

Reverse Payment Settlements: The Time for Change has Arrived

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Over the past 20 years, prescription drug spending in the U.S. has increased by 650%: from \$40 billion in 1990 to over \$300 billion in 2009.¹ Spending has risen sharply despite laws passed to make generic drugs more readily available. One reason for this is that brand-name drug manufacturers have used various tactics to limit price competition for their products by delaying generic entry into the pharmaceutical market. This is to the detriment of consumers, because generic versions of prescription drugs typically sell for a fraction of the cost of their brand-name counterparts.

One method employed by brand-name pharmaceutical companies is to obtain questionable patents designed to shield their products from competition, tying up would-be generic competitors with years of patent infringement litigation. These cases are often settled by "reverse payments" (also known as "pay-for-delay" settlements), where the brand-name company pays the alleged "infringer," the generic manufacturer, to drop its defense to the infringement suit and counterclaims challenging the patent, thereby preventing or delaying generic entry into the market-place. Whether reverse payments are anticompetitive has been a hot topic for some time.

In April of this year, the Second Circuit, in *In re Ciprofloxacin Hydrochloride Antitrust Litigation (Cipro)*,² following a previous Second Circuit decision, *In re Tamoxifen Citrate Antitrust Litigation*,³ ruled that reverse payments are not a *per se* violation of the Sherman Act. Significantly, however, in its decision, the court criticized reverse payments and invited plaintiffs to seek an *en banc* rehearing. In response, Plaintiffs requested the rehearing, but the Second Circuit just recently denied *en banc* review.⁴

In early July, the House passed H.R. 4899, which included the "Preserve Access to Affordable Generics Act," which authorized the FTC to initiate civil proceedings against brand-name and generic drug manufacturers that settle pharmaceutical patent cases with reverse payments. Though the proposed legislation died in the Senate, the issue is likely to be raised again in Congress.

This article discusses the state of the law concerning reverse payments and recent developments that may lead to a ban on such settlements.

Reverse Payments And The Harm They Cause

Payment to generic manufacturers under reverse payment settlements is often for as much as, or more than, the profits the generic would have made had the generic manufacturer invalidated the patent and entered the relevant product market.⁵ Because the generic could conceivably profit more from settling than from entering the market, a

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reverse payment constitutes an offer that hardly can be refused.

Reverse payments are an unintended consequence of the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act),⁶ which created an Abbreviated New Drug Application (ANDA) process for generic drug manufacturers to speed generic entry into the market. The ANDA process allows generic manufacturers to avoid the same time-consuming and expensive testing that brand-name manufacturers must conduct when seeking Food and Drug Administration (FDA) approval for a new drug. ANDA filers instead rely upon prior FDA findings from the relevant brand-name manufacturer's New Drug Application. In seeking FDA approval for its ANDA, the generic company must make one of four certifications:

- i. no patent was filed for the brand-name version of the drug;
- ii. the filed patent has since expired;
- iii. the generic will market the drug as of the date the patent expires; or
- iv. the patent is invalid or the generic equivalent will not infringe the patent.⁷

This last certification, known as an ANDA-IV filing, serves to expedite patent challenges and enable faster entry of lower-cost generic drugs.⁸

When the generic drug manufacturer files an ANDA-IV application, it is considered a technical form of patent infringement. Thereafter, the brand-name manufacturer generally sues the generic manufacturer for patent infringement within a 45-day statutory deadline. In doing so, it receives the benefit of an automatic stay of FDA approval of the generic of up to 30 months.⁹ Typically, patent infringement suits that settle through reverse payments do so during this automatic stay period.

Proponents of reverse payments argue that a ban would reduce both the value of patents as well as the brand-name companies' incentives to innovate. They also argue that because reverse payments

often allow generics to enter the market before the patent expires, a ban on reverse payments is itself anticompetitive since it would reduce earlier patient access to generic drugs.¹⁰ These arguments, however, assume the validity of the challenged patent and ignore the significant possibility that the generic manufacturer would win the patent infringement suit, thus allowing a competing generic product to be marketed immediately. Indeed, once challenged, approximately 50% of patents are held to be invalid or otherwise unenforceable¹¹ and generic manufacturers win nearly 75% of Hatch-Waxman suits tried to verdict.¹²

Those who oppose reverse payments argue that the settlements are anticompetitive, illegal market allocation schemes that warrant a presumption of illegality. Specifically, because the brand-name drug company easily can buy off the generic's challenge to a weak or otherwise questionable patent, the validity of the patent is not adjudicated and a possibly unlawful monopoly continues.

In January 2010, the FTC released a report stating that reverse payments delay generic entry into the market by an average of 17 months, costing consumers \$3.5 billion annually, with an "estimated to cost American consumers . . . \$35 billion over the next 10 years."¹³ The DOJ found that a one-year delay in generic entry into the market costs consumers approximately \$14 billion.¹⁴

Despite harm to consumers – or precisely because of the profit to both brand-name and generic manufacturers at consumers' expense – reverse payments are on the rise. There were 19 reverse payment settlements in fiscal year 2009, and there have already been 21 reverse payment settlements in the first nine months of fiscal year 2010, resulting in an additional \$9 billion in brand-name drug companies' profits.¹⁵ Because of the increasing frequency of, and substantial harm from, reverse payments, the FTC has made its goal of stopping reverse payments a high priority.¹⁶

While public policy generally encourages settlements, it must be weighed against the benefits of consumer protection.¹⁷ Regardless of whether the challenged patent is valid, reverse payment settlements have enabled brand-name drug manufacturers to protect their monopolies and have forced consumers to spend substantially more money on prescription drugs than they would in a competitive market. Particularly where the reverse payment is larger than the profit to be earned by the generic's invalidation of the patent and entry into the market, the only loser is the public.

Case Law – Second Circuit

The Second, Sixth, and Eleventh Circuits are split on the issue of whether reverse payments violate the antitrust laws.

In *In re Tamoxifen Citrate Antitrust Litigation*,¹⁸ the Second Circuit held that reverse payments are valid provided that (1) they are not the result of fraud or "objectively baseless" litigation and (2) delayed entry into the market or other market restrictions do not exceed the scope of the patent. Plaintiffs challenged a reverse payment made by a brand-name drug manufacturer to a generic manufacturer after the district court in the patent infringement case held, on the merits, that the brand-name manufacturer's patent was invalid. The patent infringement invalidation decision was on appeal when the settlement – which included a provision vacating the finding of the patent's invalidity – was reached. In the antitrust case, the Second Circuit affirmed the district court's grant of summary judgment for defendants (comprised of all parties to the reverse payment agreement) and held that the reverse payment did not violate the antitrust laws because the anticompetitive effects of those payments did not extend beyond the exclusionary scope of the challenged patent.

The court upheld the reverse payment settlement for three reasons: (1) the settlement did not restrict the generic from marketing products that did not violate the patent; (2) a generic version of the drug

would constitute patent infringement; and (3) the reverse payment agreement did not prevent other generic manufacturers from challenging the patent at issue.¹⁹ The court further held that because a patent grants a "lawful monopoly over the manufacture and distribution of the patented product," the reverse payment was not *per se* or otherwise unlawful because patents lawfully confer the right to exclude others from the market.²⁰

In the *Cipro* case,²¹ after filing an ANDA-IV that resulted in patent litigation, the parties entered into a reverse payment settlement, wherein the generic drug manufacturer agreed not to market a generic version of Cipro for 6.5 years, in exchange for almost \$400 million. This sum amounted to substantially more than the amount the generic manufacturer would have earned had it won the patent infringement suit and immediately begun marketing a generic version of the drug.

The reverse payment led to class action antitrust litigations against the parties to the settlement. The district court held that the reverse payment settlement did not violate the Sherman Act. The direct purchaser plaintiffs²² appealed to the Second Circuit, which heard the case in April 2009. In a change of position, the DOJ joined the FTC and each filed an amicus brief arguing that reverse payments should be presumptively unlawful.²³

In April 2010, the Second Circuit affirmed, noting that "absent a change in law by higher authority or by way of an *in banc* proceeding," it was "bound to review the *Cipro* court's rulings under the standard adopted in *Tamoxifen*."²⁴ Significantly, the panel expressed discomfort with its holding and expressly invited the plaintiffs to petition for a rehearing *en banc*. In essence, the panel encouraged the Second Circuit, *en banc*, to overrule *Tamoxifen*. The panel gave five reasons why an *en banc* rehearing would be appropriate.

First, the U.S. itself urged the court to overrule *Tamoxifen*. The DOJ abandoned the Bush Administration's policy that supported reverse payments and filed an amicus brief urging the court

to reject *Tamoxifen* because reverse payments should presumptively be unlawful. Second, reverse payments have substantially increased since *Tamoxifen*. None of the 14 Hatch-Waxman settlements prior to *Tamoxifen* involved reverse payments, whereas the vast majority of post-*Tamoxifen* Hatch-Waxman settlements involve reverse payments. Third, reverse payments conflict with the legislative intent to promote early generic entry. Senator Orrin Hatch (R-Utah) – sponsor of the Hatch-Waxman Act – criticized reverse payments and stated that they run counter to the legislative intent of the Act. He wrote: "As coauthor of the [Act], I can tell you that I find these type[s] of reverse payment collusive arrangements appalling."²⁵ Fourth, the Second Circuit noted that the court in *Tamoxifen* misinterpreted the law and "relied on an erroneous characterization of the Hatch-Waxman Act[s]" statutory 180-day exclusivity period, which may have affected the court's decision.²⁶ Lastly, the court suggested that the case's procedural posture – at the summary judgment stage – made it ripe for *en banc* review, since the court could consider reverse payment settlements with a more complete factual record.

After the Second Circuit invited plaintiffs to seek an *en banc* rehearing, many entities – including the FTC, DOJ, state attorneys general, and numerous consumer groups – filed amicus briefs supporting an *en banc* rehearing and a reversal of the Second Circuit's *Tamoxifen* and *Cipro* decisions. The DOJ suggested that reverse payments protect "undeserved patent monopolies and depriv[e] consumers of potentially enormous savings from the generic competition Congress sought to encourage in enacting the Hatch-Waxman Act."²⁷ The FTC noted that "even 'fatally weak' patents will be able to use exclusion payments to prevent competition," counter to the purposes of the Hatch-Waxman Act.²⁸ The FTC also referred to the "obvious economic sense" it makes for brand-name drug manufacturers to pay generics as much as, or more than, they would make had they entered the market.²⁹ Indeed, such settlements have increased brand-name drug manufacturers' profits, at the expense of consumers, by \$20 billion.³⁰ Notwithstanding the *Cipro* panel's strong criticism

of reverse payments and the *Tamoxifen* decision, on September 7, 2010, the Second Circuit denied *en banc* review. Judge Pooler dissented, and her opinion, describing the current split in circuit court decisions, provides a persuasive roadmap for the *Cipro* plaintiffs' possible *certiorari* petition to the Supreme Court.³¹

Case Law - Sixth Circuit

The Sixth Circuit took a sharply different approach when it first considered reverse payments. In *In re Cardizem CD Antitrust Litigation*, the brand-name manufacturer of Cardizem settled its patent infringement suit with the generic manufacturer by paying the generic a total of \$89.83 million to delay generic entry into the market. The settlement not only included a substantial payment to the generic, but also provided that the generic would not market other, non-infringing products.³² Plaintiffs challenged both the reverse payments and the impact on the drugs not at issue in the patent litigation, as an illegal antitrust violation.³³

The district court denied defendants' dismissal motions and granted plaintiffs' motions for partial summary judgment. On appeal, the Sixth Circuit affirmed – in a decision that predates *Tamoxifen* – holding the reverse payments at issue *per se* illegal. The court was not persuaded by defendants' description of the reverse payment as a lawful attempt to enforce patent rights. Nor was it comfortable with the use of the 180-day exclusivity period to delay the entry of other generics into the market. Ultimately, the court held that the reverse payment agreement was "at its core, a horizontal agreement to eliminate competition," and a "classic example of a *per se* illegal restraint of trade."³⁴

Case Law - Eleventh Circuit

Three months after the Sixth Circuit deemed reverse payments *per se* illegal in *Cardizem*, the Eleventh Circuit faced a similar inquiry in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*³⁵ The court rejected both *per se* and the traditional rule of reason analyses and formulated a new approach.

Under this new standard, formed because patents lawfully create market exclusions that the Sherman Act would otherwise forbid, the court concluded that the reverse payment at issue was permissible.

In *Valley Drug*, after a generic manufacturer sought ANDA-IV approval of the generic version of Hytrin, the brand-name manufacturer filed a patent infringement suit. The parties settled through a reverse payment, prompting purchasers to sue both the generic and brand-name manufacturers, alleging that, under *Cardizem*, the reverse payment was *per se* illegal.

The district court granted plaintiffs' motion for summary judgment, invalidating the settlements as illegal market allocation agreements and rejecting defendants' arguments that the agreements were pro-competitive.

On appeal, the Eleventh Circuit reversed. It rejected a *per se* analysis, noting its concerns that *per se* illegality would undermine incentives to innovate and counter incentives to settle.³⁶ Additionally, the court rejected a traditional rule of reason analysis, because an inquiry into whether challenged conduct has an anticompetitive effect on a product market is insufficient where a patent, by its nature, excludes competition.³⁷

Applying an "exhaustive factual inquiry,"³⁸ the court analyzed three factors to determine antitrust liability: (1) the patent holder's right to exclude; (2) the extent to which the reverse payment exceeds the scope of the exclusion; and (3) the anticompetitive effects.³⁹ Terms of the agreement that create exclusionary effects beyond the scope of the patent would then be subject to traditional antitrust review. Applying this analysis, the court upheld the reverse payments.

In *Schering-Plough Corp. v. FTC*,⁴⁰ the Eleventh Circuit reiterated its holding in *Valley Drug*, rejecting both the *per se* and traditional rule of reason analyses. The court vacated the FTC's order that the brand-name and generic drug manufacturers of K-Dur cease and desist from its

reverse payment settlement. Citing *Valley Drug*,⁴¹ the court pointed specifically to the exclusionary effect of the agreement and the scope of the patent's protection and determined that the reverse payments did not violate the Sherman Act, because the reverse payments "fell well within the protections of the [patent] and were therefore not illegal."⁴²

Potential Supreme Court And Congressional (In)Action

The current climate permitting reverse payment settlements appears to be changing. Although the Second Circuit denied a rehearing *en banc* in *Cipro*, discomfort with controlling precedent was articulated not only by the Second Circuit panel, but also by the FTC (stating that reverse payments are "bad law and should be reversed")⁴³, DOJ (now siding with the FTC), state attorneys general (stating that reverse payments are "expressly designed to delay and prevent competition")⁴⁴, and numerous consumer groups. In addition, legislation barring reverse payments continues to be proposed in Congress. With billions of dollars per year at stake, the time for change is now.

Judge Pooler's dissent, in essence, spelled out the conflicting decisions among the Second, Sixth, and Eleventh Circuits, and set forth an outline for a writ of *certiorari* to the Supreme Court. Granting *certiorari* in *Cipro* would afford the Supreme Court the opportunity to correct *Tamoxifen*, *Cipro*, *Valley Drug*, *Schering*, and other adverse decisions and to hold, once and for all, that reverse payments are prohibited under the Sherman Act. However, if the Supreme Court does not grant *certiorari*, or if it does and then upholds *Cipro*, legislation would be the only remaining solution.

Recently, by a vote of 46-51, the U.S. Senate was unable to pass amendments to the Emergency Supplemental Appropriations Act. The defeated bill would have amended the FTC Act to grant the FTC authority to initiate proceedings against any party that enters into a reverse payment settlement. Legislators will likely continue to propose bills in

Congress barring reverse payments in order to address the public's concern over rising health care costs. However, their chance of passage is uncertain.

Conclusion

The legislative, executive, and judicial branches' renewed attention to reverse payments, and the growing consensus that reverse payments are anticompetitive, hopefully will cause the Supreme Court to conclude that this critical issue is ripe for review. A bar on reverse payments would significantly benefit consumers and clearly be in the public interest.

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¹ Kaiser Family Foundation, *Prescription Drug Trends* (Sept. 2008), available at http://www.kff.org/rxdrugs/upload/3057_07.pdf; Press Release, IMS Health, *IMS Health Reports U.S. Prescription Sales Grew 5.1 Percent in 2009, to \$300.3 Billion* (Apr. 1, 2010), available at <http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnnextoid=>

d690a27e9d5b7210VgnVCM10000ed152ca2RCRD&vgnextfmt=default.

² 604 F.3d 98 (2d Cir. 2010).

³ 466 F.3d 187 (2d Cir. 2006), cert. denied sub nom. *Joblove v. Barr Labs. Inc.*, 127 S. Ct. 3001 (2007).

⁴ *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, No. 05-2863, 2010 BL 207036 (2d Cir. Sept. 7, 2010).

⁵ Laura J. Grebe, *Generic Entry In A Rough Economy--Proposed Legislation May Ease Health Care Costs*, Marquette Intellectual Property Law Review, 14 Marq. Intell. Prop. L. Rev. 167, 176 (Winter 2010); Steven W. Day, *Leaving Room For Innovation: Rejecting The FTC's Stance Against Reverse Payments In Schering-Plough v. FTC*, Case 57 W. Res. L. Rev. 223, 223 (Fall 2006); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 210.

⁶ Pub. L. No. 98-417, 98 Stat. 1585.

⁷ 21 U.S.C. § 355(j).

⁸ To induce such challenges, the Hatch-Waxman Act makes the first ANDA-IV filer eligible for a 180-day period of marketing exclusivity, during which the generic company would normally earn significant profits. 21 U.S.C. § 355(j)(5)(B)(iv).

⁹ 21 U.S.C. § 355(j).

¹⁰ Amy C. Waltz, *Closing The Deal: Making The Right Congressional Decision About Patent Settlement Agreements*, 5 Ind. Health L. Rev. 155, 181 (2008).

¹¹ Alan Devlin, *Restricting Experimental Use*, Harvard Journal of Law and Public Policy, 32 Harv. J.L. & Pub. Policy 599, 607 n.35 (Spring, 2009); Paul M. Janicke & Lilan Ren, *Who Wins Patent Infringement Cases*, 34 AIPLA Q.J. 1, 5 (Winter, 2006) (approximately 50% of all challenged patents are ultimately found invalid); Jean O. Lanjouw & Mark Schankerman, *Protecting Intellectual Property Rights: Are Small Firms Handicapped?*, 47 J.L. & Econ. 45, 59 (2004) (finding that win rates are close to 50% in patent cases); Patstats, *U.S. Patent Litigation Statistics*, University of Houston Law Center, available at <http://www.patstats.org/2003.html> (in 2003, of 201 validity decisions, the patent was found to be invalid 117 times, 58%); John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998) (study of all patent validity litigation from 1989–1996 found 46% of all patents litigated to judgment held invalid).

¹² *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at vi (July 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

¹³ Federal Trade Commission, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions 2* (Jan. 2010), available at

<http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>. Unsurprisingly, the Pharmaceutical Research and Manufacturers of America has recently released a study that disputes the FTC's conclusion that a ban on reverse payments would expedite generic entry into the market at a significant cost savings to consumers. See Bret Dickey, Jonathan Orszag, & Robert Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse Payment" Settlements*, Pharmaceutical Research and Manufacturers of America (Aug. 10, 2010), available at <http://newsroom.law360.com/articlefiles/186893-Analysis.pdf>.

¹⁴ Brief Amicus Curiae of the United States in Support of Rehearing In [sic] Banc, at 5, *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, No. 05-2851-cv(L) (2d Cir. June 3, 2010).

¹⁵ Prepared Statement of the Federal Trade Commission, Before the United States House of Representatives Committee on the Judiciary Subcommittee on Courts and Competition Policy, Oversight of the Federal Trade Commission Bureau of Competition and the Department of Justice Antitrust Division (July 27, 2010), <http://www.ftc.gov/os/testimony/100727antitrustoversight.pdf>; FTC Testimony: *Stopping "Pay-for-Delay" Drug Settlement Agreements is a Top Competition Priority: New Data Show the Number of Potential Anticompetitive Settlements is on the Rise* (July 27, 2010), <http://www.ftc.gov/opa/2010/07/antitrust.shtm>.

¹⁶ Lianne Dane, *Drugmakers entering into more pay-for-delay deals, FTC chairman says*, (July 28, 2010), available at <http://www.firstwordplus.com/Fws.do?articleid=D895F5678DE84C86848197E6AF356766>.

¹⁷ C. Scott Hemphill, *Paying For Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1561, 1575 (2006); Alden F. Abbott & Suzanne T. Michel, *The Right Balance Of Competition Policy And Intellectual Property Law: A Perspective On Settlements Of Pharmaceutical Patent Litigation*, 867 PLI/Pat 387, 391 (2006)

¹⁸ 466 F.3d at 207, 216.

¹⁹ *Id.* at 213-15.

²⁰ *Id.* at 223.

²¹ 604 F.3d 98 (2d Cir. 2010).

²² The indirect purchasers' case was transferred to the Federal Circuit because of the presence of "Walker Process" claims that more directly involved questions of patent law within the jurisdiction of the Federal Circuit. The Federal Circuit affirmed the lower court's dismissal, and certiorari was denied *In re Ciprofloxacin*

Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), rehearing and rehearing en banc denied (Dec. 23, 2008), cert. denied sub nom. *Ark. Carpenters Health and Welfare Fund, Paper, A.F. of L. v. Bayer AG*, 129 S.Ct. 2828 (2009).

²³ See 604 F.3d at 108.

²⁴ *Id.* at 106, 108.

²⁵ 148 Cong. Rec. S7565-01 (July 30, 2002).

²⁶ 604 F.3d at 109.

²⁷ Brief Amicus Curiae of the United States in Support of Rehearing In [sic] Banc, at 3, *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, No. 05-2851-cv(L) (2d Cir. June 3, 2010).

²⁸ Brief Amicus Curiae of the FTC in Support of Rehearing En Banc, at 2-3, *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, No. 05-2851-cv(L) (2d Cir. May 20, 2010) (internal citation omitted).

²⁹ *Id.* at 2 (internal citation omitted).

³⁰ *Id.* at 4.

³¹ *Ark. Carpenters*, 2010 BL 207036, at *2 (Pooler, J., dissenting).

³² The generic manufacturer's agreement to refrain from marketing non-infringing products has often been cited by those supporting reverse payment settlements as the underlying, distinguishing reason for the *Cardizem* court's holding that the settlement agreement in that case was *per se* unlawful. See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d at 1335.

³³ 332 F.3d 896 (6th Cir. 2003).

³⁴ *Id.* at 908.

³⁵ *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

³⁶ *Id.* at 1308.

³⁷ *Id.* at 1306-07.

³⁸ *Id.* at 1313 n.30.

³⁹ *Id.* at 1301.

⁴⁰ 402 F.3d 1056 (11th Cir. 2005).

⁴¹ *Id.* at 1066.

⁴² *Id.* at 1076.

⁴³ J. Thomas Rosch, Commissioner, FTC, *Prepared Remarks Before the Law Seminars International, Pharmaceutical Antitrust* (Apr. 26, 2007), 6 Health Care and Antitrust L. Appendix E148 (2010).

⁴⁴ Brief of 34 State Attorneys General as Amici Curiae in Support of Petition for Rehearing En Banc, at 2, *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, No. 05-2851-cv(L) (2d Cir. May 20, 2010).