No. 12-416

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,
v.
ACTAVIS, INC., *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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

CHARLES R. HOFFMANN
President-Elect
NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION
c/o HOFFMANN & BARON LLP
6900 Jericho Turnpike
Syosset, NY 11791
(516) 822-3550

THOMAS J. KOWALSKI
Counsel of Record
JOHN C. CLEARY
MARC B. SCHLESINGER
VEDDER PRICE P.C.
1633 Broadway
47th Floor
New York, NY 10019
(212) 407-7700
tkowalski@vedderprice.com

[Additional Counsel Listed on Signature Page]

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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 respondents.[1]

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

The arguments in this brief were approved 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, director or committee member in any law or corporate firm, represents a party to 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.

A. 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 Association is one of the largest regional IP bar associations in the United States. The NYIPLA'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 Association's members include inventors, entrepreneurs, venture capitalists, businesses, universities and industry and trade associations.

Many of the NYIPLA's members represent and counsel their clients as plaintiffs and defendants in patent litigation, including patent infringement litigation arising under the Drug Price Competition and Patent Term Restoration Act of 1984 as amended ("Hatch-Waxman Act").[2] Most notably for purposes of this brief *amicus curiae*, the Association's members represent clients, like Respondents, that are both branded innovator and generic pharmaceutical manufacturers.

B. The NYIPLA's Prior Involvement With These Important Issues

This proceeding represents the ninth time that this Court has been asked 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,[3] and the first time that such review has been granted. This is the third such proceeding in which the NYIPLA has filed a brief

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[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, Improvement, and Modernization Act of 2003 ("2003 MMA Amendment"), 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)). Counseling is also as to 35 U.S.C. §§ 154(a)(1) and 261 (2000).

[3] A "reverse payment term" in a Hatch-Waxman settlement is an undertaking by the branded innovator patentee to transfer one or more cash payments or other consideration to the potential generic seller who infringed the Orange Book patent by filing the Abbreviated New Drug Application ("ANDA") under Paragraph IV. A Hatch-Waxman settlement containing a reverse payment term is a "reverse payment settlement."

amicus curiae, and the first in which it has filed such a brief on the merits.

1. *Andrx v. Kroger*

Nine years ago, the NYIPLA filed a brief *amicus curiae* supporting the grant of certiorari to the generic petitioner seeking review of the Sixth Circuit's *Cardizem* decision,[4] the second of the nine appellate decisions involving a reverse payment settlement that this Court has been asked to review.[5] 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 its members had become problematic because of the campaign against reverse payment settlements that the Federal Trade Commission ("FTC" or "Commission") had initiated in 1999.[6]

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 antitrust analysis premised upon a nuanced

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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.*, 543 U.S. 939 (2004) ("*Andrx v. Kroger*").

[5] "Motion Of New York Intellectual Property Law Association And Brief Of *Amicus Curiae* In Support Of Petitioner in *Andrx v. Kroger*" ("NYIPLA's *Andrx v. Kroger* Brief").

[6] *Id*. at 8-15. The FTC is one of the two federal agencies that are charged with enforcement of the antitrust laws. The other is the Antitrust Division ("ATD") of the Department of Justice ("DOJ").

rule of reason inquiry by the Eleventh Circuit in *Valley Drug*.[7]

Certiorari was denied in *Andrx v. Kroger* after the Solicitor General ("SG"),[8] in response to an order of the Court soliciting the views of the SG ("SVSG order"), opined that *Valley Drug* and *Cardizem* could be harmonized.[9] In the SG's view, *Cardizem* should not be treated as a holding that reverse payment terms were *per se* illegal,[10] but rather as a holding that the settlements set forth two restraints which "extended beyond the legitimate **scope of the patent** claims by reaching non-infringing products and conduct by petitioner that the patent conferred no right to exclude or demand."[11]

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[7] *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied sub nom. Walgreen Co. v. Abbott Labs.*, 543 U.S. 939 (2004) ("*Valley Drug*").

[8] The Office of the Solicitor General ("OSG") is the segment of DOJ assigned to represent the United States before this Court and to file briefs amicus curiae on behalf of the United States in response to SVSG orders of this Court. In July 2009 the ATD, an entirely separate unit of DOJ, announced that it would henceforth support the FTC's theory that Hatch-Waxman reverse payment settlements should be evaluated under a "quick look" standard of presumptive illegality.

[9] "Brief For The United States As Amicus Curiae in *Andrx v. Kroger*" at 3-4, 11-15 ("SG's *Andrx v. Kroger* Brief").

[10] The SG noted that "per se treatment is reserved for conduct that has a predictable and pernicious anticompetitive effect." *Id*. at 7.

[11] *Id*. at 13 (emphasis supplied). Thus, the SG found both (1) that the district court and the FTC's original complaint had characterized the settlement agreement as excluding non-infringing and potentially non-infringing products from the market, and (2) that the agreement prevented Andrx from "relinquishing or otherwise compromising its right to the 180-

Four other aspects of the SG's *Andrx v. Kroger* Brief are worthy of note. First and most importantly, it seems clear that the SG's brief represented the first time that this Court was told authoritatively that (a) the "scope of the patent" standard represented an appropriate threshold adjunct to the rule of reason under which the antitrust legality of Hatch-Waxman reverse payment settlements must be assessed; and (b) the rule of reason should be deemed inherently preferable to any rule of *per se* illegality.[12] Second, the FTC through its General Counsel joined in the SG's arguments, thereby endorsing both the SG's repeated rejections of the application of any rule of *per se* illegality to Hatch-Waxman infringement settlements and his interpretation of the Sixth Circuit's *Cardizem* decision as applying the "scope of the patent" rule.[13] Third, the settlement agreements

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day period of exclusivity," thus creating a bottleneck to any further generic competition. *Id.*

[12] As developed in Section I, the "scope of the patent" threshold standard under the rule of reason actually antedates the 1890 enactment of the Sherman Act. Applied initially to patent-leveraged tying of staple goods and resale price maintenance ("RPM"), rather early in the life of the Sherman Act, the rule was revived for application to price-fixing cartel cases during and after World War II, and resurrected in two important lines of cases decided after the 1982 creation of the Federal Circuit, most notably in *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992) ("*Mallinckrodt*") and *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322 (Fed. Cir. 2000) ("*Xerox/ISO*"), *cert. denied sub nom. CSU, L.L.C. v. Xerox Corp.*, 531 U.S. 1143 (2001) ("*CSU v. Xerox*").

[13] Unfortunately, several documents issued thereafter by the FTC staff have ignored this fundamental concession, including the January 2010 FTC Staff Study entitled "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions" ("2010 Pay-for-Delay Study"), characterizing the *Cardizem* case

in *Cardizem* as construed by the SG are the same agreements construed by the D.C. Circuit in *Biovail*,[14] the first reverse payment case this Court was asked to review via certiorari. Finally, the SG quite candidly explained why the *per se* rule of illegality could not be applied in *Cardizem* by setting forth a catalogue of facts which could tip the balance of the required rule of reason inquiry in favor of a determination that any particular reverse payment settlement would have to be deemed pro-competitive.[15]

The Association believes that it was the first *amicus curiae* ever to demonstrate to this Court, within the context of reverse payment settlements, the pervasive importance of: (1) this Court's prior decision in *PRE*;[16] (2) the decision of the Court of Appeals for the Federal Circuit in *Xerox/ISO*, as well as the SG's comments thereon in *CSU v. Xerox*;[17] and (3) this Court's decision in *Gasoline Cracking*.[18]

2. *Merck v. LWDC*

After the SG had explained how the *Biovail* and *Cardizem* decisions could be harmonized with *Valley*

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as holding that reverse payment settlements "were automatically (or *per se*) illegal."

[14] *Andrx Pharms., Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001), *cert. denied*, 235 U.S. 931 (2002) ("*Biovail*").

[15] SG's *Andrx v. Kroger* Brief at 9-10.

[16] *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) ("*PRE*").

[17] "Brief for the United States as Amicus Curiae in *CSU v. Xerox*" ("SG's *CSU v. Xerox* Brief").

[18] *Standard Oil Co. (Ind.). v. United States,* 283 U.S. 163 (1931) ("*Gasoline Cracking*"); s*ee also* NYIPLA's *Andrx v. Kroger* Brief at 4, 6, 8-10, 11-12, 14-15.

Drug and certiorari had been denied in *Andrx v. Kroger*, NYIPLA and its members enjoyed a period of more than eight years during which the "scope of the patent" standard was further developed and universally applied under the rule of reason in no less than five additional reverse payment cases which eventually reached this Court via petition for certiorari, the last of which being the decision below of the Court of Appeals for the Eleventh Circuit in *FTC v. Watson* which issued on April 25, 2012.[19] During that period NYIPLA's members were able to advise their clients reliably regarding the initiation and settlement of Hatch-Waxman infringement suits.[20]

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[19] In chronological order, those cases were *In re Schering-Plough Corp.*, 136 F.T.C. 956 (2003), *vacated, Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006) ("*Schering-Plough*"); *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*"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed Cir. 2008), *cert. denied sub nom. Ark. Carpenters Health & Welfare Fund, Paper, A.F. of L. v. Bayer AG,* 129 S. Ct. 2828 (2009) ("*Cipro IV*"); *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010), *reh'g denied*, 625 F.3d 779 (2d Cir. 2010), *cert. denied sub nom. Louisiana Wholesale Drug Co., Inc. v. Bayer AG*, 131 S. Ct. 1606 (2011) ("*Cipro V*"); *Fed. Trade Comm'n v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012) ("*FTC v. Watson*"), *cert. granted sub nom. Fed. Trade Comm'n v. Actavis, Inc.*, 133 S. Ct. 787 (U.S. Dec. 7, 2012) (No. 12-416) ("*FTC v. Actavis*"). Citations to the Eleventh Circuit opinion are to Appendix A to the Government's Petition for Certiorari ("Petition") in *FTC v. Actavis* ("PA" 1a-36a).

[20] Since under the rationale of the SG's *Andrx v. Kroger* Brief each of the first seven appellate decisions to reach this Court applied the scope of the patent test, the NYIPLA believed that

On July 16, 2012, however, the Third Circuit issued its decision in *K-Dur*,[21] flatly rejecting the theretofore universally accepted "scope of the patent" threshold standard under the rule of reason as inappropriate for determining the antitrust legality of Hatch-Waxman reverse payment settlements. At the behest of the FTC and the ATD,[22] the Third Circuit panel instead reasoned (1) that it was free to ignore the rule of reason completely and instead employ a "quick look" test to find the agreements presumptively unlawful; and (2) that under *Biovail* and the opinion of the Commission in *Schering-Plough*, it could ignore the need to establish an anticompetitive effect in some properly defined relevant product market by instead presuming 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."[23]

On September 24, 2012, the Association filed with this Court its "Brief Of Amicus Curiae New York Intellectual Property Law Association In Support Of Petitioners" challenging the *K-Dur* decision in *Merck v. LWDC* ("NYIPLA's *Merck v. LWDC* Brief"),

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the conflict it perceived initially was illusory and that certiorari was properly denied by this Court in each of those cases.

[21] *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) ("*K-Dur*"), *petitions for cert. filed sub nom. Merck & Co. v. Louisiana Wholesale Drug Co.*, (U.S. Aug. 24, 2012) (No. 12-245) and (U.S. Aug. 29, 2012) (No. 12-265) ("*Merck v. LWDC*").

[22] "Brief For The United States As Amicus Curiae Supporting Plaintiffs-Appellants in *K-Dur*" ("ATD's *K-Dur* Brief"); "Brief Of The Federal Trade Commission As *Amicus Curiae* Supporting Appellants And Urging Reversal in *K-Dur*" ("FTC's *K-Dur* Brief").

[23] *K-Dur*, 686 F.3d at 218.

directed to four questions which the Association believed should be answered to provide the proper bases for determining whether the judgment of the Third Circuit panel could be sustained.

INTRODUCTION

A. The Grant Of Certiorari And The Government's Brief On The Merits

On October 4, 2012, shortly after NYIPLA's filing in *Merck v. LWDC*, the OSG filed its petition for certiorari on behalf of the FTC in this proceeding. A significant portion of that petition was devoted to arguments regarding the alleged superiority of *FTC v. Actavis* over *Merck v. LWDC* as a vehicle for determining the proper methodology under which to assess the antitrust legality of reverse payment settlements. Thus, rather than defend the **first** application by any court of appeals of the "quick look" test of presumptive illegality to **any** antitrust case involving a patent,[24] the Government has elected to challenge the **eighth** court of appeals application of the threshold scope of the patent standard under the rule of reason. The Government's petition for certiorari was granted on December 7, 2012. Presumably, the Court intends to maintain jurisdiction over *Merck v. LWDC* until it has decided *FTC v. Actavis*, and then remand the former under an appropriate

[24] As discussed in Section II, in what NYIPLA believes was the only other patent case in which the FTC ever attempted to convince a court of appeals to employ a "quick look" test of presumptive illegality, that effort was squarely rebuffed in an 8-2 ruling by the Federal Circuit sitting en banc. *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318 (Fed. Cir. 2010) (en banc) ("*Princo v. ITC*").

grant, vacate and remand ("GVR") order.[25] Despite the Government's election to attack rather than defend, its brief on the merits docketed on January 22, 2013 is sprinkled with references to the Third Circuit's decision in *K-Dur*.[26]

B. The Patent, Parties, ANDAs And Agreements

Pursuant to the admonition against duplicative briefing by *amici* in Sup. Ct. R. 37.1, NYIPLA relies upon and incorporates by reference the statements and appendix references set forth (1) at pages 3-11 of the "Brief For Respondent Actavis, Inc." ("Actavis Brief"); (2) at pages 23-31 of the "Brief For Respondents Par/Paddock" ("Par/Paddock Brief"): and (3) at pages 2-8 of the "Brief For Respondent Solvay Pharmaceuticals, Inc." ("Solvay Brief").[27]

C. The Asymmetrical Economics Of The Hatch-Waxman Act

The *Valley Drug*, *Schering-Plough*, and *Tamoxifen* courts each drew heavily from the legal and economic reasoning of three district court decisions. Thus, *Valley Drug* relied extensively upon *Cipro II*,[28]

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[25] Presumably also, the circumstances regarding the apparent recusal of Justice Alito in *FTC v. Actavis* are such that they extend to *Merck v. LWDC* as well.

[26] The Association respectfully reserves the right to rebut the Government's citations to *K-Dur* with references and arguments directed to the manifest deficiencies of the Third Circuit's reasoning.

[27] Between 2000 and 2007, revenue from the sale of AndroGel in the United States exceeded $1.8 billion. *See* PA 10a.

[28] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003) ("*Cipro II*").

Schering-Plough upon *Cipro II* and *Asahi Glass*,[29] and *Tamoxifen* upon *Cipro III*[30] and *Asahi Glass*. Each of the three district court decisions emphasized the "asymmetries" in the economics of the litigation and settlement leverage to which the parties are exposed under the Hatch-Waxman Act and cautioned lest overly zealous and unwarranted application of the antitrust laws should undermine the salutary objectives of the Congressional plan.[31]

1. *Patent Strength And "At Risk Entry"*

The agreed date of entry in any Hatch-Waxman settlement will depend upon the parties' respective views of the strength of the patent(s) in suit. This Court should note that the incentives for early challenges to Orange Book patents which Congress provided in the Hatch-Waxman Act are more than counterbalanced by the skewed economic forces which make any prospect of "at risk entry" by a generic so dangerous.[32]

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[29] *Asahi Glass Co. v. Pentach Pharm., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003) ("*Asahi Glass*").

[30] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) ("*Cipro III*").

[31] The two eminent jurists who authored those three opinions had been specifically selected to deal with the complex legal, technical and economic issues involved: the late David G. Trager, D.J. by the Judicial Panel on Multidistrict Litigation, and Richard A. Posner, C.J. sitting by special designation in the Northern District of Illinois.

[32] The term "at risk entry" refers to the market introduction of a generic product after expiration of the automatic stay of FDA approval but before any holding by the court that the patent is invalid or that the approved formulation does not infringe.

If the generic manufacturer should launch "at risk" and lose, the same price reductions which benefit consumers would raise potential damages far beyond the total profits that the generic manufacturer could reasonably expect to earn. There has been no showing that any generic respondent in this action has ever launched at risk. Given the uncertainties of patent litigation stressed by the three early district court decisions and the decision below,[33] it is not unexpected that history has confirmed the economic theory that most generic defendants will not attempt at risk entry.

The reluctance of generic manufacturers to enter the market at risk has been 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 period 2003-2009, only 28 at risk launches had occurred, an average of only four per year.[34] The RBC Study also reported that the all but nine of the at risk launches were attributable to Teva (12), Sandoz (6) and Apotex (1), the three largest generic manufacturers.[35]

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[33] "A party likely to win might not want to play the odds for the same reason that one likely to win a game of Russian roulette might not want to take a turn." PA 30a.

[34] "Pharmaceuticals: Analyzing Litigation Success Rates," RBC Capital Markets Publication (January 15, 2010) ("the RBC study").

[35] Even the largest generic manufacturers can miscalculate, as Apotex found when it was preliminarily enjoined just three weeks after launching its generic Plavix product in 2006 and then had to wait more than six years for the final bill, which totaled more than $500 million untrebled. *See Sanofi-Aventis v. Apotex Inc.*, 748 F. Supp. 2d 293 (S.D.N.Y. 2010).

2. *The Ability To Settle Remains Critically Important For Generics*

The efficient management of litigation resources is critical for a generic manufacturer. The ability to manage the Hatch-Waxman docket efficiently can be the key to the success of a generic firm as each generic manufacturer tries to be the first to challenge the weakest patent with the greatest potential sales.

A large portion of the Hatch-Waxman Act's enormous success probably can be attributed to the subjective and objective assessments of patent strength which invariably are made by the technically sophisticated and well advised litigants who conclude these settlements. The FTC is wrong to suggest that the parties are not better equipped than any potential trier of fact to determine what reasonable agreed entry dates should result from Hatch-Waxman settlements.

That being said, it is equally true that no Hatch-Waxman suit can be settled unless the generic manufacturer will agree upon a date of entry which is acceptable to the patent owner. Indeed, it is impossible to settle any patent infringement suit, including a Hatch-Waxman suit, without the consent of the patent owner. Since the patent owner is permitted to "try its losers" unless the *PRE* standards are satisfied, moreover, the potential generic entrant can often face the prospect of a more protracted and expensive litigation than its initial assessment of the Orange Book patents of its adversary may have indicated.

The Generic Pharmaceutical Association ("GPhA"), the trade association of the generic segment of the pharmaceutical industry, filed a short but compelling

brief opposing rehearing and rehearing en banc after the panel decision in *Tamoxifen*.[36] 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."[37]

The GPhA *Tamoxifen* Brief also indicates how reverse payment settlements not only permit generic manufacturers to recoup their litigation costs, but also to reallocate funds to other active cases and finance the initiation of additional litigation.

3. *The Hatch-Waxman Legislation Has Proved Enormously Successful*

Due to the Hatch-Waxman Act, the generic pharmaceutical manufacturing business in the United States has expanded exponentially since 1984, has generally become more profitable, and has experienced a high rate of success for the early introduction of generic pharmaceuticals.

Since enactment of the Hatch-Waxman Act, the percentage of United States prescriptions filled by generics has been almost exactly reversed—from 19%

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[36] "Brief Amicus Curiae Of The Generic Pharmaceutical Association In Opposition To Rehearing And Rehearing En Banc in Tamoxifen" ("GPhA *Tamoxifen* Brief"); *see also* "Brief of Amicus Curiae Generic Pharmaceutical Association in Support of Defendants-Appellees and Affirmance in *K-Dur*"; "Brief for Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Appellees in *K-Dur*."

[37] *Id.* at 5.

in 1984 to above 80% in 2011.[38] The annual consumer savings reached almost $200 billion in 2012, and totaled $1.07 trillion over the last ten years.[39] GPhA attributes about one-third of these savings to the ability to settle Hatch-Waxman lawsuits on flexible and pro-competitive terms.[40]

SUMMARY OF ARGUMENT

This case arises at the intersection of patent law, antitrust law, the asymmetrical economics of the Hatch-Waxman Act, and the implications of both (1) the policy objectives of Congress in enacting, amending and refusing to further amend that enormously successful legislation; and (2) the equally important public policy factors favoring the settlement of litigation generally, and patent litigation in particular. Indeed, patent litigation under the Hatch-Waxman Act can be even more protracted and expensive.[41]

Although the issues bearing on the proper disposition of this proceeding are broad and complex, the answers to the Government's arguments are quite

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[38] *See* "The Pharmaceutical Industry, A Discussion of Competitive and Antitrust Issues in an Environment of Change," Bureau of Economics Staff Reports, Federal Trade Commission, March 1999 (19% of scripts were generic in 1984); *see* Generic Drug Pharmaceutical Association, Generic Drug Savings in the U.S. (4th ed. 2012) *Improving Lives for Less* (August 1, 2012) (80% of scripts were generic in 2011) ("*Improving Lives for Less*"); *see also* NYIPLA's *Merck v. LWDC* Brief, Appendices A-D (economic materials).

[39] *See Improving Lives for Less.*

[40] *See id.*

[41] An average investment by the branded patentee of "more than $1.3 billion" and "10-15 years." PA at 2a.

straightforward. NYIPLA's argument will focus on four relatively narrow issues which the parties have touched only lightly if at all.

In Section I we outline the history of the threshold scope of the patent standard under the rule of reason as developed by this Court from its origins at common law and first application to the misuse doctrine almost a century ago. In the Association's view, an understanding of the history of the application of that standard to other areas of the patent-antitrust interface by this Court and, since 1982, by the Court of Appeals for the Federal Circuit, informs the propriety of the application of that threshold standard to reverse payment settlements.

In Section II we contrast the only two "quick look" appellate patent cases and analyze the FTC's success in convincing the Third Circuit to apply a rule of presumptive illegality in *K-Dur* with its complete failure to convince eight of the ten sitting judges of the Federal Circuit to do the same in *Princo v. ITC*. Since the Federal Circuit's reasoning adheres carefully to this Court's precedents, we respectfully submit that its reasoning should be endorsed.

In Section III we employ the SG's arguments regarding *Xerox/ISO*, as made before this Court in response to two separate SVSG orders, to support a broader range of application for *PRE*. The Association respectfully submits that the underlying reasoning of that precedent is so sound and compelling that it should be recognized not only as a definition of the proper scope of the *Noerr-Pennington* immunity, but also as a bright line evidentiary rule of general application at the entire patent-antitrust interface.

Finally, in Section IV we address the FTC's concession (as echoed by the Third Circuit's panel in *K-Dur*) that the rule it asks this Court and Congress to impose upon the industry inevitably would lead to fewer generic challenges to Orange Book patents. Although the Government argues that the risk involved is not great, and that the related cash flow problems the generic manufacturers will encounter if the rule is imposed are beside the point, the Association respectfully submits that any urge to tinker with success must be resisted.

ARGUMENT

I. A NUANCED APPLICATION OF THE THRESHOLD SCOPE OF THE PATENT STANDARD TO REVERSE PAYMENT SETTLEMENTS IS MANDATED BY THIS COURT'S APPLICATION OF EQUITABLE JURISPRUDENCE TO THE PATENT EXEMPTION FOR OVER A CENTURY

If the Government's legal analysis could be taken at face value, this Court would be justified in assuming that the threshold scope of the patent standard under the rule of reason represented some strange and novel approach to the patent-antitrust interface created from whole cloth during the FTC's fifteen-year ongoing crusade against reverse payment settlements. That standard, however, did not simply emerge full-grown from the federal appellate courts after enactment of the Hatch-Waxman Act in 1984, like Athena from the brow of Zeus. To the contrary, the threshold scope of the patent standard had began to develop at common law even before enactment of the Sherman Act in 1890, along with the exhaustion and misuse doctrines, and had been fully articulated

as an adjunct to the equitable defense of misuse by 1917.

A. The Constitutional Predicate For The Patent Exemption

Pursuant to Art. I, Sec. 8, clause 8 of the U.S. Constitution, the first Patent Act was enacted on April 10, 1790, more than a full century before the Sherman Antitrust Act was enacted as the first federal antitrust statute on July 2, 1890.[42] There have been many attempts to encapsulate the relationship between the antitrust and patent laws, perhaps the best and most succinct of them being that of Justice Douglas, in *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964), who found that the patent laws exist "*in pari materia* with the antitrust laws, and modify them *pro tanto.*"[43]

Accordingly, antitrust law must yield to the patent laws as properly interpreted. Conduct authorized by the patent laws cannot violate the antitrust laws. Congress can always alter the scope of what is permitted under the patent law to overrule any judicial interpretation of the antitrust laws that it might consider overzealous.[44] Before becoming a

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[42] Brief for Petitioner at Statutory Appendix.

[43] In a real sense, this formulation represented an extremely candid statement of the deference owed to the patent laws. Throughout the almost 37 years of his service on the Court, Justice Douglas consistently championed the interests of economic freedom over those of what he insisted upon calling the "patent monopoly" when considering claims at the patent-antitrust interface.

[44] The 1952 enactment of Sections 271(c) and (d)(1) through (3) of the Patent Act, codified in 35 U.S.C. §§ 271(c) and (d)(1) through (3), represents one good example—intended by Congress to overrule this Court's decisions in *Mercoid Corp. v. Mid-*

threshold adjunct to the antitrust rule of reason, the scope of the patent standard developed along with certain other common law equitable patent defenses which predated the Sherman Act, including the "exhaustion" or "first sale" defense. Since at least 1917, the rule also has represented a useful tool to govern application of the equitable defense of patent misuse, thereby also providing the eventual central doctrinal predicate for delineating the proper balance point as between patent and antitrust.

B. The Early Sherman Act Period

In the early years of the Sherman Act, this Court developed the scope of the patent threshold standard which had originated at common law and applied it (1) to the patent-leveraged tying of staple goods,; and (2) to resale price maintenance ("RPM").

1. *MPP And The Patent Leveraged Tying Of Staple Goods*

This Court announced that the scope of the patent test should be applied to proscribe the patent-based tying of staple goods in *Motion Picture Patents*.[45] Reasoning that "[t]he scope of every patent is limited to the invention described in the claims," the Court held that the language of the statute and rules which define the scope of the patent "is not concerned with,

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Continent Inv. Co., 320 U.S. 661 (1944) ("*Mercoid I*"), and *Mercoid Corp. v. Minneapolis-Honeywell Regulator Co.*, 320 U.S. 680 (1944) ("*Mercoid II*"). *See Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 188-98 (1980) ("*Dawson*"). Another involves the 1988 enactment of Section 271(d)(5), 35 U.S.C. § 271(d)(5) discussed in *Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006) ("*Independent Ink*").

[45] *Motion Picture Patents, Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917) ("*Motion Picture Patents*" or "*MPP*").

and has nothing to do with, the materials with which or on which the machine operates."[46]

Predicated upon that reasoning, the Court overruled[47] *A.B. Dick*,[48] and rejected the philosophy of the *Button-Fastener*.[49]

2. *GE/Lamp, RPM And Manufacturing Licenses*

In *GE/Lamp*,[50] this Court both (1) rejected a claim that General Electric ("GE") had engaged in unlawful resale price maintenance by employing a system of agents who were really wholesale and retail jobbers; and (2) upheld the terms of an agreement under which GE had licensed Westinghouse to manufacture light bulbs under three GE patents and sell those bulbs at prices and terms established by GE—illustrating the significance of this Court's scope of the patent standard.

In *GE/Lamp*, this Court first noted that "under the patent law, the patentee is given by statute a monopoly of making, using and selling the patented article" and concluded that:

> It is only when he adopts a combination with others by which he steps out of the **scope of his patent rights** and seeks to control and restrain those to whom he has sold his patented articles in their subsequent disposition of what is theirs

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[46] *Id*. at 510, 512.

[47] *Id*. at 512.

[48] *Henry v. A.B. Dick Co*., 224 U.S. 1 (1912) ("*A.B. Dick*").

[49] *Heaton-Peninsular Button-Fastener Co. v. Eureka Specialty Co.*, 77 F. 288 (6th Cir. 1896) ("*Button-Fastener*").

[50] *United States v. General Electric Co.*, 272 U.S. 476 (1926) ("*GE/Lamp*").

> that he comes within the operation of the Anti-Trust Act.[51]

Finding that GE had preserved the formalities of genuine agency and had not made any of the sales for full consideration that would take the price terms outside the scope of the patents, this Court held that the Government had not proved its case.[52]

In upholding the price term in the Westinghouse manufacturing license, the Court reiterated the same point, noting that at common law:

> It is well settled, as already said, that, where a patentee makes the patented article and sells it, he can exercise no further control over what the purchaser may wish to do with the article after his purchase. It has passed **beyond the scope of the patentee's rights**.[53]

C. The Cartel Price-Fixing Cases

The critical distinction between the right to control the price charged (1) by one who has purchased a patented product for full consideration in an authorized and unconditional sale; and (2) by one who manufactures a patented product under license from the patentee was again reinforced in a series of cases decided between 1940 an 1964.[54] Although the Gov-

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[51] *Id*. at 485 (emphasis supplied).

[52] *See id*. at 488.

[53] *Id*. at 489 (citing *Adams v. Burke*, 84 U.S. (17 Wall.) 453 (1873); *E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70 (1902) ("*National Harrow*").

[54] *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436 (1940); *United States v. Univis Lens Co.*, 316 U.S. 241 (1942); *United States v. Masonite Corp.*, 316 U.S. 265 (1942); *United States v. Line Material Co.*, 333 U.S. 287 (1948); *United States v. United*

ernment claims to find support for its position in five of these cases, their relevance for that purpose remains obscure, particularly in view of the fact that they all appear both (1) to confirm the continuing vitality of the scope of the patent threshold standard to which the FTC objects so strenuously; and (2) to indicate that the validity of the underlying patent must be assumed for purposes of the antitrust analysis.

D. The Federal Circuit's Approach To The Scope Of The Patent Rule

In the more than thirty years since the Court of Appeals for the Federal Circuit was established, it has applied the scope of the patent standard in two important areas other than Hatch-Waxman reverse payment settlements. First, it has used the standard to craft a rule for establishing the equitable defense of patent misuse in areas where this Court has not yet acted. The leading case is *Mallinckrodt*.[55] Second, it has employed the standard to justify refusals to license and deal in patented goods. That leading case is *Xerox/ISO*, *supra*.

In *Mallinckrodt*, *supra*, 976 F.2d at 708, Judge Newman conducted an exhaustive review of this Court's cases and harmonized the controlling principles as follows: "The appropriate criterion is whether

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States Gypsum Co., 333 U.S. 364 (1948); *United States v. New Wrinkle*, 342 U.S. 371 (1952); *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963); *Simpson v. Union Oil Co.,* 377 U.S. at 24.

[55] *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992) ("*Mallinckrodt*"); *see also Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995 (Fed. Cir. 1986) ("Windsurfing"); *U.S. Philips Co. v. Int'l Trade Comm'n*, 424 F.3d 1179 (Fed. Cir. 2005) ("*Philips I*"); *Princo v. ITC, supra*.

Mallinckrodt's restriction is **reasonably within the patent grant**, or whether the patentee has ventured beyond the patent grant and into behavior having an anticompetitive effect not justifiable under the rule of reason.[56]

Xerox/ISO, represents another important chapter in the Federal Circuit's development and application of the threshold scope of the patent standard to refusals to deal in patented goods. As developed further, *infra*, the decision also represents a significant breakthrough in terms of the expansion of the treatment of this Court's *PRE* holding from a relatively narrow immunity holding to an evidentiary ruling of general application to the entirety of the patent-antitrust interface.

E. The Scope Of The Patent Rule As Applied To Reverse Payments

As applied to reverse payments, the scope of the patent rule 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 claim unless:
>
> 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

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[56] *Mallinckrodt,* 976 F.2d at 708 (emphasis supplied).

3. Competition beyond the claimed subject matter or temporal scope of the right to exclude has been unreasonably restrained.

The three branches of this rule all derive from authoritative precedents issued by this Court. Each of the reverse payment appellate decisions to reach this Court save *K-Dur*, can be explained by its terms.

II. REVERSE PAYMENTS HAVE NEVER BEEN SHOWN DIRECTLY AND OBJECTIVELY TO RESULT IN AN ANTICOMPETITIVE EFFECT IN ANY RELEVANT PRODUCT MARKET, AND THIS COURT SHOULD CONFIRM THAT APPLICATION OF A "QUICK LOOK" RULE OF PRESUMPTIVE ILLEGALITY TO SUCH PAYMENTS IS COMPLETELY UNJUSTIFIED

The public portion of the FTC's campaign against reverse payments is now approaching its fifteenth year. Nevertheless, no federal court of appeals has ever found, absent some violation of the threshold scope of the patent standard, that an anticompetitive effect of a Hatch-Waxman reverse payment could be proved in any properly defined relevant product market before a district court or agency. Under the authoritative precedents of this Court, that fact alone forecloses the quick look presumptive illegality approach which the Government has been pressing since 2009 and which the Third Circuit erroneously adopted in *K-Dur*. No court of appeals has ever applied such a rule in any patent-antitrust or misuse case, and in *Princo v. ITC* the Federal Circuit squarely rejected the efforts of the FTC to impose one in an en banc opinion in which eight of the ten sitting judges joined.

The FTC has failed to fashion any viable theory as to why reverse payment settlements that satisfy the threshold scope of the patent adjunct to the rule of reason standard are not exempt from application of the antitrust laws. Under that threshold rule, the subjective strength or weakness of any Orange Book patent is simply irrelevant under this Court's precedents.[57]

Moreover, if a reverse payment settlement passes muster under the scope of the patent test, the federal appellate courts have repeatedly confirmed that there can be no competent objective proof of what a court would have ruled on validity. The FTC's alternative argument on putative entry date likewise is not susceptible of objective proof and, what is more, totally ignores the significance of the "at risk" entry problem under the peculiar asymmetrical economics imposed under the Hatch-Waxman Act.[58]

On the other hand, a large part of the Hatch-Waxman Act's enormous success certainly can be attributed to the subjective and objective assessments of patent strength which invariably are made by the technically sophisticated and well advised litigants who conclude these settlements. The FTC is wrong to conclude that the parties are not better

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[57] Any doubt on that score—along with the FTC's argument that Section 282 of the Patent Act can be read merely as a burden-shifting tool—evaporated with this Court's decision in *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S.Ct. 2238, 2242, 2245-47 (2011). *See also American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed Cir. 1984) (Rich, J.); *Radio Corp. of America v. Radio Eng'g Labs., Inc.*, 293 U.S. 1 (1931).

[58] Private plaintiffs are even worse off than the FTC, since Section 4 of the Clayton Act imposes even greater burdens upon a private plaintiff.

equipped than any potential trier of fact to determine what reasonable agreed entry dates should result from Hatch-Waxman settlements.

Finally, there is no reason whatsoever to make any distinction between Hatch-Waxman reverse payment terms and the large credits for legal expenses and infringement damages forgiveness for pre-settlement periods which represent common terms in standard patent infringement settlements.

Before a *per se* rule of illegality or a "quick look" rule of presumptive illegality can be applied or even contemplated, both the threshold scope of the patent test and the full or truncated rule of reason inquiry must be satisfied. This conclusion was fully anticipated in 2004 by the SG's *Andrx v. Kroger* Brief.[59]

Princo v. ITC, the final chapter of an important Federal Circuit case addressing the scope of the equitable doctrine of misuse, significantly affects patent pooling and rights clearance agreements for research joint ventures (RJVs) and standard setting organizations (SSOs).[60] The case was filed before the International Trade Commission (ITC) under Section 337, 19 U.S.C. § 1337, and sought to bar former licensees under six patents owned by U.S. Philips

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[59] As the SG phrased it in his 2004 *Andrx v. Kroger* Brief, "*per se* treatment is reserved for conduct that has a predictable and pernicious anticompetitive effect." *Id*. at 7. The Federal Circuit's decision in *Cipro IV* illustrates how the appropriate truncated rule of reason analysis should be applied after the settlement terms have been found exempt from antitrust liability under the scope of the patent rule. The Federal Circuit's approach, moreover, is internally consistent with that of the analogous Second and Eleventh Circuit formulations.

[60] *See generally Gasoline Cracking*.

Corp. ("Philips") from importing foreign CD-R and CDR-W storage discs into the United States.

The administrative law judge ("ALJ") initially found the Philips patents valid and infringed but unenforceable for patent misuse. The Commission affirmed. A panel of the Federal Circuit reversed in *Philips I*,[61] a scholarly and well-reasoned opinion by Judge Bryson, ruling that the package-licensing allegations of defendants were neither sufficient to make out a case of per se misuse under this Court's precedents, nor supported by adequate proof of some anticompetitive effect in some properly defined relevant product market.

The FTC had filed an amicus brief after the period for briefing by the parties and amici curiae had closed,[62] arguing – just as it does here, and citing virtually the same authorities – that the Federal Circuit could reverse the injunction against importation without finding an anticompetitive effect in some properly determined relevant product market by employing the "quick look" analysis to determine that the challenged agreement was "inherently suspect."[63]

The Federal Circuit rejected the FTC's position in the pertinent portion of Judge Bryson's opinion (Part II.C) by an 8-2 vote, with only the reversed panel majority accepting the FTC's arguments. The rea-

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[61] *U.S. Philips Corp. v. Int'l Trade Comm'n*, 424 F.3d 1179 (Fed. Cir. 2005).

[62] "Brief Of Amicus Curiae Federal Trade Commission On Rehearing En Banc Supporting Neither Party in *Princo v. ITC*" ("FTC *Princo v. ITC Brief*"). *See also* NYIPLA's *Princo v. ITC* Brief.

[63] *Id.* at 19, 21.

soning of the majority speaks volumes and should be applied directly to this case:

> The dissenting opinion seems to sidestep the Commission's adverse factual findings by arguing that the burden of proof should have been placed on Philips, not *Princo* * * * . The dissent advocates a "quick look" rule of reason analysis on the ground that any agreement not to compete is inherently suspect and that competitive harm therefore should be presumed.

After reviewing *California Dental Ass'n v. F.T.C.*, 526 U.S. 756 (1999) ("*CDA*"), and *Texaco Inc. v. Dagher*, 547 U.S. 1 (2006) ("*Dagher*"), however, the majority went on to hold that:

> [T]he Supreme Court has cautioned that presumptions of anticompetitiveness should not be lightly invoked [citing BMI[64]]
>
> Rather the Court has stated:
>
> [B]efore a theoretical claim of anticompetitive effects can justify shifting to a defendant the burden to show empirical evidence of procompetitive effects, as quick look analysis in effect requires, there must be some indication that the court making the decision has properly identified the theoretical basis for the anticompetitive effects and considered whether the effects are actually anticompetitive. Where, as here, the circumstances of the restriction are somewhat complex, assumption alone will not do.[65]

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[64] *Broad. Music, Inc. v. Columbia Broadcast Sys.*, 441 U.S. 1, 8-9 (1979) ("*BMI*").

[65] *Princo v. ITC*, 616 F.3d at 1339 (citing *CDA*, 526 U.S. at 776, n.12).

III. APPLICATION OF A RULE OF PRESUMPTIVE ILLEGALITY TO REVERSE PAYMENTS ALSO IS PRECLUDED BY THE LETTER AND SPIRIT OF *PROFESSIONAL REAL ESTATE*

It is completely permissible under the antitrust laws for the branded manufacturers to litigate fiercely and attempt to "try their losers" to final judgment so long as the applicable standard of *PRE* is not violated. The Government makes no attempt to distinguish *PRE*, or to suggest that *Xerox/ISO* and *Asahi Glass* were wrong, respectively, to extend *PRE* as an evidentiary rule of general application to refusals to deal in patented goods in 2000 and to Hatch-Waxman reverse payment settlements in 2003. Indeed, the FTC and the ATD have tried to ignore *PRE* ever since *Xerox/ISO* was first cited to this Court by the SG in 2004.

This Court should announce that the rule of *PRE* both (1) fixes the level and nature of the proof required to satisfy the "sham" exception to the *Noerr-Pennington* immunity doctrine, and (2) applies the same standard to the Government's burden of proving an anticompetitive effect in some properly defined relevant product market in any full or truncated rule of reason trial that may be required (a) not only to assess Hatch-Waxman reverse payment settlements, (b) but also to adjudicate other alleged patent-antitrust matters to which the threshold scope of the patent standard must be applied, such as the refusals to deal in patented goods addressed in *Xerox/ISO*.

There, after finding that the threshold scope of the patent standard had been met the court ruled that

> our inquiry is at an end. Xerox was under no obligation to sell or license its patented parts and did not violate the antitrust laws by refusing to do so.[66]

In reaching this result, the court relied heavily upon *PRE* to reject the approach applied by the Ninth Circuit in *Kodak/ITS*,[67] under which the jury had been permitted to assess whether the patentee's conduct had been "pretextual." Taking note of the statement in *PRE* that "if a suit is not objectively baseless, an antitrust defendant's subjective motivation is immaterial," the Federal Circuit refused to follow *Kodak/ITS*, reasoning that:

> [w]e see no more reason to inquire into the subjective motivation of Xerox in refusing to sell or license its patented works than we found in evaluating the subjective motivation of a patentee in bringing suit to enforce that same right.[68]

After the petition for certiorari had been filed in *CSU v. Xerox*, the SG filed an amicus brief pursuant to another SVSG order addressing both of the arguments which the Federal Circuit had accepted in *Xerox/ISO*.[69] The SG took no position, however, on the Federal Circuit's rejection of *Kodak/ITS* based

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[66] *Xerox/ISO, supra*, 203 F.3d at 1328.

[67] *Image Tech. Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997) ("*Kodak/ITS*").

[68] *Xerox/ISO,* 203 F.3d at 1327. *See also* NYIPLA's *Xerox/ISO* Brief.

[69] SG's *CSU v. Xerox Brief*.

upon PRE, instead recommending that the issue be left to "percolate further."[70]

When the FTC filed a certiorari petition seeking to reverse its court of appeals loss in *Schering-Plough*, the SG again filed an *amicus* brief in response to an SVSG order. The SG criticized certain aspects of "the FTC's approach," which was perceived "to place undue weight on the parties' subjective views,"[71] and recommended that certiorari be denied.

Given the very real prospect of treble damages and even the potential for criminal liability, bright line antitrust standards must be clear, objective and fair. Extended application of the rule of *PRE* at the patent-antitrust interface will provide just such a standard.

IV. APPLICATION OF A RULE OF PRESUMPTIVE ILLEGALITY TO REVERSE PAYMENTS WOULD THREATEN THE ENORMOUS SUCCESS OF THE HATCH-WAXMAN ACT AND COULD UNDERMINE THE RATIONALE FOR ITS ENACTMENT BY CONGRESS

One principal objective of Congress in enacting the Hatch-Waxman Act was to maximize challenges to Orange Book patents well before their expiration and thereby increase the availability of generic substitutes for branded innovator drugs at earlier dates. We already have seen that, judged by any applicable standard, that aspect of the legislation has been enormously successful.

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[70] *Id*. at 16.

[71] *Id*. at 12.

Another involves the safe harbor provisions of Section 271(e) of the Patent Act, 35 U.S.C. § 271(e)(1), as discussed by this Court in *Merck v. Integra*.[72] By overruling the Federal Circuit's *Roche v. Bolar* decision in the 1984 legislation,[73] Congress eliminated the *de facto* temporal extension of the monopoly which invariably delayed generic entry due to the regulatory requirements of the FDA.[74]

While profits of branded innovators were pinched by both aspects of the new legislation, Congress realized that the R&D burden for financing new drug research and development would remain on the branded innovators.

A. The FTC Has Conceded That Imposition Of A Quick Look Rule Of Presumptive Illegality Would Reduce Net Generic Challenges

An alleged savings target of $3.5 billion a year may translate to good public relations for an agency with a $300 million budget,[75] but that figure becomes

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[72] *Merck KGaA v. Integra Lifesciences, Ltd.*, 545 U.S. 193 (2005) ("*Merck v. Integra*").

[73] *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984) ("*Roche v. Bolar*").

[74] *See* "Brief Of New York Intellectual Property Law Association As *Amicus Curiae* In Support Of Petitioner in *Merck v. Integra*" ("NYIPLA *Merck v. Integra* Brief").

[75] When FTC Chairman Jon Leibowitz spoke last September at Fordham University, he cited the staff estimates from the 2010 Pay-For-Delay Study as grounds for self-congratulation on the agency's role in achieving the *K-Dur* decision: "We're a tiny agency by Washington standards . . . and if an agency of $300 million a year can save $3.5 billion a year for American consumers, I think that's a terrific accomplishment." FTC

considerably less attractive when compared to a total annual market of almost $200 billion which may well be threatened by the FTC's crusade.

Irrespective of who will eventually win the battle of economic experts, the FTC already has conceded that the rule it asks this Court to impose would have the effect of reducing net challenges to Orange Book patents.

Indeed, both the FTC and the Third Circuit panel in *K-Dur* have recognized that any statute or judicial rule making reverse payments unlawful under the antitrust laws inevitably would reduce the net number of validity challenges under the Hatch-Waxman Act. The FTC's concession is set forth in footnote 24 of the 2010 Pay-For-Delay Study, which goes on to suggest that the effect of this reduction "would likely be very low" predicated solely upon the FTC's assertion that "only 24% of all cases settled" under the Hatch-Waxman Act contain reverse payment terms.

NYIPLA respectfully suggests that changes which threaten to reverse the gains in early generic entry heretofore achieved simply cannot be risked upon such tenuous evidence.

B. Limiting Generic Flexibility Likewise Would Reduce Net Challenges

The FTC today also seems oblivious to the fact that freedom to conclude reverse payment settlements is important to the vigorous competition within the generic sector which must be preserved to ensure the continuing success of Hatch-Waxman. In 2004,

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Sets Sights on High Court Pay-For-Delay-Fight, *available at* http://law.fordham.edu/newsroom/ 27940.htm.

however, the catalogue of concessions made in the Commission's *Schering-Plough* decision, as set forth in the SG's *Andrx v. Kroger* Brief and identified as "legitimate justifications" for reverse payment settlements, included both (1) that a "cash starved" generic drug firm might well benefit from the availability of "some up-front support from the pioneer manufacturer," and (2) that a "judgment-proof generic manufacturer whose downside risks of damage exposure are small."

We have also seen from the discussion, *supra*, of the GPhA *Tamoxifen* Brief, that freedom to settle and litigation flexibility based upon adequate cash reserves represent important factors for potential generic manufacturers in achieving the goals of the Hatch-Waxman Act.

The generic manufacturer has no fiduciary relationship to the public, and answers only to its shareholders. It has no obligation to take any case to final judgment and its interest is to negotiate whatever mix of early entry and reverse payment which best suits its optimum cash position.

Within that framework, the generic segment of the industry was disappointed to learn of the recent comments of Marcus Meier, the FTC's assistant director for health care in the Bureau of Competition, at the annual meeting of the New York State Bar Association. Meier simply dismissed the notion previously accepted by the full Commission and the SG that reverse payment settlements should be deemed pro-competitive when they are employed to restore the litigation war chests of cash poor generics: "Sometimes businesses succeed and sometime businesses

fail, and that's just too bad. That doesn't justify an anti-competitive settlement."[76]

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

CHARLES R. HOFFMANN
President-Elect
NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION
c/o HOFFMANN & BARON LLP
6900 Jericho Turnpike
Syosset, NY 11791
(516) 822-3550

THOMAS J. KOWALSKI
Counsel of Record
JOHN C. CLEARY
MARC B. SCHLESINGER
VEDDER PRICE P.C.
1633 Broadway
47th Floor
New York, NY 10019
(212) 407-7700
tkowalski@vedderprice.com

ROBERT J. RANDO
AMICUS BRIEFS COMMITTEE
NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION
c/o THE RANDO LAW FIRM
4940 Merrick Road
Massapequa Park, NY 11762
(516) 799-9800

DAVID F. RYAN
Co-Chair
AMICUS BRIEFS COMMITTEE
NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION
1214 Albany Post Road
Croton-on-Hudson, NY 10520
(914) 271-2225

Counsel for Amicus

February 28, 2013

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[76] *See* Pay-For-Delay Antitrust Test Sets Bar Too High: FTC Official (Jan. 24, 2013), available at http://www.law360.com/articles/409984/pay-for-delay-antitrust-test-sets-bar-too-high-ftc-official.