Nos. 10-2077, 10-2078 & 10-2079

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

IN RE K-DUR ANTITRUST LITIGATION

ON APPEAL FROM THE MARCH 24, 2010 ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY
CIVIL ACTION NO. 01-1652, MDL DOCKET NO. 1419
THE HONORABLE JOSEPH A. GREENAWAY

BRIEF OF THE STATES OF OHIO, ALASKA, ARIZONA, ARKANSAS, IDAHO, ILLINOIS, IOWA, KANSAS, LOUISIANA, MAINE, MARYLAND, MASSACHUSETTS, MINNESOTA, MISSISSIPPI, NEVADA, NEW MEXICO, SOUTH CAROLINA, TENNESSEE, UTAH, VERMONT, WASHINGTON, AND WYOMING AS AMICI CURIAE SUPPORTING APPELLANTS

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INTEREST OF AMICI

The Amici States have three interests in this matter: 1) through their chief law enforcers, the Attorneys General, the States enforce federal and state antitrust laws against anticompetitive "reverse payment" agreements of the type effectively immunized by the Special Master's Report and Recommendation in *In re K-Dur Antitrust Litig.*, Civ. No. 01-1652, 2009 WL 508869 (D.N.J. Feb. 6, 2009) ("*K-Dur*")**;** 2) as *parens patriae*, the States seek to protect their consumers and businesses from anticompetitive conduct that blocks access to lower-cost generic pharmaceuticals; and 3) as their Medicaid agencies and other governmental programs are significant third-party payors for, and direct purchasers of pharmaceuticals, the States have a strong pecuniary interest in the availability of low-cost generic drugs.

The States have a long history of prosecuting antitrust actions where collusion between pharmaceutical companies limits or excludes generic competition.[1] When, as here, a court adopts a legal standard immunizing reverse payment agreements

[1] *See, e.g., FTC v. Watson Pharm., Inc.*, 611 F. Supp. 2d 1081 (C.D. Cal. 2009); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005); *Colorado v. Warner Chilcott Holdings Co. III, Ltd.*, No. 1:05-CV- 2182 (CKK), 2007 WL 6215857 (S.D.N.Y. Nov. 7, 2005); *Ohio v. Bristol-Myers Squibb Co.*, No. 1:02-CV-01080 (EGS), 2003 WL 21105104 (D.D.C. May 13, 2003); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

from proper antitrust scrutiny, the States' ability to fulfill their role to protect their consumers and businesses from anticompetitive agreements is undermined.

SUMMARY OF ARGUMENT

Following in the steps of the Second Circuit's erroneous decision in *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006) ("*Tamoxifen*"), *K-Dur* establishes almost irrebuttable presumptions of patent validity and infringement based solely on the patent holder's untested assertions. These judicially-made presumptions, subject to only minor exceptions, have no basis in law or fact, and are contrary to Supreme Court precedent. Moreover, the *de facto* presumption of infringement in this case consciously disregards the compelling if not overwhelming evidence of non-infringement identified by Plaintiffs in this case. These presumptions, in turn, effectively immunize collusive competitor agreements from the antitrust scrutiny that such agreements traditionally receive.

Further, the decision below abandons common sense by not only ignoring the facts and circumstances surrounding reverse payment agreements, but also attributing the delay in generic competition solely to the exclusionary power of the patent. This attribution is based on the flawed assumption that the statutory privileges of a patentee include a right to collude with and pay competitors to allocate markets. Such an assumption is inconsistent with the Supreme Court's

long-standing condemnation of licensing arrangements that exceed the scope of licensed patents.

Reverse payment agreements also thwart the letter and spirit of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act" or the "Act"), 21 U.S.C. § 355(j) (2006). One of the Act's specific goals was to foster the speedy entry of generic competition by encouraging litigation to remove the threat of weak patents that wrongly delay generic competition.

REASONS FOR REVERSAL

I. A SURGE IN REVERSE PAYMENT AGREEMENTS IS THREATENING THE EXISTENCE OF GENERIC COMPETITION AND THE AVAILABILITY OF AFFORDABLE DRUGS TO THE STATES AND THEIR CITIZENS.

Maintaining open competition in pharmaceutical markets is critical to the States' ability to provide drugs to their consumers at a reasonable cost, and to control escalating drug costs that threaten to swamp already-strained State budgets. In 2008, State and local governments nationwide spent some $14.5 billion for drug prescriptions, while health-care spending consumed some 24% of state revenues.[2]

[2] Centers for Medicare and Medicaid Services, U.S. Dep't of HHS, *National Health Expenditures, by Source of Funds and Type of Expenditure: Calendar Years 2003-2008* (*"HHS Study"*), Table 4, http://www.cms.gov/NationalHealthExpendData/downloads/tables.pdf; California Health Care Foundation, *Health Care Almanac, Health Care Costs 101* (2010), at 11, http://www.chcf.org/~/media/Files/PDF/H/PDF%20HealthCareCosts10.pdf.

Nationally, drug prescriptions in 2008 cost some $234 billion, more than five times the $40.3 billion spent in 1990.[3]

Brand name drugs, many of which have patent protection, account for most of the increase in the nation's burgeoning drug costs. Generic drugs, on the other hand, typically cost less than a third of the price of branded drugs, and are one of the primary factors responsible for slowing the rate of increase in drug costs.[4] Yet robust generic competition is being seriously undermined by a surge of reverse payment agreements that force States and consumers to pay monopolistic prices for branded drugs.

In *K-Dur*, Schering's patent covered only a narrow sustained release formulation of potassium chloride, an ingredient that was not itself patentable. Schering's patent application was initially rejected by the U.S. Patent and Trademark Office, and the patent was only granted after Schering narrowed its patent claims to a very specific combination of ingredients in the sustained release coating applied to potassium chloride crystals. *K-Dur*, 2009 WL 508869 at *5. Both of Schering's rival generic companies disclaimed the use of that narrow

[3] *HHS Study*, *supra* note 2, at Table 2.

[4] Kaiser Family Foundation, *Prescription Drug Trends* (2010), at 1-3, http://www.kff.org/rxdrugs/upload/3057-08.pdf; Center for Drug Evaluation and Research, U.S. FDA, *Generic Competition and Drug Prices*, http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm.

formulation, and had motions for summary judgment of non-infringement pending, when Schering chose to pay them millions of dollars not to launch generic versions of K-Dur. *K-Dur*, 2009 WL 508869 at *6-9. Yet the Special Master in *K-Dur* totally disregarded Plaintiffs' evidence of non-infringement, and presumed that the patent was valid and infringed, thus effectively blessing this agreement despite its obvious anticompetitive effects. *K-Dur*, 2009 WL 508869 at *25-26.

The aggregate financial burden of these types of collusive reverse payment agreements on consumers is staggering. Recent studies by the Federal Trade Commission ("FTC") and prominent academics gauge the impact to be between $3.5 billion and $14 billion annually.[5]

The surge in reverse payment agreements is largely the result of the decision in *Tamoxifen*, widely viewed as sanctioning and encouraging these agreements.[6] Before that decision, patent litigation rarely settled with payments being made by

[5] FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, at 2 (Jan. 2010) ("FTC Recent Study"), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf; C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 650 (2009).

[6] *FTC Recent Study*, *supra* note 5, at 1; Jon Leibowitz, Comm'r, FTC, *Exclusion Payments to Settle Pharmaceutical Patent Cases*: *They're B-a-a-a-ck!*, at 7-8 (Apr. 26, 2006), http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf.

the patent holders to the alleged infringers.[7] Moreover, the reverse payments made under *Tamoxifen's* protective umbrella secure generic companies' agreements to delay marketing lower-cost drugs beyond what they would agree to do in the absence of the monetary payments.[8] A recent FTC study estimates that these payments delay entry of competition for nearly 17 months relative to patent settlements lacking reverse payments.[9]

This Court should not further encourage these anticompetitive agreements by following, as *K-Dur* does, the erroneous reasoning of *Tamoxifen*.

II. *K-DUR* ESTABLISHES ALMOST CONCLUSIVE PRESUMPTIONS OF VALIDITY AND INFRINGEMENT NOT SUPPORTED BY STATUTE, FACT OR JUDICIAL PRECEDENT.

Patents that are not valid or that are asserted against non-infringers can impede innovation and choke off competition from lower-priced drugs. Hence, the Supreme Court has recognized that it "is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *Pope Mfg. Co. v.*

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[7] Hemphill, *supra* note 5, at 638, 657.

[8] FTC Recent Study, *supra* note 5, at 2, 4; Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. Econ. 391, 394 (2003); Herbert Hovenkamp, Mark Janis & Mark. A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1749-63 (2003).

[9] *FTC Recent Study, supra* note 5, at 2, 4.

Gormully, 144 U.S. 224, 234 (1892); *see also Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-01 (1993) (explaining the "importance to the public at large of resolving questions of patent validity").

Despite this well-recognized principle that the range of competition restricted by a patent depends upon its validity and scope, *K-Dur* adopted a curious "bury-your-head-in-the-sand" approach to the patent's exclusionary power. The decision requires that courts turn a blind eye to the subject, rejecting all evidence of the exclusionary scope of the patent, except in two limited instances: 1) where the infringement claims that are settled are sham and objectively baseless; or 2) where the patent was procured by fraud. *K-Dur*, 2009 WL 508869 at *28 & n.27 (declining to conduct "a detailed inquiry into the merits of the patent case" which were "resolved" when Schering made payments to the generics, and granting summary judgment where plaintiffs had not alleged that the patent was procured by fraud and the Special Master concluded on his limited review that the underlying patent lawsuit was not objectively baseless).

In *K-Dur*, the record before the district court contained ample evidence of non-infringement. Indeed, the Schering/Upsher litigation resulted in thousands of pages of documents produced during discovery and testimony from experts on both sides. *K-Dur*, 2009 WL 508869 at *6. However, the Special Master ignored the

evidence entirely, stating that "it is inappropriate to conduct an *ex post* inquiry into infringement issues that were resolved by the parties' settlement." *Id.* at *25; ("I decline to discount the exclusionary power of Schering's patent based on the possibility that it was not infringed by the Upsher and ESI products"). By doing so, the Special Master effectively created a presumption of infringement despite his express acknowledgment that the law does not provide such a presumption. *K-Dur*, 2009 WL 508869 at *25 ("[T]here is no presumption of infringement . . . .").

K-Dur's acceptance, without inquiry, of the "facial" asserted scope of the patent creates what amounts to irrebuttable or conclusive presumptions of patent validity and infringement, enabling anticompetitive conduct whenever a patent is asserted. Such presumptions are not only rejected by other Circuits,[10] but have no basis in statute, fact or judicial precedent.

There is no statutory support for the presumptions created in this case. The statutory presumption of patent validity, 35 U.S.C. § 282, is simply a procedural device for allocating the burden of proof to an infringer on validity issues, and "has no separate evidentiary value." *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d

[10] *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003) (court reviewed the strength of the patent at the time of the settlement agreement); *In re Cardizem*, 332 F.3d at 900 ("The Agreement whereby HMR paid Andrx $40 million per year not to enter the United States market for Cardizem . . . is *per se* illegal under the Sherman Act and under the corresponding state antitrust laws.").

1540, 1553 (Fed. Cir. 1983); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983). This presumption is rebuttable, and only affects the burden of proof on a full adjudication of the patent merits. Thus, for example, it provides no evidence to weigh in determining whether a preliminary injunction should issue. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007); *New Eng. Braiding Co. v. A. W. Chesteron Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992) (existence of issued patent is not evidence which can be "weighed" in determining likelihood of success for determining if injunction should issue). And, the presumption of validity is completely irrelevant when infringement is at issue. With respect to infringement, the law clearly presumes that the accused product does *not* infringe, and that the patent holder bears the burden to prove infringement. *See, e.g.*, *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1578 (Fed. Cir. 1993) ("The burden is on the patent owner to prove infringement . . . .").

Moreover, the presumptions created by *Tamoxifen* and the Special Master are contrary to the facts in this case as well as to the reality that many asserted patents are ultimately found to be either invalid or not infringed. Studies of fully-litigated pharmaceutical patents found that the generics prevailed in establishing that the asserted patents were either invalid or not infringed in 70% of the cases, according to one study, and in 73% of the cases, according to another study. Paul Janicke & Lilan Ren, *Who Wins Patent Infringement Cases*?, 34 AIPLA Q.J. 1, 20 (2006);

FTC, *Generic Drug Entry Prior to Patent Expiration* 1, 20 (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. These results are consistent with other studies finding that patents of all kinds challenged in litigation were held invalid in some 46% to 58% of the cases. Alden Abbott and Suzanne Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 11-12, n.41 and n.42 (2005).

A presumption that patents are valid and not infringed will render most, if not all, reverse payment agreements *per se* legal. The States, the Federal Trade Commission, the Department of Justice, the American Antitrust Institute and 86 professors of law or economics all agree that the Second Circuit standard followed by the Special Master here is too lax, shields harmful competitor collusion, and must be modified to permit some examination of the true confines of the patent. *In re Ciprofloxacin* (2d Cir. 2010) (Nos. 05-2851-cv(L), 05-2852-cv(CON), 05-2863-cv(CON)), Amicus Curiae Briefs supporting *en banc* review by the Second Circuit, by the 34 Attorneys General (May 20, 2010), by the United States (May 19, 2010), by the FTC (May 20, 2010), by the American Antitrust Institute (May 20, 2010) and by 86 Intellectual Property Law, Antitrust Law, Economics, and Business Professors, *et al.* (May 20, 2010).

III. IN *K-DUR*, COMPETITION WAS EXCLUDED BY USE OF MONEY AND COMPETITOR COLLUSION, NOT THE POWER OF THE PATENT.

By their nature, reverse payments call into question precisely what the party is purchasing in exchange for the monetary payment. The court in evaluating a reverse payment settlement must determine whether the source of the competitive exclusion is within or outside the scope of the patent grant, because, as the Supreme Court has consistently maintained, there is no antitrust exemption for restrictions that are not plainly and fairly within the patent monopoly. *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942) (patentee cannot extend grant by contract or agreement); *United States v. New Wrinkle Inc.*, 342 U.S. 371, 378 (1952); *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948) ("It is equally well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly.").

It is through this prism that the Court must address the $64,000 question: what was the quid pro quo for Schering's payments to the generics? The record in this case is consistent with the common sense conclusion that Schering paid the generics to delay entry so it could preserve its undeserved monopoly profits. A cursory review of the record demonstrates the troubling nature of Schering's payments to Upsher. On the eve of trial, after Upsher had developed significant

evidence of non-infringement, the parties reached a deal whereby Schering agreed to pay Upsher $60 million over a period of two years in exchange for Upsher's agreement to refrain from introducing its generic for more than four years. *K-Dur*, 2009 WL 508869 *7. While Schering claimed that the $60 million also included payment for unrelated licensing agreements, the Special Master admitted that the issues of whether those agreements were sham or bona fide were unresolved. *K-Dur*, 2009 WL 508869 *8.

Schering's payments to ESI are equally troubling. Absent some explanation—and none was forthcoming here—Schering's payments to ESI secured a delay of competition not obtainable through the exclusionary power of the patent alone. The "pay for delay" nature of the ESI settlement is evident in the sliding scale approach that Schering employed in its payment scheme. The earlier the FDA approved ESI's ANDA, the larger the payment Schering would make to ESI. In other words, the greater the threat of early entry by ESI, the more money Schering was willing to pay to delay such entry. *K-Dur*, 2009 WL 508869 *10.

Thus, it is evident from the payments that the parties did not settle because they viewed the Schering patent to be strong and valid. To the contrary, it is clear that the generics were induced to abandon their efforts to enter the market for several years because they were paid millions of dollars to do so. The exclusionary

power of the Schering patent was not viewed as sufficient to induce the generics to quit the market, so Schering paid for the market exclusion that the patent could not provide. Thus, Schering was not exercising the power of its patent, but rather the power of its bank account to suppress competition through combination with its competitors.

IV. PATENT RIGHTS DO NOT INCLUDE THE RIGHT TO PAY COMPETITORS NOT TO COMPETE OR TO COLLUDE WITH COMPETITORS.

The Special Master in *K-Dur* incorrectly reasoned that a valid patent not only includes the right to exclude through enforcement of the patent, but also to exclude through payments to rivals not to compete. *K-Dur*, 2009 WL 508869 at *22 (by paying the generic, the brand is merely "'protect[ing] that to which it is presumably entitled'") (quoting *Tamoxifen*, 466 F.3d at 208-09). No cases from this Court support such an expansive view of the patent monopoly. Furthermore, the Supreme Court has consistently rejected patentees' efforts to expand the "narrow monopoly" of patents by engrafting ingenious "private perquisites" onto them. *Line Material*, 333 U.S. at 316-17.

The patent monopoly consists of the patentee's exclusive right to make, use and vend the invention, and it "affords no immunity for a monopoly not fairly or plainly within the grant." *Masonite*, 316 U.S. at 277; *United States v. Univis Co., Inc.*, 316 U.S. 241, 250 (1942). Since "patents are privileges restrictive of a free

economy," the Supreme Court has long required that patent rights be "strictly construed" so as "not to derogate from the general law beyond the necessary requirements of the patent statute." *Masonite*, 316 U.S. at 280.

A patentee may vindicate its exclusive rights either through litigation or by entering license agreements. However, if the patentee does the latter, the fact that it has the right to refuse a license agreement does not mean that it can attach any conditions on the license that are not within the strict limits of the patent monopoly. *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 666 (1944) (fact that the patentee has the power to refuse a license does not enable it to enlarge the monopoly of the patent by the expedient of attaching conditions to its use); *Masonite*, 316 U.S. at 279 (while the patentee has the power to refuse a license, he "does not have the lesser power to license on his own conditions" as there are "strict limitations" on the patentee's power).

The Supreme Court has consistently applied the Sherman Act to prohibit patent license agreements that extend beyond the strict exclusionary scope of the patent to suppress competition with respect to price. *See Masonite*, 316 U.S. at 279 (agreements fixing prices for sale of patented product "secure protection from competition which the patent law unaided by restrictive agreements does not afford"); *Std. Sanitary Mfg. Co. v. United States*, 226 U.S. 20, 48 (1912) (price

limitations in pooled patent licenses "transcend what was necessary to protect the use of the patent"). The exclusion resulting from reverse-payment agreements is more pervasive and pernicious; it eliminates not only price competition between the competitors, but all other forms of competition between the parties. *Blue Cross & Blue Shield United of Wisc. v. Marshfield Clinic*, 65 F.3d 1406, 1415 (7th Cir. 1995) ("It would be a strange interpretation of antitrust law that forbade competitors to agree on what price to charge, thus eliminating price competition among them, but allowed them to divide markets, thus eliminating all competition among them.").

V. REVERSE PAYMENTS THWART CONGRESSIONAL INTENT BEHIND THE PROVISIONS OF THE HATCH-WAXMAN ACT PROMOTING EARLIER GENERIC ENTRY.

Realization of the great savings and benefits of generic competition both to government programs and consumers inspired Congress' enactment of the Hatch-Waxman Act in 1984. H.R. Rep. No. 98-857(I) at 14, 17 (1984), reprinted in 1984 U.S.C.C.A.N. 2647. Through this Act, Congress established a regulatory structure designed to place lower-cost generic drugs in the hands of consumers at reasonable prices and to do so "fast." *Andrx Pharms., Inc. v. Biovail Corp.*, 256 F.3d 799, 809 (D.C. Cir. 2001).[11] A significant part of the regulatory scheme recognizes that

[11] In exchange, branded drug makers received an extended patent term and the ability to trigger an automatic 30-month stay of generic competition, a power unique among patent holders. 35 U.S.C. § 156; 21 U.S.C. § 355(j)(5)(B)(iii).

(continued...)

weak and dubious patents could be used to thwart generic competition, so the Act included various market incentives for generic drug makers to promptly challenge these patents. Thus, the Hatch-Waxman Act encourages a patent holder to commence patent litigation prior to the generic firm bringing its drug to market,[12] and reduces a generic entrant's potential loss in mounting the patent challenge.[13] Most importantly, the generic company is provided with a powerful financial incentive—in the form of a 180-day marketing exclusivity—to challenge weak pharmaceutical patents. 21 U.S.C. § 355 (j)(5)(B)(iv) (2006). Congress also amended the Hatch-Waxman Act in 2003 to require that reverse payment settlements be reviewed by two federal enforcement agencies, the Federal Trade Commission and the Department of Justice. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. § 355(j)(5)(D)(i)(V); 148 Cong. Rec. S7348 (Jul. 25, 2002) (statement of Sen. Hatch, co-author of the Hatch-

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(continued...)

[12] The Hatch-Waxman Act deems the mere filing of a generic drug maker's Paragraph IV certification with the U.S. Food and Drug Administration ("FDA") a technical act of infringement. 35 U.S.C. § 271(e)(2)(A). To encourage patent holders to promptly file a patent infringement suit, the Hatch-Waxman Act provides a 30-month automatic stay of FDA approval to those firms that file a patent infringement action within 45 days of a Paragraph IV filing. 21 USC § 355(j)(5)(B)(iii).

[13] Under the Hatch-Waxman Act, the generic does not face damages or the loss of its investments necessary to launch a drug where it has not actually competed in the market with a generic drug. *See Tamoxifen*, 466 F.3d at 206-07.

Waxman Act.) ("The FTC is doing the right thing in taking enforcement actions against those who enter into anti-competitive agreements that violate our Nation's antitrust laws").

Thus, Congress, via the Hatch-Waxman Act, mandated prompt generic competition and swift patent challenges, and subjected reverse payment agreements to federal enforcers for review. Unfortunately, the Second Circuit standard adopted by *K-Dur* here renders most reverse payment agreements *per se* legal, making any antitrust review under the Act nearly meaningless except in extreme cases.

Overturning *K-Dur* and permitting broader antitrust scrutiny of reverse payments would reinforce Congressional intent underlying the Hatch-Waxman Act. Doing so also would not undermine the courts' general policy of promoting settlement. Without reverse payments, patent litigants can settle with licensed entry, in which the license terms are based on the strength of the patent rather than sharing of monopoly profits. Reverse payments are not necessary to settle patent cases, and the payments "serve no obvious redeeming social purpose." *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 625 F.3d 779, 780 (2d Cir. 2010) (J. Pooler, dissenting). State antitrust enforcers have a keen interest in ensuring that generic exclusion results from the strength of the patent rather than rivals'

common interest in eliminating competition and sharing the spoils at the consumers' expense.

CONCLUSION

The Attorneys General respectfully urge the Court to reverse the decision of the district court.

Dated: May 18, 2011

Respectfully submitted,

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CERTIFICATE OF BAR MEMBERSHIP

In accordance with Local Rule of Appellate Procedure 28.3(d), I, Werner L. Margard III, certify that I am a member of the bar of the United States Court of Appeals for the Third Circuit.

Dated: May 18, 2011

/s Werner L. Margard III
Werner L. Margard III

CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(A) AND LOCAL RULE 31.1(C)

1. I certify that this brief complies with Fed. R. App. P. 32(a)(7)(B)(i) with respect to word type-volume. It contains 4,529 words, excluding those portions exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14 point New Times Roman font.

3. The text of the electronic pdf version of this brief is identical to the text in the paper copies.

4. Symantec AntiVirus Program 10.1.5.5000 Version 5/16/2011 Rev.2 was used to scan the pdf version of this brief and no virus was detected.

Dated: May 18, 2011

/s Werner L. Margard III
Werner L. Margard III

CERTIFICATE OF SERVICE

I, Werner L. Margard III, certify that counsel for Appellants and Appellees are Filing Users of the Court's CM/ECF system, and, that on this day, this Brief of Amici Curiae and was served by filing them on the court's CM/ECF system. I further certify that ten hard copies of this Brief were delivered to the Office of the Clerk for the United States Court of Appeals for the Third Circuit.

Dated: May 18, 2011

/s Werner L. Margard III
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