-Waxman settlement agreements that contain reverse payment terms. Both the Second Circuit sitting en banc in *Cipro V* and the Eleventh Circuit panel in *Watson* had rejected this theory before it was accepted by the Third Circuit in *K-Dur*,

10. *See* David F. Ryan, *Reverse Payment Terms in ANDA Settlement Agreements*, NYIPLA Bulletin (February/March 2011) 1, 3-9 (available on the Association's website, www.nyipla.org).

> 1. The patent under which the suit was brought is shown to have been fraudulently obtained;
>
> 2. The suit for the patent's enforcement is shown to have been objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits; or
>
> 3. Competition beyond the subject matter or temporal scope of the patent is shown to have been unreasonably restrained.

The three branches of this rule all derive from authoritative precedents issued by this Court, and each of the first seven appellate holdings as to which petitions for certiorari were filed in this Court can be explained by its terms.[11]

Once the Solicitor General had opined that *Biovail* and *Cardizem* could be harmonized with the *Valley Drug* court's initial formulation of the "scope of the patent" test, the remaining elements of that test were quickly added. The complete "scope of the patent" or "consensus" rule was first announced in the Second Circuit's *Tamoxifen* decision[12] as follows:

> Unless and until [1] the patent is shown to have been procured by fraud, or [2] a suit for its enforcement is shown to be objectively baseless,

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11. As can *Watson* which has not yet reached this Court.

12. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2nd Cir. 2006), *cert. denied sub nom. Joblove v. Barr Labs., Inc.*, 551 U.S. 1144 (2007) ("*Tamoxifen*").

> there is no injury to the market cognizable under existing antitrust law, [3] as long as competition is restrained only within the scope of the patent [*citing Cipro III*[13]].
>
> We further agree with the *Cipro III* court that [3] absent an extension of the monopoly beyond the patent's scope * * * * and [1] absent fraud * * * * [2] the question is whether the underlying infringement lawsuit was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" [*citing Professional Real Estate*[14]].

[466 F.3d at 213 (numerical brackets supplied)].

This Court denied certiorari in *Tamoxifen*, again at the behest of the Solicitor General.[15] Thereafter, the consensus rule was applied by a Federal Circuit panel in *Cipro IV*,[16] by the Second Circuit sitting en banc

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13. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp.2d 514, 539 (E.D.N.Y. 2005) (Trager, J.) ("*Cipro III*").

14. *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 60 (1993) ("*Professional Real Estate*" or "*PRE*").

15. The Solicitor General had also advised against grant of the FTC's petition for certiorari in *Fed. Trade Comm'n v. Schering-Plough*, thus presenting the unusual prospect of the two antitrust enforcement agencies filing opposing briefs on the same antitrust issue before this Court.

16. *In re Ciprofloxacin HCl Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 131 U.S. 1606 (2011) ("*Cipro IV*").

in *Cipro V*,[17] and by yet another Eleventh Circuit panel in *Watson*.

The Alleged "Delay" Below

Under the settlement agreements found presumptively unlawful by the Third Circuit, Upsher-Smith was permitted to enter the market with its generic product on September 1, 2001 and ESI was permitted to enter the market with a second generic product on January 1, 2004. The K-Dur patent did not expire until September 5, 2006.

The Economics Of The Generic Manufacturing Industry

The *Valley Drug*, *Schering-Plough* and *Tamoxifen* courts each drew heavily from the legal and economic reasoning of three district court decisions.[18] Thus, *Valley Drug* relied extensively upon *Cipro II*, *Schering-Plough* upon *Cipro II* and *Asahi Glass*, and *Tamoxifen* upon *Cipro III* and *Asahi Glass*.

Each of the three district court decisions emphasized the "asymmetries" in litigation and settlement leverage that the Hatch-Waxman Act itself imposes and cautioned

17. *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2nd Cir.), *on petition for rehearing*, 625 F.3d 779 (2nd Cir. 2010), *cert. denied sub nom. Louisiana Wholesale Drug Co. v. Bayer, AG*, ___ U.S. ___, 131 S.Ct. 1606 (2011) ("*Cipro V*")

18. *In re Ciprofloxacin HCl Antitrust Litig.*, 261 F. Supp.2d 188 (E.D.N.Y. 2003) (Trager, J) ("*Cipro II*"), *Asahi Glass Co. v. Pentach Pharm., Inc.*, 289 F. Supp.2d 986 (N.D. Ill. 2003) (Posner, J) ("Asahi Glass"); and *Cipro III, supra*.

lest unwarranted or overly zealous applications of the antitrust laws should undermine the salutary objectives of the Congressional plan.[19] Three specific aspects of Hatch-Waxman economics are pertinent to portions of the argument set forth below.

"At Risk" Entry Remains Rare

"At risk" entry refers to introduction of a generic product to the market after expiration of the automatic 30-month stay of FDA approval but before any holding by the court that the patent is either invalid or not infringed. If the generic defendant launches at risk and ultimately loses the infringement suit, the potential damages suffered by the branded plaintiff (even discounting the prospect of trebling) may exceed the profits that the generic can actually earn. Thus, given the uncertainties of patent litigation stressed in the three early district court decisions, in theory most generic defendants will not attempt at risk entry, as history has confirmed.

The theoretical evidence of the reluctance on the part of generic manufacturers to enter the market at risk was recently confirmed by a 2010 Royal Bank of Canada study which showed that while 158 Hatch-Waxman patent infringement suits had settled during the seven-year

19. The two eminent jurists who authored those three decisions had each been specially selected to deal with the complex legal and economic issues that were involved: the late David G. Trager, United States District Judge for the Eastern District of New York, by the Judicial Panel on Multidistrict Litigation; and Richard A. Posner, United States Circuit Judge for the Seventh Circuit, sitting by special designation in the Northern District of Illinois.

period 2003-2009, only 28 at risk launches had occurred, an average of only four per year.[20] The RBC study also reported that the majority of the 28 at risk launches were attributable to Teva (12), Sandoz (6), and Apotex (1), the three largest generic firms.

This strongly suggests that many generic firms will not take on the potential cost of a miscalculation in at risk entry. Indeed, one cautionary tale illustrates the potential ramifications of such a miscalculation.

When Apotex elected to launch a generic Plavix product in 2006, it was enjoined preliminarily some three weeks later.[21] Eventually, the patent was found valid and infringed,[22] the court awarded damages in late 2010,[23] and this year the amount of damages and pre-judgment interest was finalized at $551 million – after five years of uncertainty which many generic defendants may not want to risk. Indeed, in the absence of a settlement agreement between the parties, a higher damages amount might have been awarded and thereupon trebled by the Court.

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20. "Pharmaceuticals: Analyzing Litigation Success Rates", RBC Capital Markets Publication (January 15, 2010) ("the RBC study") (Appendix A).

21. *Sanofi-Synthelabo v. Apotex, Inc.*, 488 F. Supp. 2d 317 (S.D.N.Y. 2006), *aff'd*, 470 F.3d 1368 (Fed. Cir. 2006) ("*Plavix PI*").

22. *Sanofi-Synthelabo v. Apotex, Inc.*, 492 F. Supp. 2d 353 (S.D.N.Y. 2007), *aff'd*, 550 F.3d 1075 (Fed. Cir. 2008), *cert denied*, ___ U.S. ___, 130 S.Ct. 493 (2009) ("*Plavix Liability*").

23. *Sanofi-Aventis v. Apotex, Inc.*, Case No. 02 Civ. 2255 (SHS), Document 486 (Opinion & Order Filed Oct. 19, 2010) ("*Plavix Damages Order*").

The Ability To Settle Has Become Increasingly Important

The efficient management of the available litigation resources represents a critical aspect of management for a generic manufacturer. Indeed, the ability to manage the Hatch-Waxman docket efficiently can be the key to the success of a generic firm. Each generic manufacturer tries to be the first to challenge the weakest patent with the largest potential sales. Optimization of internal and external legal resources, however, can be extremely difficult.

The Generic Pharmaceutical Association ("GPhA"), the trade association of the generic segment of the pharmaceutical manufacturing industry, filed a short but compelling brief in *Tamoxifen* opposing rehearing and rehearing en banc.[24] A substantial portion of the business of every generic manufacturer is devoted to researching and challenging Orange Book patents and the brief points out that at any one time every such manufacturer may have upwards of a dozen patents in litigation with full knowledge that it cannot afford "to try all of those to final judgment on appeal" (GPhA Br. at 5).

The GPhA's *Tamoxifen* brief also indicates that reverse payments from the cases settled permit the generic manufacturers not only to recoup their litigation costs, but to reallocate the funds to other active cases and finance the initiation of additional litigation.

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24. "Brief Amicus Curiae Of The Generic Pharmaceutical Association In Opposition To Rehearing And Rehearing En Banc" filed in *Tamoxifen*, No. 03-7641 (2nd Cir. Feb. 23, 2006) ("GPhA Br."). The brief also confirms some of the economic insights set forth in *Asahi Glass*.

This Court should decide whether, when both parties wish to settle a Hatch-Waxman patent litigation, reverse payments which facilitate the initiation or continuation of challenges to other pharmaceutical patents must be deemed presumptively pro-competitive rather than anticompetitive.

Tinkering With The Successful Congressional Plan Cannot Be Justified

Several recent authoritative studies confirm the enormous success of the Hatch-Waxman programs. One 2011 study commissioned by GPhA and carried out by IMS reports that the total savings attributable to the availability of generic pharmaceuticals amounted to $931 billion over the ten-year period from 2001 through 2010, with $157 billion attributable to 2010 alone.[25]

A 2012 report just issued by PricewaterhouseCoopers LLP confirms that Paragraph IV challenges continue to rise and confirms that "the majority of ANDA litigations continue to end in settlement."[26]

Loss of the ability to settle with reverse payment funding would inevitably result in loss of the litigation management and financing flexibility that is critical to the success of the generic manufacturers and, eventually,

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25. $931 Billion Savings: An Economic Analysis of Genereic Drug Usage in the U.S." (September 2011) [Appendix B]. A recent GPhA press release dated August 2, 2012 (Appendix C) indicates that an updated version of the study shows that savings to the public totaled $193 billion in 2011 and that generic pharmaceuticals now "fill 80% of the prescriptions dispensed in the U.S."

26. "2012 Patent Litigation Study" at 27 [Appendix D].

would frustrate the Congressional objective by forcing a reduction in the net number of Hatch-Waxman challenges.

Both the FTC and the Third Circuit have recognized that any statutory or judicial rule making reverse payments unlawful under the antitrust laws inevitably would reduce the net number of Hatch-Waxman validity challenges. Footnote 24 of the FTC Staff's January 2010 "Pay-for-Delay Study" concedes that "if a future legislative or judicial action" were to make "pay-for-delay agreements illegal", then:

To the extent that such an action would reduce generic firms' incentives to file Paragraph IV challenges, it could reduce the sales volume of drugs facing such challenges.[27]

That same footnote in the FTC's Pay-for-Delay Study goes on to suggest, since "only 24% of all [Hatch-Waxman Paragraph IV infringement] cases settled with both payment and delay", that "[a]ny such deterrent effect would likely be very low". The Third Circuit panel employed the same reasoning in rejecting the scope of the patent test.[28] Both the generic and branded branches of the pharmaceutical industry strongly disagree, and this Court should determine the issue on certiorari.

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27. The January 2010 FTC Staff Study is entitled "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions" ("Pay-for-Delay Study") and is available on the FTC's website, www.ftc.gov.

28. *K-Dur*, 686 F.3d at 218.

Difficult And Complex Issues Require Guidance From This Court

There are always difficulties in applying the antitrust laws where they interface with the patent statutes. Those difficulties are further complicated in this litigation by the addition of the asymmetries of the litigation and settlement economics imposed by Congress in 1984 via the framework of the Hatch-Waxman Act.

In the Third Circuit, neither the respondents nor the enforcement agencies in their separate *amicus curiae* briefs developed any nuanced approach to these complicated issues. Rather, they simply ignored many of the significant legal and economic questions raised by the other federal district and appellate courts that have considered reverse payments in Hatch-Waxman settlements.

The Renewed Peril Facing Hatch-Waxman Counselors

After the Solicitor General had explained how the *Biovail* and *Cardizem* decisions could be harmonized with *Valley Drug* and certiorari had been denied in *Andrx v. Kroger*, the NYIPLA's members enjoyed a period of more than eight years during which the consensus rule was developed and applied in no less than five additional appellate decisions. During that period the Association's members were able to advise their clients reliably regarding the initiation and settlement of Hatch-Waxman infringement suits.

The Third Circuit's panel elected to turn the clock back to the unique approach adopted by the Federal Trade Commission in December 2003. In doing so, the panel flatly rejected the reasoning employed by the Eleventh Circuit in reversing the Commission as well as the unanimous endorsement of that reasoning set forth in each of the five federal appellate court opinions which have addressed the issue in the interim.

The petitions should be granted so that this clear conflict between the circuits can be resolved by this Court.

II. SUMMARY OF ARGUMENT

The argument as set forth below is divided into four sections, each of which is predicated upon one of the four subsidiary questions set forth above which the NYIPLA respectfully submits should be addressed by this Court on certiorari.

Point A addresses Subsidiary Question 1 (the "at risk" economic question) which pertains to the Third Circuit panel's presumptions that it was free to find both the fact of delay and a causal nexus between the reverse payment and that alleged delay under the putative authority of *Biovail* and the Commission's 2003 decision in *Schering-Plough*. Although the Court could simply dispose of those presumptions on the merits by determining that the authorities cited by the Third Circuit had been vitiated, the NYIPLA respectfully submits that certiorari should be granted for the purpose of determining whether the presumptions should be rejected on the additional ground that the panel did not take into account the important economic issue of whether "at risk" entry would have been likely absent the settlement.

Point B addresses Subsidiary Question 2 (the *PRE* legal question) which pertains to the Third Circuit panel's rejection of the "scope of the patent" or *Tamoxifen* rule which was predicated in part upon this Court's *PRE* decision. The NYIPLA respectfully submits that certiorari should be granted so that this Court can announce whether, in the absence of allegations that an infringement suit was objectively baseless, *PRE* must be read to foreclose the type of inquiry regarding hypothetical entry dates in the absence of settlement which the Third Circuit panel purported to resolve by presumption.

Point C addresses Subsidiary Question 3 (the "quick look" legal question) which pertains to the Third Circuit Panel's application, at the behest of the enforcement agencies, of a "quick look" rule of presumptive illegality as a substitute for the full-blown rule of reason inquiry required under the scope of the patent rule. The NYIPLA respectfully submits that certiorari should be granted so that this Court can determine whether a quick look rule which reverses the burdens of proof should be eschewed in a private antitrust litigation involving complex issues respecting both the patent-antitrust interface and Hatch-Waxman economics.

Point D addresses Subsidiary Question 4 (the Hatch-Waxman economics question) which pertains to the predictable economic havoc that will be wreaked if the Third Circuit panel's decision is allowed to stand. The NYIPLA respectfully submits that certiorari should be granted so that this Court can determine whether the panel's decision would interfere directly with the ability of the generic manufacturers to effectively manage their Hatch-Waxman litigation docket and eventually

frustrate the Congressional objective of maximizing patent challenges.

III. ARGUMENT

A. As To Subsidiary Question 1

This Court Should Determine Whether The Third Circuit's Implicit Inference That The Generic Manufacturers Would Have Entered The Market "At Risk" Absent The Settlement Payments Can Be Sustained

The decision of the Third Circuit panel contains no discussion whatsoever of the likelihood of "at risk" entry by a generic defendant in an ANDA patent infringement suit. This Court should consider whether this omission alone should obviate the panel's presumptions regarding the alleged fact of delay and the alleged causal nexus between "pay" and "delay". Before turning to that issue, however, a brief discussion of the importance of those presumptions under the controlling statutes may be helpful.

1. The Threshold Requirements For An Antitrust Recovery

This is a private action seeking recovery of alleged treble damages for violation of the antitrust laws. As such the plaintiffs' burdens of proof are governed by Section 4 of the Clayton Act, 15 U.S.C. § 15 and Section 1 of the Sherman Act, 15 U.S.C. § 1.

Respondents are purchasers of patented pharmaceutical formulations. The alleged overcharges

that they seek to recover are predicated upon an implicit assumption that, absent the reverse payments, "at risk" entry would have occurred earlier than the dates specified in the settlement. Before an alleged restraint can be found "unreasonable" under Section 1 of the Sherman Act, a private or Government civil plaintiff must establish, by a preponderance of the evidence, the existence of an anti-competitive effect in a properly defined relevant product market.

In the context of Hatch-Waxman settlements containing reverse payment terms, the anti-competitive effect is virtually always pleaded as some delay in introduction of the competitive generic product which is alleged to result in the continuation of monopoly pricing for the duration of such delay. Thus, although "pay for delay" is a phrase which presupposes that any reverse payment in a Hatch-Waxman settlement agreement will result in delay, independent proof of some such delay normally will be required before a Section 1 violation can be established.

Moreover, Section 4 of the Clayton Act limits the recovery of antitrust damages to those suffered "by reason of anything forbidden in the antitrust laws." This requirement presupposes that, before antitrust damages can be awarded under Section 4, the existence of a causal nexus between the "pay" and the "delay" likewise must be established.

2. The Third Circuit's Presumptions Regarding The Fact Of Delay And Causal Nexus

At the heart of the Third Circuit panel's willingness to find the agreements presumptively unlawful under Section 1 of the Sherman Act was its belief that both a finding of

delay and the requisite causal nexus to the payment can be presumed under *Biovail* and the Commission's 2003 decision in *Schering-Plough*:

> In holding that a reverse payment is *prima facie* evidence of an unreasonable restraint of trade, we follow the approach suggested by the D.C, Circuit in [*Biovail*] and embrace that court's common sense conclusion that "[a] payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties entering the agreement . . . ." 256 F.3d at 809 (internal quotation marks and citation omitted)
>
> We agree, moreover with the FTC 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 payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.

[686 F.3d at 218].

Thus the Third Circuit panel assumed, without any discussion whatsoever, the existence of some causal nexus between the reverse payment and the alleged fact of delay. Although the reverse payment here is unquestioned, the fact of delay represents an indispensable element of respondents' proof under Sherman Act Section 1, as does the causal nexus between such delay and the allegedly

unlawful reverse payments under Section 4 of the Clayton Act.

3. This Court Should Consider Whether The Panel's Presumptions Are Inconsistent With Undisputed Facts Regarding At Risk Entry

Arguably, the SG's Amicus Brief in *Andrx v. Kroger* undermined any significance the passage from *Biovail* may have possessed and the reversal by the Eleventh Circuit in *Schering-Plough* completely attenuated the force of the quotation from the Commission's opinion. Nevertheless, this Court should consider whether the economics of "at risk" entry under the Hatch-Waxman Act represent an independent justification for rejecting the twin presumptions of the Third Circuit panel.

The facts regarding at risk entry while Hatch-Waxman patent litigations remain unresolved are not subject to dispute. The uncertainties of patent litigation and the asymmetric litigation and settlement economics imposed by the Hatch-Waxman Act mandate that at risk entry remains unusual and subject to risk. Indeed, only the largest of the generic manufacturers seem willing to undertake that risk on a regular though still unusual basis. As illustrated by the decision of Apotex to launch its generic Plavix, moreover, expensive mistakes are sometimes made. As the magnitude of the Plavix damages indicate, a miscalculation regarding an at risk launch might well bankrupt a smaller generic manufacturer.

B. As To Subsidiary Question 2

This Court Should Announce Whether *Professional Real Estate* Must Be Read To Control The Antitrust Legality Of Reverse Payments Within The Context Of Hatch -Waxman Patent Litigation Settlements

In *PRE* this Court ruled that before initiation of an intellectual property infringement lawsuit can be proscribed under the antitrust laws, a two-part test must be satisfied:

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits . . . Only if challenged litigation is objectively baseless may a court examine the litigant's subjective motivation . . . This two-tiered process requires the plaintiff to disprove the challenged lawsuit's **legal** viability before the court will entertain evidence of the suit's **economic** viability.

[508 U.S. at 60-61 (emphasis in original)].

In *Tamoxifen*, the Second Circuit concluded that, absent fraudulent procurement of the asserted patent or any attempt to expand the subject matter or temporal scope of the asserted claims, this Court's *Professional Real Estate* holding must be read to foreclose any Section 1 challenge to reverse payment terms in settlements of Hatch-Waxman suits which were not "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits".

This Court should grant certiorari for the purpose of determining whether the Third Circuit panel's subjective solution to the problem represents a reasonable alternative to the objective rule of *PRE*. The enforcement agencies have failed to propose any solution other than that which the Third Circuit has now adopted.

The previous eight decisions of the appellate courts have unanimously rejected the subjective approach, as well as the notion of holding a trial to test the merits of the settlement as both unwieldy and unreliable. As the Eleventh Circuit found in *Watson*:

> In closing, it is worth emphasizing that what the FTC proposes is that we attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment. If we did that we would be deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task. Even if we found that prospect palatable, we would be bound to follow the simpler recipe for deciding these cases that is laid out in our precedents.

[677 F.3d at 1315].

This Court should announce whether the objective standard of *PRE* should be preserved.

C. As To Subsidiary Question 3

This Court Should Announce Whether Application Of The Rule Of Presumptive Illegality By The Third Circuit At The Behest Of The Enforcement Agencies Can Be Justified Under Its Precedents

Some years ago the FTC began to request the courts to apply a rule of presumptive illegality to settlement agreements containing reverse payment terms in Hatch-Waxman patent infringement litigations. In 2009, the DOJ announced that it would support the FTC's theory in *Cipro V.* More recently, the FTC has begun asserting in briefs *amicus curiae* filed in other types of complicated patent cases involving misuse and antitrust allegations that a rule of presumptive illegality should be invoked by the court.[29] We believe that the Third Circuit panel decision represents the first time that a court has ever applied such a rule in a case that involved patents.

As the DOJ and FTC argued to this Court in *Dagher*, moreover, "[p]er se condemnation is reserved for conduct that" can be characterized as "manifestly anticompetitive".[30] The FTC's Supreme Court brief in *California Dental*[31] is also instructive regarding the

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29. See "Brief Of Amicus Curiae Federal Trade Commission On Rehearing *En Banc* Supporting Neither Party" filed in *Princo Corp. v. Int'l Trade Comm'n* (Feb. 16, 2010).

30. "Brief Of The United States As Amicus Curiae Supporting Petitioners" at 7-8 (September 2006) in *Texaco Inc. v. Dagher*, 547 U.S.1 (2006) ("*Dagher* Br."), citing *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49-50 (1977).

31. "Brief For The Respondent" at 30-34 in *California Dental Ass'n v. Fed. Trade Comm'n*, 526 U.S. 756 (1999) ("*California Dental* Br.").

conditions precedent which must be satisfied before the "quick look" rule can be applied.

This Court should grant certiorari in order to announce whether any "quick look" rule of presumptive illegality can legitimately be applied in a complex case involving both patent-antitrust interface and Hatch-Waxman issues.

D. As To Subsidiary Question 4

The Court Should Determine Whether Application Of The Rule Of Presumptive Illegality Would Interfere Directly With Litigation Resource Allocation By The Generic Manufacturers And Thereby Eventually Frustrate The Congressional Objective Of Maximizing Patent Challenges Under The Hatch-Waxman Act As Amended

Due in large measure to the regulatory and economic framework of the Hatch-Waxman Act, the generic pharmaceuticals business has evolved exponentially since 1984, has become profitable, and has resulted in a high success rate for the introduction of generic pharmaceuticals before the expiration of Orange Book patents – due in no small part to the ability of litigants to settle on terms which include reverse payments.

It has also saved consumers $931 billion over the last ten years, with at least one-third of the total attributable to settlements.

In enacting the Hatch-Waxman Act, the Congressional objective was to encourage challenges. Any rule of

presumptive illegality, however, would seem calculated to reduce net challenges, thereby frustrating that objective.[32]

This Court should grant certiorari in order to determine whether settlements that have fostered both industry growth and savings for the consumer should be sustained as pro-competitive under the appropriate rule of reason analysis.

32. Indeed, as we have seen, the FTC conceded as much in its 2010 "Pay-for-Delay" Study.

IV. CONCLUSION

The NYIPLA respectfully submits that the petitions of Merck and Upsher-Smith should be granted.

Respectfully submitted,

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