No. 10-

IN THE
Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP, formerly doing business as Miles Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Hatch-Waxman Act provides a pathway and financial incentives for a manufacturer of generic drugs to enter the market by obtaining a judicial determination that the brand drug maker's patent is invalid or not infringed. Brand firms can prevent or delay generic entry by paying the generics to forgo judicial review of the patents. In the case below, the Second Circuit held that, absent fraud on the patent office or sham litigation, such payments do not violate the Sherman Act, however weak the patent and even if the agreement delays generic entry until the patent expires.

The question presented is whether, absent patent fraud or sham litigation, a brand drug maker's substantial payment to a competing generic drug maker to forgo judicial testing of the patent and restrict entry is per se lawful under the Sherman Act.

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 14.1(b), Petitioners state that all parties to the proceedings below appear in the caption of the case on the cover page.[1]

Pursuant to Supreme Court Rule 29.6, Petitioners state that Petitioner Louisiana Wholesale Drug Company, Inc. does not have a parent corporation and no publicly held corporation owns 10% or more of its stock. Petitioner CVS Pharmacy, Inc. is a wholly-owned subsidiary of CVS Caremark Corporation, a publicly traded corporation. No publicly held corporation owns 10% or more of CVS Caremark Corporation's stock. Petitioner Rite Aid Corporation is a publicly traded corporation. The Jean Coutu Group (PJC), Inc. is the only publicly held corporation that owns 10% or more of Rite Aid Corporation's stock. Petitioner Arthur's Drug Store, Inc. does not have a parent corporation and no publicly held corporation owns 10% or more of its stock.

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1. The Second Circuit transferred one of three consolidated appeals, 05-2863, to the Federal Circuit on November 7, 2007. Although the transferred appellants remained in the Second Circuit caption, they were not parties to the Second Circuit appeal at the time the decision was rendered. The transferred appellants were Arkansas Carpenters Health and Welfare Fund, Maria Locurto, Paper, Allied-Indus, United Food and Commercial Workers Union-Employer, Sol Lubin, Ann Stuart and Linda K. McIntrye.

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The opinion of the court of appeals (Pet. App. 9a-35a) is reported at 604 F.3d 98. The denial of the rehearing en banc (Pet. App. 1a-8a) is not yet published but is electronically reported at 2010 WL 3464382. The district court's order granting Respondents' summary judgment motions (Pet. App. 36a-110a) is reported at 363 F. Supp. 2d 514.

JURISDICTION

The judgment of the court of appeals was entered on April 29, 2010. Rehearing en banc was denied on September 7, 2010. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant portions of the Sherman Antitrust Act, 15 U.S.C. § 1; Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §§ 355, 360cc, 35 U.S.C. §§ 156, 271, 282) (the "Hatch-Waxman Act" or the "Act"); the Patent Act, 35 U.S.C. §§ 1 et seq.; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003) (the "Medicare Modernization Act"), are set out in an appendix to this petition.

INTRODUCTION

This case involves one of the most controversial business practices in the United States in one of the most important segments of our economy. Makers of branded pharmaceuticals are today routinely — 15 to 20 agreements every year — paying generic drug manufacturers not to challenge the validity of pharmaceutical patents and to delay entering the market. These agreements are annually costing consumers and taxpayers billions of dollars.

This Court has repeatedly "emphasiz[ed] the necessity of protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid." *Edward Katzinger Co. v. Chicago Metallic Mfg. Co.,* 329 U.S. 394, 400 (1947). The Second Circuit nevertheless held, contrary to the decisions of three other circuits and the views of the United States and the Federal Trade Commission, that, except in very limited circumstances, a pharmaceutical patentee may lawfully pay a generic drug manufacturer to forgo judicial testing of the patent's validity and stay out of the market. The Second Circuit's decision cannot be squared with those of other circuits or with this Court's prohibition on patentees "muzzling" those who otherwise would have an "economic incentive to challenge the patentability of an inventor's discovery." *Lear, Inc. v. Adkins,* 395 U.S. 653, 670 (1969).

This issue has repeatedly arisen, and continues to arise, in the context of patent litigation under the Hatch-Waxman Act. The Act was intended to promote

consumer welfare by balancing incentives for brand manufacturers to innovate against protections for consumers from unwarranted patent-based monopolies. The Act extends the effective term of pharmaceutical patents, but provides a financial incentive and streamlined procedures for manufacturers of generic drugs to enter the market by contesting patent validity or infringement in court. *See, e.g.*, 21 U.S.C. §§ 355(j)(2), 355(j)(5)(B)(iv). The Act relies on judicial testing in patent litigation to ensure that monopolies created by the extended patents are legitimate and thus in fact promote consumer welfare.

The increased patent litigation prompted by the Act revealed that many patent-based monopolies in the pharmaceutical industry are not in fact warranted. From 1992 to 2001 generics won 73% of the Hatch-Waxman cases litigated to conclusion. Pet. App. 31a n.7. With huge sums at stake, however, brand manufacturers began paying generics to concede patent validity and infringement and to waive or delay entry into the market. These payoffs from the brand to the generic have been referred to as "reverse payments," because they are cash payments from the plaintiff in the infringement action to the defendant, or as "exclusion payments" or "pay-for-delay payments" because they are made in exchange for forgoing judicial examination and restricting market entry.

In the late 1990s, the FTC obtained several consent decrees against manufacturers that had paid or accepted exclusion payments. The first courts of appeals to rule on the issue concluded that the payments are anticompetitive, explaining that the brand will pay the

generic only if the patent is otherwise not likely strong enough on its own to prevent the generic from entering the market: if the patent were strong enough to prevent entry, the brand "would not have paid [the generic] $89 million to effect what the patent and infringement suit had already accomplished." *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 915 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004); *see also Andrx Pharm. Inc. v. Biovail Corp. Int'l,* 256 F.3d 799, 809 (D.C. Cir. 2001) (same), *cert. denied*, 535 U.S. 931 (2002).

In the early 2000s, Congress considered legislation to prohibit exclusion payments, but stayed its hand after pharmaceutical industry representatives testified that remedial legislation was unnecessary because exclusion payment settlements "would have been violations of the antitrust laws and/or the patent laws whether the Hatch-Waxman Act existed or not." *See* Pet. App. 4a & n.4. Congress therefore solved the problem of exclusion payments — or so it thought — by amending the Act in 2003 to require manufacturers to report exclusion payment agreements to the FTC and the Department of Justice (*see* Medicare Modernization Act, Title XI, Subtitle B, §1112) so that the agencies could "do[] the right thing in taking enforcement actions against those who enter into anti-competitive agreements that violate our Nation's antitrust laws." 148 Cong. Rec. S7348 (daily ed. July 25, 2002) (remarks of Sen. Hatch).

After Congress acted, however, the circuits became fractured on the standard for antitrust plaintiffs to prove that exclusion payments are anticompetitive, with courts affording the agreements increasingly lenient

antitrust treatment. The D.C. Circuit, Sixth Circuit, and the FTC had all concluded that the fact that the brand paid the generic was itself strong economic evidence that the payment resulted in less competition than the litigants themselves believed was likely to result from the patent litigation — otherwise, the brand would not have made the payment. The circuit split first developed when the Eleventh Circuit ruled that the lawfulness of an exclusion payment is determined by relitigating the patent issues as part of the antitrust case. *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004). The current three-way split occurred when a panel majority of the Second Circuit relied on the Patent Act's rebuttable presumption of patent validity (35 U.S.C. § 282) to conclude that, absent proof that the patent was obtained by fraud or the patent suit was a sham, the court analyzing the antitrust claim must conclusively presume that the brand manufacturer would have won the underlying patent litigation, and therefore that the exclusion payment was not anticompetitive. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006), *cert. denied sub nom. Joblove v. Barr Labs, Inc.*, 551 U.S. 1144 (2007).

The *Tamoxifen* panel acknowledged that, if exclusion payments are permissible, brands will use them routinely to protect even "fatally weak" patents. *Id.* at 211. Indeed, after the *Tamoxifen* decision in late 2005, 20 of the next 27 settlements between brands and generics used exclusion payments to restrict generic entry. Pet. App. 33a. By protecting unwarranted patent-based monopolies from judicial review, these exclusion payment settlements have already cost consumers and

taxpayers more than $12 billion, and threaten to cost another $3.5 billion annually. Pet. App. 5a & n.6.

In the present case, the brand paid the generic $398 million to acknowledge patent validity and stay out of the market for all but six months of the remaining seven-year patent term. When the case reached the Second Circuit, the United States, the FTC, 36 State Attorneys General, 86 professors of law or economics, and the major consumer rights organizations filed briefs asserting that the circuit's liability standard is unduly lenient and is causing enormous consumer harm. The Second Circuit panel here unanimously concluded that the circuit's *Tamoxifen* standard should be revisited, but that the panel was nevertheless bound to follow it. Pet. App. 26a, 31a-35a.

The Court should grant review to resolve the circuit split, reject the Second Circuit standard, require compliance with this Court's precedents that favor judicial testing of patent validity, and restore the Hatch-Waxman Act balance by prohibiting brand manufacturers from paying competitors to forgo judicial examination of patents and thereby preserve unwarranted monopolies.

STATEMENT OF THE CASE

Respondent Barr Laboratories submitted a Paragraph IV Certification[1] under the terms of the

1. Such a Certification asserts that the patent on the brand drug "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Hatch-Waxman Act, asserting that the patent on Respondent Bayer Corporation's ("Bayer") best-selling antibiotic, Cipro, was invalid and unenforceable. Pet. App. 40a. In Bayer's ensuing patent suit, its motions for summary judgment were denied and the case was scheduled for trial. *Id.* at 41a. Bayer knew there was a "substantial question" as to the patent's validity, and Barr[2] had additional significant defenses of unenforceability due to inequitable conduct. If Barr won the patent case, the opening of the market to generic competition would have generated enormous savings for consumers. *Id.* at 50a. Bayer estimated that a loss in the patent case and the ensuing price competition would cause it to lose more than $1.6 billion in monopoly profits. *Id.*

Shortly before trial, Bayer and Barr settled. In exchange for Barr's agreement to confess judgment and stay out of the market for all but six months of the remaining patent term, Bayer agreed to pay Barr quarterly payments totaling $398 million. *Id.* at 42a. Alternatively, Bayer had the option to grant Barr a license to enter the market for six of the remaining seven years — a license that would have brought hundreds of millions of dollars in savings to consumers. *See id.* at 42a, 50a. Rather than permit this competition, Bayer elected under the agreement to pay Barr the $398 million, which was roughly one to two times the amount

2. Respondents Hoechst Marion Roussel and the Rugby Group, which was later acquired by Respondent Watson, contracted with Barr to share the patent litigation expenses and any resulting profits from sale of generic Cipro, and were also signatories to the challenged exclusion payment agreement. For convenience, we refer to Barr and HMR/Rugby collectively as "Barr."

Barr would have earned by winning the patent case and competing in the market.

Petitioners, direct purchasers of Cipro, filed claims against Bayer and Barr for money damages, asserting that the exclusion payment agreement violated Section 1 of the Sherman Act.[3] In opposition to Respondents' motions for summary judgment, and in support of their own motions for partial summary judgment, Petitioners offered evidence, under the rule of reason, that the six months of competition that resulted from the $398 million payment was less competition than was likely to have occurred absent the payment. This evidence included:

First, economic evidence that the payment resulted in less competition than Bayer and Barr themselves expected the patent litigation to yield, given their views of the patent's strength. If the exclusion payments did not bring less competition than both Bayer and Barr expected, one or both of them would have chosen to

3. The district court proceedings also included the claims of a putative class of indirect purchasers of Cipro. Those plaintiffs, unlike Petitioners, asserted a claim that Bayer committed fraud in obtaining the patent from the Patent and Trademark Office — a claim that the Second Circuit held "arises under" the patent laws and is thus within the exclusive appellate jurisdiction of the Federal Circuit. The Second Circuit transferred those plaintiffs' appeal to the Federal Circuit while retaining jurisdiction over Petitioners' appeals. Pet. App. 20a. The Federal Circuit affirmed the grant of summary judgment against those plaintiffs. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied sub nom. Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 129 S. Ct. 2828 (2009). *See infra* at 20-21.

litigate rather than settle. *See* Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1758-59 (June 2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. OF ECON. 391, 394-95 (Summer 2003).

Second, this economic evidence was confirmed by the terms of Respondents' agreement, which provided that Bayer must give Barr either $398 million and a license to enter for six months, or a license to enter for six years. These alternative contract terms demonstrate "with unusual clarity" that exclusion payments buy the absence of competition that otherwise would likely have resulted from the patent case. Brief for the United States ("U.S. Br.") at 24 (2d Cir. July 6, 2009).

Third, deposition testimony confirmed that Barr demanded to receive in settlement an "overall value" commensurate with its view of the patent's strength. Barr demanded receipt of this value either through a license allowing it to compete in the market or through cash payments in exchange for not competing. Likewise, Bayer calculated how much to pay Barr based on a detailed expected-value analysis based on the patent's strength.

Petitioners did not — and do not — allege that it is unlawful for patent litigants to settle Hatch-Waxman cases. Litigants routinely and lawfully settle patent cases through licenses that permit the alleged infringer to enter the market before the patent expires. The patentee gauges the patent's strength and offers to give a license for, say, five years of the remaining ten-year term. The alleged infringer also gauges the patent's strength and may accept the five-year license.

These licensed-entry settlements, like exclusion payment settlements, avoid authoritative judicial testing of patents. The former generally do not violate the Sherman Act, however, because judicial testing of patents is not an end in itself, but a means of eliminating unwarranted patent-based monopolies. *See*, *e.g.*, *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971); *Lear*, 395 U.S. at 670. Absent an exclusion payment, settlement via a license eliminates the monopoly to the extent dictated by the patent's strength: competition occurs, and consumers benefit, for a period of time determined solely by the patent litigants' respective views of the patent's strength. Licensed entry, without exclusion payments, thus mirrors the risk-adjusted outcome of the patent litigation. *See* Hovenkamp, *Anticompetitive Settlement*, 87 MINN. L. REV. at 1758-59; Shapiro, *Antitrust Limits*, 34 RAND J. OF ECON. at 397-99.

Exclusion payment settlements are entirely different. If the patent's strength would have dictated, say, a five-year license, the generic will accept instead an exclusion payment that gives it at least five years' worth of forgone profits (or will accept a fig-leaf six month license plus a payment equal to at least 4.5 years' profit). The brand and generic avoid five years of expected competition and divide the eliminated consumer savings between themselves. In contrast, limiting the "coin" of settlement to licensed entry ensures that the generic will agree to stay out of the market for a period of time determined solely by the strength of the patent, and not by receipt of a share of the preserved monopoly profits.

The district court here found "quite powerful" the basic economic fact that "the greater the chance a court would hold the patent invalid, the higher the likelihood that the patentee will seek to salvage a patent by settling with an exclusion payment." Pet. App 77a-78a. The court nevertheless granted Respondents' motions for summary judgment, holding that exclusion payments are lawful under Section 1 of the Sherman Act unless the antitrust claimant proves that the underlying patent was procured by fraud or that the patent litigation was a sham. *Id.* at 79a. This result was "compelled by the presumption of validity Congress accorded patents." *Id.* at 109a. According to the court, the rebuttable presumption of validity gives the patentee "the right to exclude competition entirely for ciprofloxacin for the term of the patent," including the right to pay the alleged infringer to concede validity and stay out of the market. *Id.* at 53a.

While the district court's ruling was on appeal in the Second Circuit, that court decided another exclusion payment case — *Tamoxifen*. A divided panel in *Tamoxifen* relied heavily on the *Cipro* district court's analysis and likewise concluded that exclusion payments are lawful unless the patent was obtained by fraud or the patent claim was a sham. *Tamoxifen,* 466 F.3d at 213. The panel majority acknowledged the "troubling dynamic" of permitting exclusion payments that "inevitably protect patent monopolies that are, perhaps, undeserved," and that, indeed, protect "fatally weak" patents. *Id.* at 211, 212. But, said the majority, the rebuttable presumption of validity requires this result: in paying the generic, the brand is merely "protect[ing] that to which it is presumably entitled." *Id*. at 208.

In this case, a Second Circuit panel affirmed the grant of summary judgment against Petitioners solely because the panel "is bound by *Tamoxifen*." Pet. App. 31a. The panel enumerated "several reasons why this case might be appropriate for reexamination," including the argument that the "*Tamoxifen* standard inappropriately permits patent holders to contract their way out of the statutorily imposed risk that patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract." *Id.* at 31a-32a (quoting U.S. Br. at 14-15). Moreover, permitting patentees to prop up weak patents by shielding them from judicial scrutiny "offers no protection to the public interest in eliminating undeserved patents." *Id.* The panel also acknowledged the argument "that *Tamoxifen* runs afoul of the purpose of the Hatch-Waxman Act" by undermining its "incentive . . . for generic manufacturers to challenge presumptively valid patents." *Id.* at 30a.

Judge Pooler's dissent from the subsequent denial of Petitioners' request for en banc consideration elaborated on the panel's disagreement with *Tamoxifen*.[4] The "presumption of patent validity is simply a procedural device that assigns burdens in litigation challenging the validity of an issued patent. There is no basis for treating that presumption as virtually conclusive and allowing it to serve as a substantive basis

4. The two senior judges on the panel could not participate in deciding whether to grant rehearing en banc, but Judge Pooler reported that "the panel opinion endorses the views expressed in" her dissent from the denial of en banc rehearing. Pet. App. 3a n.1.

to limit the application of the Sherman Act." *Id.* at 6a (quoting U.S. Br. at 6-7). The Second Circuit standard is also "plainly inconsistent with the stated purpose of the Hatch-Waxman Act, which is to encourage patent challenges as a way of increasing consumer access to low-cost drugs." Pet. App. 6a. The standard "unambiguously deserves reexamination," the "'enormous importance' of the issues that this case raises is beyond dispute," and the Supreme Court should "resolve the conflict among the Courts of Appeals." *Id.* at 8a.

REASONS FOR GRANTING THE PETITION

I. The Court Should Grant Review Because the Circuit Courts Are Divided Over the Standard for Evaluating Whether Exclusion Payments Are Anticompetitive.

The circuits are split three ways over the proper standard for determining whether an exclusion payment is anticompetitive. The Sixth and D.C. Circuits hold that the fact that the brand made a payment to the generic is substantial economic evidence that, in the litigants' view, the patent was not strong enough on its own to prevent competition. The Eleventh Circuit determines whether an exclusion payment is anticompetitive by requiring that the patent issues be relitigated as part of the antitrust case. The Second Circuit relies on the rebuttable presumption of patent validity, unless there was fraud on the PTO or sham litigation, to conclude that the patentee would have won the patent case and therefore the exclusion payment is not anticompetitive.

A plaintiff makes a prima facie case of anticompetitive conduct under Section 1 of the Sherman Act by producing evidence that the challenged agreement resulted in less competition than was likely to occur absent the agreement. *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 240-41 (1918). The proper standard for determining whether exclusion payments are anticompetitive — whether they result in less competition than was otherwise likely to occur — must account for three statutory regimes: (1) the Sherman Act, which has long prohibited incumbent manufacturers from paying competitors not to enter a market, including when potential economic or legal barriers make it uncertain whether the competitor would have been successful in entering, *see, e.g., Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 48-49 (1990); XII Hovenkamp, Antitrust Law ¶ 2030b at 213 (2d ed. 2005); (2) the Patent Act, which includes a rebuttable presumption of validity, but depends on judicial review to prevent unwarranted patent-based monopolies, *e.g., Blonder-Tongue Labs*, 402 U.S. at 343; and (3) the Hatch-Waxman Act, which includes a statutory incentive for generics to enter the market by means of contesting patent validity or infringement in court, 21 U.S.C. § 355(j)(5)(B)(iv). The circuit split is over the proper standard, given these statutory mandates, for an antitrust plaintiff to prove that an exclusion payment resulted in less competition than was likely to occur "but for" the payment.

Sixth Circuit/D.C. Circuit/FTC: The Sixth Circuit, D.C. Circuit, and the FTC have adopted the "patent strength" standard, which bases the but-for amount of competition on the patent litigants' own view of the likely outcome of the litigation, as reflected in their objective

conduct. The fact that the generic demanded and the brand agreed to make an exclusion payment is strong economic evidence that, in those litigants' own judgment, the patent was not otherwise strong enough to prevent earlier generic entry. The patent strength standard recognizes that exclusion payments are "naturally viewed as consideration for the generic's agreement to delay entry beyond the point that would otherwise reflect the parties' shared view of the likelihood that the patentee would ultimately prevail in the litigation." U.S. Br. at 22.

In *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), the court applied the patent strength standard where the brand paid the generic to stay out of the market pending resolution of the patent litigation (the Hatch-Waxman Act automatic 30-month stay of generic entry, 21 U.S.C. § 355(j)(5)(B)(iii), had expired). Thus, *Cardizem* arose in a different factual context than here — the exclusion payment in *Cardizem* was made in exchange for the generic forgoing judicial testing of the patent in a preliminary injunction proceeding, and staying out of the market until entry of a final and unappealable judgment. But the legal issue is the same — the proper legal standard for determining whether it is anticompetitive for the brand to pay the generic to forgo the relevant judicial examination (preliminary injunction or trial on the merits) and stay out of the market for the relevant period of time (until the case conclusion or for a defined period).

Recognizing that many litigated patents are found to be invalid or not infringed, the Sixth Circuit held that a brand's patent does not create an "'impenetrable' legal

impediment" to generic entry. 332 F.3d at 914. Instead, the generic's analysis of the patent's strength may or may not cause it to "unilaterally, and legally [refrain from] bring[ing] its generic product to a manifestly profitable market." *Id.* at 915. An exclusion payment alters the generic's unilateral calculation based on the patent's strength and results in less competition than otherwise would likely have occurred: if the "independent durability of [HMRI's] patent and the validity of its infringement claim" had been sufficient on their own to exclude the generic from the market, then the brand "would not have paid [Andrx] $89 million to effect what the patent and infringement suit had already accomplished." *Id.* at 915. "[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." *Id.* at 908. The court upheld the grant of partial summary judgment to plaintiffs as to antitrust liability, concluding that the anticompetitive consequences of the payment were so clear that they not only satisfied plaintiffs' prima facie case, but rendered the agreement per se unlawful. *Id.*

Considering the same agreement that was at issue in *Cardizem,* the D.C. Circuit had earlier also relied on the patent strength standard in reversing the dismissal of the antitrust claims of another generic competitor whose entry was blocked by the HMRI/Andrx agreement. *Andrx Pharm.,* 256 F.3d at 799. The court held that the agreement caused antitrust injury — injury of the type the antitrust laws are designed to prevent — because:

> HMRI's ten million dollar quarterly payments were presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic. Andrx's argument that any rational actor would wait for resolution of the patent infringement suit [before entering the market] is belied by the *quid* of HMRI's *quo*.

Id. at 813. An exclusion payment thus "harms consumers by slowing the introduction of lower priced products into the market and thwarts the intent of the Hatch-Waxman Amendments." *Id.* (quoting 54 Fed. Reg. 42,873, 42,882-83).

The FTC applied the same standard in an administrative proceeding in *In re Schering-Plough Corp.*, F.T.C. Docket No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003), *rev'd, Schering-Plough Corp. v. Federal Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006). Evaluating an exclusion payment made in exchange for forgoing a final judicial decision on the merits, the FTC held that, "it is reasonable to assume that an agreed-on entry date [in an entry-license settlement], without cash payments, reflects a compromise of differing litigation expectations." *Id.* at 14. The fact that the patentee made a payment is economic evidence that the agreement resulted in less competition than the litigants themselves expected: "[i]f there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the

generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *Id.* Accordingly, evidence that the brand made a significant payment satisfied plaintiff's initial burden under the rule of reason. *Id.* at 15.

Eleventh Circuit: The Eleventh Circuit has expressly rejected the patent strength standard applied by the Sixth and D.C. Circuits and the FTC. *Valley Drug*, 344 F.3d at 1310. Instead, it determines the amount of but-for competition by engaging in an *ex-post* judicial determination of the patent issues as part of the antitrust case. *Id.* at 1312.

In *Valley Drug,* as in *Cardizem,* the 30-month stay had expired and the brand paid the generics to stay out of the market pending resolution of the patent case. The Eleventh Circuit held that antitrust analysis of exclusion payments requires "an identification of the protection afforded by the patents and the relevant law and consideration of the extent to which the Agreements reflect a reasonable implementation of these." *Id.* To determine whether it was anticompetitive for the brand to pay the generic not to try to enter the market before resolution of the patent case, "the provisions of this Agreement should be compared to the protections afforded by the preliminary injunction and stay mechanisms and considered in light of the likelihood of [the brand's] obtaining such protections. *Cf.* Hovenkamp at § 2046 ('some care must be taken to ensure that . . . the settlement . . . is not more anticompetitive than a likely outcome of the litigation')." 344 F.3d at 1312. On remand, the district court conducted an exhaustive analysis of the merits of the underlying patent case and

found the exclusion payments unlawful because "[t]he chance that the '207 patent would be held valid — an essential part of the equation for defining the legitimate exclusionary value of the patent — was not high as of [the date of the Agreement]." *In re Terazosin Hydrochloride Antitrust Litig.,* 352 F. Supp. 2d 1279, 1298 (S.D. Fla. 2005).

The Eleventh Circuit subsequently reaffirmed this "patent relitigation" approach and applied it to an exclusion payment made in exchange for forgoing final adjudication of the patent. *Schering-Plough Corp. v. Federal Trade Comm'n,* 402 F.3d 1056, 1076 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006). In *Schering*, which was the appeal from the FTC's order finding the Schering-Upsher agreement unlawful under the patent strength standard, the court faulted the FTC for relying on *ex ante* economic evidence of the patent's strength rather than conducting an *ex post* judicial evaluation. According to the court, the FTC, "cavalierly dismissed our holding in *Valley Drug*, stating that [an *ex-post* judicial] determination on the merits of the underlying patent dispute was 'not supported by law or logic.'" *Id.* at 1068 n.18.[5] The court reaffirmed that the but-for amount of competition should be determined by an *ex-post* judicial determination of the patent issues: "a settlement cannot [lawfully] be more anticompetitive than litigation." *Id.* at 1075. "*Valley Drug* established the law in our Circuit. . . . This alone underscores the

5. Relying on the patent strength standard, the FTC complaint counsel had argued that relitigating the merits of the patent case was unnecessary, and so had offered no independent evidence that the patent was invalid or not infringed.

need [for the court in the antitrust case] to evaluate the strength of the patent." *Id.* at 1076.[6]

The Eleventh Circuit's standard is subject to criticism because of the potential complexity and inefficiency of relitigating patent issues in an antitrust case. Moreover, deferring the patent issues into the antitrust case is likely to result in a significant temporal extension of the monopoly — the appeal of the FTC's order against the Schering-Upsher agreement was not concluded until nine years after execution of the agreement, and private antitrust claims over the agreement are still pending. Equally troubling, the generics, which have expertise in challenging pharmaceutical patents, switch sides in the antitrust case: Upsher asserted in the patent case that Schering's infringement claim was so weak as to constitute a sham, then joined with Schering in the antitrust case to argue that the infringement claim was not a sham. *See In re K-Dur Antitrust Litig.,* No. 01-1652, 2009 WL 508869, at *30 (D.N.J. Feb. 6, 2009).

Second and Federal Circuits: The Second and Federal Circuits have expressly rejected the Sixth/D.C. Circuit patent strength standard and have refused to apply the Eleventh Circuit's relitigation standard. *See Tamoxifen*, 466 F.3d at 203-04, 213; *Ciprofloxacin*, 544 F.3d at 1337. They have instead conclusively presumed for purposes of the antitrust case that the patent was valid, and thus that no competition was likely to result

6. The Eleventh Circuit also reversed, on the record before it, the FTC's factual finding that the brand had made a payment to the generic. *Schering-Plough Corp.,* 402 F.3d at 1071.

from the patent litigation, unless the patent was obtained by fraud or the patent claim was a sham.

As noted above, the panel majority in *Tamoxifen* concluded that this sham litigation standard is required by the rebuttable presumption of patent validity. *Tamoxifen,* 466 F.3d at 213. The Second Circuit panel here unanimously disagreed with that conclusion but felt bound to adhere to *Tamoxifen.*

The Federal Circuit considered the same agreement at issue here, at the behest of indirect purchasers of Cipro whose appeal was transferred to that circuit.[7] The Federal Circuit concluded it was required to decide the case "[u]nder the law of the Second Circuit." *Ciprofloxacin*, 544 F.3d at 1332. The court held that the rebuttable presumption of validity required adoption of the sham litigation standard, reasoning that, "[a] settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled — a monopoly over the manufacture and distribution of the patented invention. *In re Tamoxifen,* 466 F.3d at 208-09." *Ciprofloxacin,* 544 F.3d at 1337.[8]

The sham litigation standard is legally and factually insupportable. This Court has endorsed such a lenient antitrust standard only for a monopolist's unilateral, constitutionally protected conduct in petitioning the government to restrain competition. *See infra* at 32. That standard is wholly inappropriate for judging

7. *See supra* footnote 3.

8. We discuss *infra* at 33 the circumstances in which this Court declined to review the Federal Circuit's decision.

erstwhile competitors' joint conduct in withdrawing a patent dispute from judicial oversight and restraining competition by private agreement.

The sham litigation standard also ignores the commercial reality that, despite the rebuttable presumption of validity, nearly half of all litigated patents are found invalid, John R. Allison and Mark Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q. J. 185, 206 (1998), and that generics have won 73% of Hatch-Waxman cases, Pet. App. 31a n.17. Under the sham litigation standard, a patentee with merely a colorable claim, with, say, an 80% chance of *losing*, may lawfully pay the generic a share of the monopoly profits in exchange for staying out of the market. *Cf. Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466-67 (1992) ("[l]egal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law"). The rebuttable presumption of validity was designed merely to allocate burdens of proof in a patent litigation that determines *whether* the patent-based monopoly is legitimate, not to authorize the patentee to pay to prevent judicial review and thereby preserve the monopoly *regardless* of its legitimacy. As Judge Pooler noted:

> [E]ven though we are required to presume that Bayer's patent is valid, . . . "[t]he presumption of patent validity is simply a procedural device that assigns burdens in litigation challenging the validity of an issued patent. There is no basis for treating that presumption as virtually conclusive and

> allowing it to serve as a substantive basis to limit the application of the Sherman Act."

Pet. App. 6a (quoting U.S. Br. at 6-7). If upheld, the sham litigation standard "would essentially afford pioneer drug manufacturers an unbridled power to exclude others without regard to the strength of their patent rights." *Terazosin,* 352 F. Supp. 2d at 1298.

The Second Circuit's sham litigation standard conflicts with the patent relitigation standard of the Eleventh Circuit and with the patent strength standard of the Sixth and D.C. Circuits and the FTC. Under the sham litigation standard, exclusion payments are nearly per se lawful; under the patent strength standard, the fact that the brand made an exclusion payment is, at a minimum, sufficient evidence to satisfy the antitrust plaintiff's initial burden under the rule of reason, and, under the Sixth Circuit approach, renders the agreement per se unlawful. Shunning both of these standards, the Eleventh Circuit requires the patent issues to be litigated anew as part of the antitrust case. The conflict between the circuits is clear and wide.

II. The Court Should Grant Review Because the Second Circuit's Standard Conflicts with This Court's Precedents.

The Second Circuit has elevated the rebuttable presumption of validity into an ironclad right of patentees to exclude competition — a right enforceable by paying generics to forgo judicial examination of patent validity and stay out of the market. The Second Circuit's newly created right conflicts with two lines of this Court's cases.

Conflict With the Court's Patent Cases. The Second Circuit standard conflicts with this Court's patent cases, which emphasize that a patentee's right to exclude competitors is limited and qualified, and that "[i]t 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." *United States v. Glaxo Group Ltd.,* 410 U.S. 52, 58 (1973) (citation omitted). "A patent by its very nature is affected with a public interest" because of its potentially "far-reaching social and economic consequences." *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.,* 324 U.S. 806, 816 (1945). Consequently, the alleged infringer's right to challenge the patent's validity in court "is not only a private right to the individual, but it is founded on public policy, which is promoted by his making the defense, and contravened by his refusal to make it." *Edward Katzinger Co.,* 329 U.S. at 401 (citation omitted).

The Second Circuit asserted that it had safeguarded the public interest by limiting the exclusion effected by the brand's payments to the subject matter and temporal scope of the patent, assuming that the patent is valid. *Tamoxifen*, 466 F.3d at 213-14. But under this Court's precedents, the requirement that exclusion not exceed the subject matter or temporal scope of the patent is just "one obvious manifestation" of the public interest in patents. *Blonder-Tongue Labs,* 402 U.S. at 343. The Second Circuit ignored a second aspect of this interest — "[a] second group of authorities [that] encourage authoritative testing of patent validity." *Id.*

at 344.[9] Although patents carry a rebuttable presumption of validity, "Congress has from the outset chosen to impose broad criteria of patentability while lodging in the federal courts final authority to decide that question." *Id.* at 332.

Accordingly, this Court has repeatedly emphasized that judicial testing of patent validity is essential precisely because the issuance of a patent by the PTO was not intended to have — and does not have — the conclusive significance accorded by the Second Circuit:

> A patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office. Moreover, the legal conclusion is predicated on factors as to which reasonable men can differ widely. Yet the Patent Office is often obliged to reach its decision in an *ex parte* proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity.

Lear, 395 U.S. at 670.

This Court has held, for example, that requiring patent licensees to continue paying royalties as a prerequisite to challenging patent validity would

9. We again note that this does not mean that litigants should be precluded from settling Hatch-Waxman patent cases. The purpose of judicial testing of patent validity is to protect consumers from unwarranted patent-based monopolies. Licensed entry settlements, unlike exclusion payment settlements, eliminate monopolies — and benefit consumers — to the extent dictated by the strength of the patent. *See supra* at 10.

impermissibly "muzzle[]" those who otherwise have an "economic incentive to challenge the patentability of an inventor's discovery." *Id.*; *see also Medimmune, Inc. v. Genentech, Inc.,* 549 U.S. 118 (2007) (federal courts have jurisdiction to decide patent validity even when parties are complying with license terms). Permitting brands to simply pay generics to forgo judicial testing of patents is the antithesis of "protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid." *Edward Katzinger Co.*, 329 U.S. at 400.

This Court also held that it is "inconsistent with the aims of federal patent policy" to permit patentees to "postpone the day of final judicial reckoning." *Lear*, 395 U.S. at 673; *see also Cardinal Chem. Co. v. Morton Int'l Inc.,* 508 U.S. 83, 101 n.24, 102 (1993) (prohibiting practice of vacating declaratory judgments of invalidity because it improperly "multipl[ies] the opportunities for holders of invalid patents" to try to enforce them and "prolongs the life of invalid patents"). Permitting the brand to pay the first generic challenger to forgo judicial review delays challenges by other generics. "The regulatory scheme for pharmaceutical patents [*i.e.*, the 30-month Hatch-Waxman stay of generic entry] means that by settling with an ANDA filer, a patent owner can delay entry by any other generic for three years or more." Herbert Hovenkamp, et al., IP And Antitrust, §15.3 at 15-45 (2d ed. 2010). For example, here subsequent challengers to the Bayer patent did not even get to the summary judgment stage until over four years after the Bayer/Barr trial was to have begun. *See Bayer AG v. Schein Pharm., Inc.,* 129 F. Supp. 2d 705 (D.N.J. 2001), *aff'd*, 301 F.3d 1306 (Fed. Cir. 2002). And as is often

the case, this not only delayed, but also reduced the potency of, those subsequent challenges. Given the imminent expiration of the Bayer patent, the delayed subsequent challengers waived all fact-intensive defenses to Bayer's patent, with the result that the best defenses that Barr intended to pursue at trial have never been litigated. *See* Plaintiffs-Appellants' Brief at 15 (2d. Cir. May 5, 2008). *See also Tamoxifen*, 466 F.3d at 194 (exclusion payment settlement was contingent on vacatur of district court judgment finding patent invalid). The Second Circuit standard permits the patentee to buy multiple opportunities and to unfairly tilt the litigation landscape in the very ways this Court has condemned as against public policy.

The Second Circuit standard also disregards this Court's critical distinction between a patentee's substantive right to exclude competition and the limited, qualified remedies available to the patentee to enforce that right. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392 (2006). The Court held that even after a final judgment finding infringement, the patentee is not automatically entitled to exclude the adjudged infringer, but instead must satisfy the traditional requirements for equitable relief. *Id.* at 392-93. Under *eBay,* even a patent judicially tested and found valid and infringed may not merit excluding competition; under the Second Circuit standard, wholly untested, exceedingly weak patents — all except those whose attempted enforcement would constitute a sham — merit excluding competition.

The Second Circuit standard is even less supportable when considered in light of the Hatch-

Waxman Act's statutory incentives for generics to enter the market through patent challenges. The Act provides that the first generic that challenges the patent can receive 180 days as the exclusive generic version of that product on the market. 21 U.S.C. § 355(j)(5)(B)(iv). This reward is valuable to the generic only if it enters the market and sells a low-price product to consumers. The statutory incentive was designed to bring consumer savings through generic entry, not to enrich generic firms that accept payments to forgo entry.

The Hatch-Waxman Act also precludes any notion that unreviewed patents grant an ironclad right to exclude competitors. The Act gives patentees a procedure to obtain automatic exclusion of generics — without the need to satisfy the criteria for a preliminary injunction — for up to 30 months.[10] After 30 months, however, the FDA is free to approve a generic drug for

10. The Second Circuit seemed to suggest that the Act's 30-month stay provision somehow makes exclusion payments "natural" because it prevents the generic from entering the market and amassing potential liability for infringement damages that the brand could use as a bargaining chip in settlement negotiations. *Tamoxifen,* 466 F.3d at 206-07. The idea seems to be that this reduced settlement leverage makes exclusion payments the only viable means of settling the case. But the Act does not require the brand to invoke the 30-month stay; the brand may instead renounce the stay and then try to collect damages for infringement. 35 U.S.C. § 271(a). Even when brands relinquish some settlement leverage in exchange for 30-month stays, the patent cases still can be settled without exclusion payments, and thus they "serve no obvious redeeming social purpose." Pet. App. 5a. The cases can be settled – and, until *Tamoxifen*, routinely were settled — through early-entry licenses. *See id.* at 33a.

marketing regardless of ongoing patent litigation and despite the rebuttable presumption of validity. *See* 21 U.S.C. § 355(j)(5)(B)(iii). After the 30 months, the patentee can obtain exclusion only by obtaining a preliminary injunction — a proceeding in which "the *patentee* carries the burden of showing likelihood of success on the merits with respect to the patent's validity." *Nutrition 21 v. United States,* 930 F.2d 867, 869 (Fed. Cir. 1991). Yet the Second Circuit relies on the rebuttable presumption of validity to justify the brand's obtaining the equivalent of an automatic, unreviewed, post-30-month permanent injunction through the expedient of sharing some of the monopoly profits with the generic.

Exclusion payments are plainly antithetical to the core purpose of the Act:

> [T]hrough the [Hatch-Waxman] Amendments, "Congress sought to get generic drugs into the hands of patients at reasonable prices — fast." We disagree with Andrx that "its conduct was not only permitted under but clearly contemplated by the Hatch-Waxman" Amendments. Although it is true that the first to file an ANDA is permitted to delay marketing as long as it likes, the statutory scheme does not envision the first applicant's agreeing with the patent holder of the pioneer drug to delay [entry].

Andrx Pharm., 256 F.3d at 809 (citations omitted); *see also Mova Pharm. Corp. v. Shalala,* 140 F.3d 1060, 1067 (D.C. Cir. 1998) (collusion between brand and generic

manufacturers is "at odds with Congress's apparent purposes, in enacting [the Act], of rewarding innovation and bringing generic drugs to market quickly").[11]

This Court has repeatedly emphasized the policy in favor of judicial examination of patent validity as a means of protecting consumers from unwarranted patent-based monopolies. The Hatch-Waxman Act specifically incentivized patent challenges in this sector of the economy where unwarranted monopolies cause grievous consumer harm. The Second Circuit standard allows patentees to countermand the statutory incentive and buy a shield from judicial examination of the legitimacy of their patents.

Conflict With the Court's Antitrust Cases. The Second Circuit standard also violates this Court's fundamental antitrust principles. For more than a century, this Court has held that it is anticompetitive for a firm to pay a competitor to exit or stay out of the market. *See*, *e.g.*, *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 293-94 (6th Cir. 1898), *aff'd*, 175 U.S. 211 (1899); *United States v. Topco Assocs., Inc.*, 405 U.S.

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11. *See also Terazosin,* 352 F. Supp. 2d at 1298 (sham litigation standard "would give the patent holder rights beyond those granted by the Patent Act, and beyond the structure contained in the Hatch-Waxman Act"); C. Scott Hemphill, *Paying For Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1614-16 (2006) ("The Hatch-Waxman Act's calibration between innovation and competition is disrupted if firms are free to engage in self-help. The resulting disruption is difficult to square with the policies that animate the Hatch-Waxman Act. . . .").

596, 608-09 (1972). Paying competitors not to enter is anticompetitive even when potential entry barriers — whether economic or legal — make it uncertain whether the competitor's attempt to enter would have succeeded. *See*, *e.g.*, *Palmer*, 498 U.S. at 48-49; *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc); XII Hovenkamp, ANTITRUST LAW ¶ 2030b at 213 (2d ed. 2005). "Such agreements are anticompetitive regardless of whether the parties split a market within which both [currently] do business. . . ." *Palmer*, 498 U.S. at 49.

A patent is a potential entry barrier, and this Court has never afforded patentees antitrust immunity for paying competitors not to try to overcome them. The Second Circuit derived its patent fraud/sham litigation standard from this Court's decisions in *Walker Process Equip., Inc. v. Ford Mach. & Chem. Corp.*, 382 U.S. 172, 175-77 (1965), and *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993). But those cases provide the standard for imposing antitrust liability on a monopolist's constitutionally protected conduct in petitioning the government to restrain competition by granting and enforcing a patent. An exclusion payment settlement withdraws such a petition from the government and instead restrains competition by private treaty. This private conduct enjoys no immunity warranting such a lenient antitrust standard. *See, e.g., Federal Trade Comm'n v. Superior Court Trial Lawyers Ass'n,* 493 U.S. 411, 424-25 (1990) (immunity applies only when "the alleged restraint of trade [is] the intended consequence of public action"). A patentee that makes exclusion payments helps itself to guaranteed exclusion that government procedures simply do not provide:

> What the pharmaceutical patentees who agree to exclusion payments seek is something more [than the legitimate exclusionary power of the patent] — a guaranteed insulation from competition, without the risk that the patent is held invalid. IP policy does not offer such a guarantee, and does not immunize from antitrust scrutiny those who seek it by entering into agreements that exclude potential competitors.

Hovenkamp, *Anticompetitive Settlements,* 87 MINN. L. REV. at 1761-62.

Moreover, *Walker Process* and *PRE* provide the standards for imposing antitrust liability on a defendant's *unilateral* conduct in obtaining and enforcing a patent. But making and accepting an exclusion payment is collusive, not unilateral; it combines the economic interests of two competitors whose unilateral interests were previously to affirm, and to deny, respectively, the patent's validity. This Court's precedents apply significantly more stringent antitrust standards to collusive than to unilateral conduct. *See, e.g., Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984); *accord United States v. Singer Mfg. Co.*, 374 U.S. 174, 199-200 (1963) (White, J., concurring) (settlement of patent interference was unlawful because it was not "purely unilateral action" but instead reflected "collusion among applicants to prevent prior art from coming to or being drawn to the [PTO's] attention"). The Second Circuit standard would impose antitrust liability on exclusion payment agreements only when the patentee's request that the government restrain

competition would itself be unlawful under Section 2 of the Sherman Act; the standard accords no independent antitrust significance to a patentee's payment to a competitor to forgo having a court decide whether the patent meets the statutory requirements and whether restraining competition is in the public interest.

III. The Court Should Grant Review Because This Case Is the Right Vehicle to Resolve This Recurring Issue of Enormous Public Importance.

This case is the right vehicle for the Court to resolve the circuit split and require compliance with the Court's antitrust and patent precedents. The Court has previously denied certiorari in a number of exclusion payment cases. This case, however, does not suffer from any of the procedural impediments that may have counseled against using those prior cases to resolve these issues whose "'enormous importance' . . . is beyond dispute." Pet. App. 8a.

In both *Tamoxifen* and the Federal Circuit's decision in *Ciprofloxacin*, the petitioners were indirect purchasers who could not recover damages under federal antitrust law, *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), and whose federal claims for injunctive relief had been rendered moot by the expiration of the patents. Brief for the United States as Amicus Curiae, *Joblove v. Barr Labs., Inc.*, No. 06-830 at 17 (S. Ct. May 2007) (advising Court that petitioners' claims were moot); Brief for Bayer, *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, No. 08-1194 at 18 (S. Ct. May 22, 2009) (same). Petitioners here have live federal antitrust claims for damages.

When the Eleventh Circuit's adoption of the patent relitigation standard first caused the circuit split, the United States recommended against review because of, *inter alia*, a threshold factual dispute in that case as to whether the brand had made any payment to the generic. Brief for the United States as Amicus Curiae, *Federal Trade Comm'n v. Schering-Plough Corp.*, No. 05-273 (S. Ct. May 2006).[12] The brand had agreed to pay royalties to the generic ostensibly for use of some of its technology, and the threshold issue was whether this was an above-market-price agreement that was in reality a disguised exclusion payment, or was instead a bona fide royalty agreement. *Id*. at 12-13.

A comprehensive analysis of all known exclusion payment settlements has concluded that all recent agreements, unlike the one at issue here, have taken the form of a disguised payment from the brand to the generic, similar to the one used in *Schering.* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 649 (2009). Thus, every antitrust case premised on those exclusion payments will present a threshold factual question of whether the brand made a payment to the generic. *See, e.g., In re Androgel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1375 (N.D. Ga. 2010) (alleging disguised payment

12. The United States also disagreed with the FTC on the merits of that case. U.S. Br., *Schering-Plough Corp.,* No. 05-273 at 11-12. In contrast, the United States has consistently argued that the Second Circuit standard is "incorrect" and "insufficiently stringent." U.S. Br., *Joblove*, No. 06-830 at 1, 8; *see also* U.S. Br. at 6 (quoting *Tamoxifen,* 466 F.3d at 224 (Pooler, J., dissenting)).

in form of above-market-price contract); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d. 514, 522-23 (E.D. Pa. 2010) (same); *K-Dur*, 2009 WL 508869 at *7 (same).

The problem of exclusion payments and the proper liability standard is not abating — manufacturers used at least forty exclusion payment agreements to restrict generic entry in the last two years. This case provides the Court with its best opportunity to resolve the circuit split over the appropriate legal standard without having to address it in the context of a factual dispute as to whether a complex commercial arrangement between the brand and generic is actually a disguised exclusion payment. Hemphill, *An Aggregate Approach to Antitrust*, 109 Colum. L. Rev. at 663.

The question of the proper standard for determining whether an exclusion payment is anticompetitive has been percolating in the courts, and thoroughly debated in academia, for over a decade. The three potential standards that have emerged are reflected in the three-way circuit split. This case presents the best opportunity for the Court to resolve the circuit split, require compliance with the Court's patent and antitrust precedents, and restore the Hatch-Waxman Act balance between extending pharmaceutical patent terms and preserving judicial review of those patents to ensure that the resulting monopolies are warranted.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DATED SEPTEMBER 7, 2010

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

05-2851-cv(L)
05-2852-cv(CON)
05-2863-cv(CON)*

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 7th day of September, two thousand ten.

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ARKANSAS CARPENTERS HEALTH AND WELFARE FUND, MARIA LOCURTO, PAPER, ALLIED-INDUS, UNITED FOOD AND COMMERCIAL WORKERS UNION-EMPLOYER, LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Plaintiffs-Appellants,

*The appeal docketed under 05-2863-cv has been transferred to the United States Court of Appeals for the Federal Circuit. *See* Nov. 7, 2007 Order.

Appendix A

SOL LUBIN, ANN STUART,
LINDA K. MCINTYRE,

Plaintiffs,

- v.-

BAYER AG, BAYER CORP., formerly doing business as MILES INC., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES INC.,

Defendants-Appellees.

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ORDER

Following disposition of this appeal on April 29, 2010, Plaintiffs-Appellants Louisiana Wholesale Drug Co., Inc.; Arthur's Drug Store, Inc.; CVS Pharmacy, Inc.; and Rite Aid Corporation filed a petition for rehearing *in banc*. An active judge requested a poll on whether to rehear the case *in banc*. A poll having been conducted and there being no majority favoring *in banc* review, rehearing *in banc* is hereby **DENIED**.

Judge Pooler dissents in an opinion.

FOR THE COURT:
CATHERINE O'HAGAN WOLFE, CLERK

Appendix A

ROSEMARY S. POOLER, Circuit Judge, dissenting:[1]

In 1991, Barr Labs sought to market a generic version of ciprofloxacin hydrochloride ("Cipro"). Bayer, which holds the Cipro patent, sued Barr for infringement, lost its motion for summary judgment, and subsequently settled with Barr on the eve of trial. Under the terms of the settlement agreement, Bayer paid Barr nearly $400 million and in exchange Barr agreed not to market a generic version of Cipro during the life of the patent.

The Bayer-Barr settlement agreement was unusual in a number of respects. Most obviously, under the terms of the settlement the *patent holder* agreed to pay the *alleged infringer* to settle the suit in exchange for the alleged infringer's agreement to stay out of the marketplace during the life of the patent. In the industry parlance, this is called a "reverse exclusion payment," or, more evocatively, a "pay-for-delay" settlement.[2]

This type of settlement, once unheard of, has become increasingly common. This Court has played a

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1. Senior Circuit Judges Jon O. Newman and Barrington D. Parker, members of the original panel, are not authorized to participate in the *en banc* poll, but the panel opinion endorses the views expressed in this opinion.

2. *See generally* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553 (2006).

significant role in encouraging this unfortunate practice. In *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), a panel of this Court, over my dissent, held that exclusion payment settlements are lawful unless the branded firm's patent is "shown to have been procured by fraud, or a suit for its enforcement is objectively baseless ..." *Id.* at 213. What followed was a dramatic surge in the practice of pharmaceutical patent holders paying potential competitors to concede the validity of their patents. In the five years before *Tamoxifen* was decided, there were no settlements involving exclusion payments,[3] and even pharmaceutical industry representatives appear to have conceded the illegality of the practice, testifying before Congress that proposed amendments to the Hatch Waxman Act explicitly prohibiting exclusion payment settlements were unnecessary because such settlements "would have been violations of the antitrust laws and/or the patent laws whether the Hatch-Waxman Act existed or not."[4] In the four years since *Tamoxifen*, by contrast, the Federal Trade Commission has identified fifty-three pharmaceutical patent settlements involving exclusion

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3. *See* Jon Leibowitz, Commissioner, Federal Trade Commission, Prepared Statement to the Committee on the Judiciary of the United States Senate: *Anticompetitive Patent Settlements in the Pharmaceutical Industry*, at 13 (Jan. 17, 2007), available at http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf.

4. *See Hearing No. 107-1081 Before S. Comm. On Commerce, Science, and Transportation*, 107th Cong. (Apr. 23, 2002), at 71 (statement of Greg Glover, Pharmaceutical Research and Manufacturers of America).

payments.[5] The Commission estimates that such settlements cost consumers approximately $3.5 billion per year.[6] Further, such settlements serve no obvious redeeming social purpose. Put simply, what the patent holder purchases by means of an exclusion payment settlement is the continuation of a patent the patent holder must have thought had some significant probability of being declared invalid.[7]

Of course, all of this would not be this Court's concern if the Hatch-Waxman Act explicitly permitted exclusion payment settlements. However, the Act is silent on the legality of such settlements, and the Act's sponsors have openly criticized the practice.[8] Further,

5. *See* Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions: An FTC Staff Study*, at 4 (Jan. 2010), available at www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

6. *Id.* at 8; *see also* Br. of the United States, available at http://www.justice.gov/atr/cases/f259300/259325.htm, at 4 (relying on FTC Staff Study). *Cf.* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 650 (2009) (estimating the exclusion payments have already cost consumers over $12 billion).

7. Nor, it should be noted, are exclusion payments a patent holder's only means of hedging against this probability. Instead, the probability of invalidation could be reflected in a settlement by means of which the patent holder agrees to some reduction in the unexpired term of the patent.

8. *See* 148 Cong. Rec. S7566 (July 20, 2002) (remarks of Sen. Hatch); *Protecting Consumer Access to Generic Drugs Act of 2007, Hearing No. 110-39 Before H. Comm. on Energy and Commerce*, 110th Cong. At 7 (May 2, 2007) (statement of Rep. Waxman).

exclusion payment settlements seem plainly inconsistent with the stated purpose of the Hatch Waxman Act, which is to encourage patent challenges as a way of increasing consumer access to low-cost drugs.[9]

More significantly, the Hatch Waxman Act does nothing to change the general rule that market-sharing agreements violate the antitrust laws. *See Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49 (1990) (per curiam); *United States v. Sealy, Inc.*, 388 U.S. 350, 357-58 (1967). This is just as true when one of the parties to a market-sharing agreement happens to hold a patent. *See Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49 (1990); *United States v. Sealy, Inc.*, 388 U.S. 350, 357-58 (1967). Thus, even though we are required to presume that Bayer's patent is valid, 35 U.S.C. § 282, as the United States points out in its *amicus* brief,

> [t]he presumption of patent validity is simply a procedural device that assigns burdens in litigation challenging the validity of an issued patent. There is no basis for treating that presumption as virtually conclusive and allowing it to serve as a substantive basis to limit the application of the Sherman Act.

Br. of United States, at 6-7 (internal citations omitted).

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9. H.R. Rep. No. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48.

It should not be surprising, therefore, that our *Tamoxifen* decision has inspired vigorous criticism from a variety of sources. The United States has described our *Tamoxifen* rule as "incorrect,"[10] and has supported the plaintiffs' petition for *en banc* rehearing in this case.[11] Also supporting the petition for rehearing are the majority of State Attorneys General,[12] the Federal Trade Commission,[13] the American Medical Association,[14] and an impressive array of consumer groups and academic commentators.[15] As *amici* point out, although "commentators are divided on the treatment to be accorded [exclusion payment] settlements … none take the position adopted by [] *Tamoxifen*."[16]

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10. Br. of the United States, *Joblove v. Barr Labs., Inc.*, S. Ct. No. 06-830, available at http://www.justice.gov/osg/briefs/2006/2pet/6invit/2006-0830.pet.ami.inv.html, at 1 (2007).

11. *See* Br. of the United States, *supra* note 5.

12. *See* Br. of 34 State Attorneys General, available at http://www.prescriptionaccess.org/docs/Cipro_2010_May_AG_Amicus.pdf.

13. *See* Br. of FTC, available at http://www.ftc.gov/os/2010/05/051202amicuscarpentershealth.pdf.

14. *See* Br. of AARP & AMA, available at http://www.fdalawblog.net/files/cipro—aarpama.pdf.

15. *See generally* http://blog.prescriptionaccess.org/?cat=422 (collecting links to *amicus* briefs in this case).

16. Br. of 86 Law, Economics, Pub. Pol'y, & Bus. Professors, at 6-7, available at http://www.law.stanford.edu/news/details/3793/Profs%20File%20Amici%20Curiae%20Seeking%20En%20Banc%20Rehearing%20of%20Second%20Circuit%20Pharma%20Reverse%20Payment%20Antitrust%20Decision%20/.

In the light of all this, I think that our *Tamoxifen* decision unambiguously deserves reexamination. The *Tamoxifen* majority recognized the "troubling dynamic" of permitting exclusion payments that "inevitably protect patent monopolies that are, perhaps, undeserved." 466 F.3d at 211. Subsequent experience has shown that the majority was right to be "troubled." Although the "enormous importance" of the issues that this case raises is beyond dispute, Fed. R. App. P. 35(a)(2), a majority of this Court has voted against *en banc* rehearing. I respectfully dissent from that decision. It will be up to the Supreme Court or Congress to resolve the conflict among the Courts of Appeals. *Compare In re Ciprofloxacin Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008) (exclusion payments legal), and *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005) (same) *with In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) (exclusion payments *per se* illegal).

APPENDIX B — DECISION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DECIDED APRIL 29, 2010 CORRECTED JUNE 17, 2010

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

Docket Nos. 05-2851-cv(L), 05-2852-cv(CON)

August Term, 2008
Argued: April 28, 2009
Decided April 29, 2010
Corrected June 17, 2010

ARKANSAS CARPENTERS HEALTH AND WELFARE FUND, MARIA LOCURTO, PAPER, ALLIED-INDUS, UNITED FOOD AND COMMERCIAL WORKERS UNION-EMPLOYER, LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Plaintiffs-Appellants,

v.

BAYER AG, BAYER CORP., formerly doing business as Miles Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES INC.,

Defendants-Appellees.

Appendix B

Before: NEWMAN, POOLER, PARKER, *Circuit Judges*.

Plaintiffs appeal from a judgment of the United States District Court for the Eastern District of New York (Trager, *J.*) granting summary judgment for defendants, manufacturers of the antibiotic ciprofloxacin hydrochloride ("Cipro") or generic bioequivalents of Cipro. Plaintiffs argue that defendants violated Section 1 of the Sherman Act when they settled their dispute concerning the validity of Bayer's Cipro patent by agreeing to a reverse exclusionary payment settlement. Bayer agreed to pay the generic challengers, and in exchange the generic firms conceded the validity of the Cipro patent.

After the district court entered judgment below, a panel of this Court held that reverse payment settlements of patent lawsuits do not violate antitrust laws. *See Joblove v. Barr Labs., Inc., (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187, 208-12 (2d Cir. 2005). Because *Tamoxifen* is dispositive of plaintiffs' claims, we AFFIRM. However, because of the "exceptional importance" of the antitrust implications of reverse exclusionary payment settlements of patent infringement suits, we invite plaintiffs-appellants to petition for rehearing in banc. *See* Fed. R. App. P. 35(a)(2).

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Taus, and Jan Bartelli, Garwin, Gerstein, & Fisher LLP, New York, NY, *on the brief*), for *Plaintiffs-Appellants.*

PAUL E. SLATER, Sperling & Slater, P.C., of counsel to Amicus Curiae American Antitrust Institute, Chicago, IL, in support of *Plaintiffs-Appellants*.

STACY J. CANAN, (Bruce Vignery, *on the brief*), AARP Foundation Litigation, (Michael Schuster, AARP, *on the brief*), Washington, D.C., as Amici Curiae for *Plaintiffs-Appellants*.

DON L. BELL, II, National Association of Chain Drug Stores, Inc., Alexandria, VA, as Amicus Curiae for *Plaintiffs-Appellants*.

FRED H. BARTLIT, Jr., (Peter B. Bensinger, Jr., Michael J. Valaik, and Paul J. Skiermont, *on the brief*), Bartlit Beck Herman Palenchar & Scott LLP, Chicago, IL, (Philipp A. Proger, Kevin D. McDonald, and Lawrence D. Rosenberg, Jones Day, Washington, DC), for *Defendants-Appellees Bayer AG and Bayer Corporation*.

KAREN N. WALKER, (Edwin John U, Bridget K. O'Connor, and Gregory L. Skidmore, *on the brief*), Kirkland & Ellis LLP, Washington, DC, (David E. Everson, Heather S. Woodson, and Victoria L. Smith, Stinson Morrison Hecker LLP,

Kansas City, MO, *on the brief*), for *Defendants-Appellees Barr Laboratories, Inc., Hoechst Marion Roussel, Inc., The Rugby Group, Inc., and Watson Pharmaceuticals, Inc.*

CHRISTINE A. VARNEY, Assistant Attorney General, (Philip J. Weiser, Deputy Assistant Attorney General, and Catherine G. O'Sullivan and David Seidman, Attorneys), U.S. Department of Justice, Washington, D.C., for *the United States*.

PER CURIAM:

Plaintiffs appeal from a judgment of the United States District Court for the Eastern District of New York (Trager, *J.*) granting summary judgment for defendants. Defendants Bayer AG and its subsidiary Bayer Corporation (collectively "Bayer") own the patent for the active ingredient in the antibiotic ciprofloxacin hydrochloride ("Cipro"). Defendants Barr Laboratories, Inc. ("Barr"), Hoechst Marion Roussel, Inc. ("HMR"), and Watson Pharmaceuticals, Inc. ("Watson") were potential generic manufacturers of Cipro. Plaintiffs are direct purchasers of Cipro, who allege that defendants violated federal antitrust law when they settled a patent infringement lawsuit by entering into collusive agreements that blocked the entry of low-cost generic versions of Cipro into the prescription drug market.

Appendix B

BACKGROUND

Hatch-Waxman Settlement Agreements

Bayer is the owner of the patent relating to the active ingredient in Cipro, which has been described as the most prescribed antibiotic in the world. The Cipro patent, U.S. Patent No. 4,670,444, was issued on June 2, 1987 and was scheduled to expire on December 9, 2003.[1]

In 1991, Barr sought to market a generic version of Cipro pursuant to the expedited FDA approval process established by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585. Under the Hatch-Waxman Act, a pharmaceutical company can seek approval to market generic versions of an approved branded drug without having to re-establish the drug's safety and effectiveness by filing an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j)(2)(A), (8)(B). Where, as here, a generic manufacturer seeks to enter the market before the expiration of the branded firm's patent, it must file a pre-expiration challenge ("paragraph IV" or "ANDA-IV" certification). 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The ANDA-IV certification requires the generic firm to demonstrate the bioequivalence of its proposed version of the drug, *see*

1. Bayer obtained an additional six-month period of pediatric exclusivity from the Food and Drug Administration (FDA) until June 9, 2004. *See* 21 U.S.C. § 355a(b)(1)(B)(i)(II).

21 C.F.R. § 314.94(a)(9), and to state the basis for its claim of invalidity or noninfringement of the branded firm's patent, *see* 21 U.S.C. § 355(j)(2)(B)(iv)(II).

An ANDA-IV certification itself constitutes an act of infringement, triggering the branded manufacturer's right to sue. 35 U.S.C. § 271(e)(2)(A). Indeed, the branded manufacturer *must* sue within 45 days of receiving notice of the ANDA-IV in order to stay the generic firm's entry into the market. 21 U.S.C. § 355(j)(5)(B)(iii).[2] Thus, the Hatch-Waxman Act redistributes the relative risks between the patent holder and the generic manufacturer, allowing generic manufacturers to challenge the validity of the patent without incurring the costs of market entry or the risks of damages from infringement. *See Ark. Carpenters Health & Welfare Fund v. Bayer AG (In re Ciprofloxacin Hydrochloride Antitrust Litig.)*, 544 F.3d 1323, 1338 (Fed. Cir. 2008).

The first generic firm to file an ANDA-IV is rewarded with a 180-day exclusive right to market its

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2. Although this statutory stay is typically called the "thirty-month stay," in fact the stay can last for over four years. *Compare* 21 U.S.C. § 355(j)(5)(B)(iii) (default maximum duration of stay is thirty months provided notice of ANDA IV is received more than five years after ANDA approval) *with* § 355(j)(5)(F)(ii) (result of earlier-filed ANDA IV is that stay is lengthened, ending five years plus thirty months after FDA approval of the branded drug).

generic version of the drug. 21 U.S.C. § 355(j)(5)(B)(iv).[3] However, *only* the first-filed ANDA-IV is eligible for the 180-day exclusivity period: even if the first filer loses, withdraws, or settles its challenge, subsequent filers do not become eligible for the exclusivity period.[4]

The Bayer-Barr Lawsuit

Barr filed an ANDA-IV challenging Bayer's Cipro patent in October 1991.[5] Bayer sued Barr for patent infringement in the Southern District of New York

3. This 180-day exclusivity period became law without discussion in the relevant House Report and without debate. *See* H.R. Rep. No. 98-857, p. 1, at 28 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2661. Moreover, it was apparently not contemplated at the time of passage that the regulatory scheme would facilitate collusion between branded and generic firms. *See* e.g., S. Rep. No. 107-167, at 4 (2002) ("Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law . . . .").

4. In *Joblove v. Barr Labs. Inc, (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187 (2d Cir. 2005) ("*Tamoxifen*"), the panel majority suggested otherwise, repeating the district court's claim that the exclusivity period cedes to the first ANDA filer to successfully defend. *Compare Tamoxifen*, 466 F.3d at 214, *with In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 134 (E.D.N.Y. 2003). As we discuss in Section 5, *infra*, this aspect of our *Tamoxifen* decision was erroneous. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1583-86 (2006).

5. Barr claimed that the patent was invalid on the following grounds: (1) obviousness; (2) obviousness type double counting; and (3) inequitable conduct.

within 45 days of its receipt of notice of Barr's filing, triggering the Hatch-Waxman statutory stay.[6] Barr subsequently entered into an agreement with other defendants herein, also potential generic manufacturers of Cipro, to share the costs and benefits of the patent litigation.

In June 1996, the district court denied the parties' cross-motions for summary judgment. In January 1997 — approximately two weeks prior to the scheduled trial — Bayer and Barr entered into a "reverse exclusionary payment" (or "pay-for-delay") settlement: that is, the patent holder (Bayer) agreed to pay the alleged infringer to settle the lawsuit, and in exchange, the alleged infringer agreed not to enter the market.[7] Under the terms of the settlement agreement, Bayer agreed to (1) pay $49.1 million immediately; (2) make quarterly payments of between $12.5 and $17.125 million for the duration of the patent except for the last six months prior to the patent's expiration;[8] and (3) provide the

6. The parties subsequently agreed to extend the stay until after the entry of final judgment.

7. To be more precise, the parties executed separate settlement agreements between: (1) Bayer and Barr, and (2) Bayer and HMR/Rugby, which was subsequently acquired by Watson. Bayer, Barr, and HMR also executed a supply agreement.

8. As an alternative to quarterly payments, the settlement gave Bayer the right to either provide Barr with a license to sell Bayer-manufactured Cipro at a royalty rate of 70% of Bayer's average selling price for brand-name Cipro. Bayer elected to make quarterly payments instead. Settlement payments ultimately totaled $398.1 million.

generic manufacturers a guaranteed license to sell brand-name Cipro at a reduced rate for six months prior to the patent's expiration. In exchange, Barr conceded the patent's validity and agreed not to market a generic version of Cipro prior to the patent's expiration.[9]

Plaintiffs' Antitrust Lawsuit

In 2000, direct and indirect purchasers of Cipro filed over thirty antitrust lawsuits against Bayer under federal and state law. These cases were consolidated by the Multi-District Litigation Panel in the Eastern District of New York. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740, 745 (E.D.N.Y. 2001) ("*Cipro I*"). Plaintiffs allege that defendants' settlement exceeded the scope of Bayer's patent rights because Bayer effectively paid its potential competitors hundreds of millions of dollars not to challenge its patent. Plaintiffs also allege that the agreements were unlawful because Barr was permitted to reclaim the 180-day market exclusivity period if a subsequent challenger was successful in having the

9. Barr reserved its right to reinstate its ANDA-IV if Bayer's patent were later held to be invalid. Four generic manufacturers – Ranbaxy, Schein, Mylan, and Carlsbad – subsequently challenged the Cipro patent. Ranbaxy's challenge was dismissed as moot in October 1999. Mylan's and Schein's consolidated challenges were dismissed at summary judgment and this dismissal was affirmed on appeal. *Bayer AG v. Schein Pharm., Inc.*, 129 F. Supp. 2d 705 (D.N.J. 2001), *aff'd*, 301 F.3d 1306 (Fed. Cir. 2002). Carlsbad's challenge was rejected after a nine-day bench trial. *Bayer AG v. Carlsbad Tech., Inc.*, No. Civ. 01-867-B (S.D. Cal. Aug. 26, 2002).

patent invalidated, and because the generic manufacturers agreed not to file any ANDA-IV certifications for products that relate to Cipro. But for the challenged agreements, plaintiffs assert that (1) Barr would have entered the market pending resolution of the patent litigation; (2) Barr would have prevailed in the litigation and entered the market; or (3) Bayer would have granted Barr a license to market a generic version of Cipro to avoid a trial on the patent's validity. On cross-motions for summary judgment, the district court granted summary judgment for the defendants. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 548 (E.D.N.Y. 2005) ("*Cipro III*"). The court stated:

> The ultimate question – and this is the crux of the matter – is not whether Bayer and Barr had the power to adversely affect competition for ciprofloxacin as a whole, but whether any adverse effects on competition stemming from the Agreements were outside the exclusionary zone of the '444 Patent. It goes without saying that patents have adverse effects on competition. However, any adverse effects within the scope of a patent cannot be redressed by antitrust law.

Id. at 523-24 (citations omitted). In eschewing a "*post hoc* determination of the potential validity of the underlying patent," the court reasoned that "such an approach would undermine the presumption of validity of patents in all cases, as it could not logically be limited

to drug patents, and would work a revolution in patent law." *Id.* at 529.

The district court also found that the agreements did not allow Barr to manipulate the exclusivity period to obstruct subsequent challengers of the patent. *Id.* at 540-41; *see also Cipro II*, 261 F. Supp. 2d at 243-47. The court summarized as follows:

> [I]n the absence of any evidence that the Agreements created a bottleneck on challenges to the '444 Patent, or that they otherwise restrained competition beyond the scope of the claims of the '444 Patent, the Agreements have not had any anti-competitive effects on the market for ciprofloxacin beyond that which are permitted under the '444 Patent. The fact that Bayer paid what in absolute numbers is a handsome sum to Barr to settle its lawsuit does not necessarily reflect a lack of confidence in the '444 Patent, but rather the economic realities of what was at risk. There is simply no precedent for plaintiffs' argument that the parties to a settlement are required to preserve the public's interest in lower prices. Such a rule would only result in parties being less likely to reach settlements, aside from undermining well-settled principles of patent law. Finally, to even attempt to quantify the public's interest in a patent settlement between private parties would require

> devaluing patents across the board, a result that would contravene the presumption of validity afforded by Congress and impact the very way patent licenses are handled in countless daily transactions.

Cipro III, 363 F. Supp. 2d at 540-41.

Plaintiffs timely appealed. This Court retained jurisdiction over the direct purchaser plaintiffs' appeals, but transferred the indirect purchaser plaintiffs' appeal to the Federal Circuit.[10]

DISCUSSION

We review the district court's grant of summary judgment *de novo*, construing evidence in the manner most favorable to the nonmoving party. *Horvath v. Westport Library Ass'n*, 362 F.3d 147, 151 (2d Cir. 2004)

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10. The indirect purchaser plaintiffs amended their complaint to add state-law, *Walker Process* antitrust claims, so-called based on the Supreme Court's decision in *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, which recognized an antitrust claim when patents are obtained by fraud. 382 U.S. 172, 177 (1965). Because the *Walker Process* claims are preempted by patent law, *see Cipro III*, 363 F. Supp. 2d at 543-44, we transferred the indirect purchaser plaintiffs' appeal to the Federal Circuit, while retaining jurisdiction over the direct purchaser plaintiffs' appeals. The Federal Circuit ultimately affirmed the district court on the indirect purchaser plaintiffs' claims, agreeing with the district court's conclusion that the settlement did not restrain competition beyond the exclusionary zone of the Cipro patent. 544 F.3d 1323, 1333 (Fed. Cir. 2008).

(citation omitted). Summary judgment is appropriate only where "there is no genuine issue as to any material fact and . . . the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

1. Section 1 of the Sherman Act

The Sherman Act provides that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal." 15 U.S.C. § 1. Although by its terms, the Act prohibits "every" restraint of trade, the Supreme Court "has long recognized that Congress intended to outlaw only unreasonable restraints." *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997). Agreements that have a "predictable and pernicious anticompetitive effect, and . . . limited potential for procompetitive benefit" are deemed per se unlawful. *Id.* Most conduct, however, is subject to so-called "rule of reason" analysis. *See Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006).

Rule of reason analysis proceeds in three steps. First, the plaintiff bears the initial burden of showing that the defendant's conduct "had an *actual* adverse effect on competition as a whole in the relevant market." *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc.*, 996 F.2d 537, 543 (2d Cir. 1993) (emphasis in original). If plaintiff satisfies this burden, the burden then shifts to defendant to offer evidence that its conduct had pro-competitive effects. *Id.* If defendant is able to offer such proof, the burden shifts back to

plaintiff, who must prove that any legitimate competitive effects could have been achieved through less restrictive alternatives. *Id.*

2. Reverse Exclusionary Payment Settlements, Antitrust Law, and *Tamoxifen*

Plaintiffs argue that when Bayer paid Barr to withdraw its challenge to the Cipro patent, defendants effectively entered into a market-sharing agreement in restraint of trade. Patent settlements, like all private contracts, are subject to antitrust scrutiny. *Cf. Standard Oil Co. v. United States*, 283 U.S. 163, 169 (1931) ("The limited monopolies granted to patent owners do not exempt them from the prohibitions of the Sherman Act . . . ."); *see also B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426-27 (Fed. Cir. 1997) (the Sherman Act prevents patentees from obtaining a greater monopoly than was inherent in the relevant patent grant). Thus, like ordinary contracts, patent settlements cannot take the form of "market-sharing agreements." *See Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49 (1990) (per curiam) (market-sharing agreement is unlawful on its face); *United States v. Sealy, Inc.*, 388 U.S. 350, 357-58 (1967) (same); *see also* 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2030b, at 213 (2d ed. 2005) ("[T]he law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition").

The question, therefore, is whether patent settlements in which the generic firm agrees to delay

entry into the market in exchange for payment fall within the scope of the patent holder's property rights, or whether such settlements are properly characterized as illegal market-sharing agreements. Authorities are divided on this question. The Federal Trade Commission ("FTC"), the U.S. antitrust enforcement agency charged with supervising the pharmaceutical industry, has long insisted that reverse exclusionary payment settlements violate antitrust law and has challenged numerous agreements as unreasonable restraints of trade.[11] Although it initially took a different view, the United States has since maintained that reverse exclusionary payment settlements may violate antitrust laws. *See* Brief for the United States as Amicus at 12, *Joblove v. Barr Labs., Inc.*, No. 06-830, 2007 WL 1511527 (U.S. May 23, 2007). Many academic commentators share the United States's view.[12]

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11. *E.g. Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (2007) (statement of Jon Leibowitz, FTC Commissioner), available at http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf (criticizing the "extremely lenient view" taken by some toward reverse exclusionary agreements and alleging that reverse exclusionary agreements result in massive wealth transfers from consumers to pioneer drug producers); *see also Concurring Statement of Commissioner Jon Leibowitz, FTC v. Watson Pharmaceuticals et. al.* (Feb. 2, 2009), available at http://ftc.gov/speeches/leibowitz/090202watsonpharm.pdf.

12. *See, e.g.*, C. Scott Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. at 1561-62 (2006) (arguing that a settlement should be accorded a presumption of illegality if the settlement both

(Cont'd)

Most courts, by contrast, including this Court, *Joblove v. Barr Labs. Inc., (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187, 216 (2d Cir. 2005) ("*Tamoxifen*"), have held that the right to enter into reverse exclusionary payment agreements fall within the terms of the exclusionary grant conferred by the branded manufacturer's patent. *See In re Ciprofloxacin Antitrust Litig.*, 544 F.3d at 1333; *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005). *But see La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (In re Cardizem CD Antitrust Litig.)*, 332 F.3d 896, 908 (6th Cir. 2003) (holding such agreements to be per se illegal); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005) (same).

Particularly relevant here is this Court's decision in *Tamoxifen*. The plaintiffs in *Tamoxifen* challenged a reverse exclusionary payment settlement between

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restricts the generic firm's ability to market a competing drug and includes compensation from the innovator to the generic firm); Herbert Hovenkamp, Mark Janis, & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1759-60 (2003) (proposing that a defendant would overcome the presumptive unlawfulness of a reverse payment settlement by "showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit"). *But see* Alan Devlin, *The Stochastic Relationship Between Patents and Antitrust*, 5 J. Competition L. & Econ. 75, 108 (2009) ("uncritical application of standard principles of competition law to information markets may be myopic.").

Zeneca and Barr that the parties entered into after a district court had declared Zeneca's patent invalid. 466 F.3d at 193. At the 12(b)(6) stage, *Tamoxifen* rejected as speculative plaintiffs' allegation that Barr would have prevailed on appeal but for the settlement agreement. *Id.* at 203-04. Assuming the truth of plaintiffs' allegation that the exclusion payments exceeded the profits Barr would have obtained upon entering the market as a generic competitor, the *Tamoxifen* court determined that the plaintiffs had no antitrust claim because a patent holder is entitled to protect its "lawful monopoly over the manufacture and distribution of the patented product." *Id.* at 205, 208-09.

Notably, *Tamoxifen* expressly adopted aspects of the lower court's summary judgment decision in this case, holding:

> Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.

Id. at 213 (citing *Cipro III*, 363 F. Supp. 2d at 535). The *Tamoxifen* court ruled that the settlement agreement did not exceed the scope of the patent where (1) there was no restriction on marketing non-infringing products; (2) a generic version of the branded drug would necessarily infringe the branded firm's patent; and (3)

the agreement did not bar other generic manufacturers from challenging the patent. *Id.* at 213-15; *cf. Cipro III*, 363 F. Supp. 2d at 540-41; *Cipro II*, 261 F. Supp. 2d at 241-47.

Since *Tamoxifen* rejected antitrust challenges to reverse payments as a matter of law, we are bound to review the *Cipro* court's rulings under the standard adopted in *Tamoxifen*. *See* 466 F.3d at 208-12. We therefore proceed to evaluate plaintiffs' claims under *Tamoxifen*.[13] Plaintiffs do not argue that the patent infringement lawsuit was a sham or that the Cipro patent was procured by fraud. Thus, the only reasonable basis for distinguishing *Tamoxifen* would be if plaintiffs demonstrated that the settlement agreement here, unlike in *Tamoxifen*, exceeded the scope of the Cipro patent. Plaintiffs cannot establish this because a generic version of Cipro would necessarily infringe Bayer's patent. *Tamoxifen* explained that unlike "formulation patents," which cover only specific formulations or delivery methods for a compound, a "compound patent" "by its nature, excludes all generic versions of the drug." 466 F.3d at 214. Bayer's Cipro patent is a compound patent. *Id.* Thus, Barr's agreement to refrain from manufacturing generic Cipro encompasses only conduct that would infringe Bayer's patent rights.

Plaintiffs also claim that the challenged agreements contained ancillary restraints outside the scope of the

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13. Our jurisdiction over plaintiffs' claims is also established by *Tamoxifen*. *See* 466 F.3d at 199-200.

patent: (1) Barr was permitted under the agreements to manipulate its rights to the 180-day market exclusivity period; and (2) Barr and HMR agreed to refrain from filing future ANDA-IV certifications related to Cipro.[14] *Tamoxifen* recognized that a plaintiff can have antitrust claims where a Hatch-Waxman settlement allows the generic manufacturer to manipulate the 180-day exclusivity period in a manner that bars subsequent challenges to the patent or precludes the generic manufacturer from marketing non-infringing products unrelated to the patent. *See Tamoxifen*, 466 F.3d at 213-19; *see also Cardizem CD*, 332 F.3d at 907-09. In this case, however, plaintiffs have not shown that the settlement agreements allowed manipulation of the exclusivity period or prohibited the marketing of non-infringing products.

Plaintiffs contend that Barr's insistence on its right to reclaim the 180-day exclusivity period caused other generic manufacturers to delay subsequent challenges. Specifically, they maintain that Mylan delayed its challenge because it perceived Barr's continued assertion of a right to the 180-day exclusivity as an obstruction to their entry into the market. This argument is unpersuasive. Although the settlement agreement allows Barr to reinstate its ANDA-IV if a subsequent patent challenge were successful, a

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14. Plaintiffs argued below that the agreements were unlawful because Barr and HMR conceded the validity of several additional patents related to Cipro. *See Cipro II*, 261 F. Supp. 2d at 254. Plaintiffs do not press this argument on appeal.

reinstated ANDA-IV certification would not have entitled Barr to the 180-day exclusivity period based on the law in effect at the time of settlement.[15] Thus, the district court properly determined that Barr forfeited its challenge to the patent and thus any right to 180-day exclusivity, and that other generic manufacturers were able to subsequently challenge the Cipro patent.

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15. When Bayer and Barr entered the settlement in January 1997, an ANDA filer's right to 180-day exclusivity was contingent on their "successful defense" of a patent infringement suit. *See* 21 C.F.R. § 314.107(c)(1). Since Barr did not successfully defend the lawsuit by entering a settlement, the court found it had no claim to the exclusivity period. *Cipro II*, 261 F. Supp. 2d at 243, 247. After courts rejected the FDA's "successful defense" requirement, *see, e.g.*, *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), the FDA permanently removed it. *See* Effective Date and Approval of an Abbreviated New Drug Application, 63 Fed. Reg. 59710, 57911 (Nov. 5, 1998). But this occurred after the agreements in this case were executed. Plaintiffs argue that the questionable validity of the regulation suggests that Barr tried to exploit it in order to keep other manufacturers from the market, but *Tamoxifen* specifically rejected this argument. 466 F.3d at 218-19. Plaintiffs assert that the *Tamoxifen* panel did not consider a district court case that found an earlier FDA exclusivity requirement contrary to the Hatch-Waxman statute. *See Inwood Labs., Inc. v. Young*, 723 F. Supp. 1523 (D.D.C. 1989), *vacated as moot*, 43 F.3d 712 (D.C. Cir. 1989). However, this argument is unavailing because the FDA promulgated the "successful defense" requirement in effect at the time of the agreements here after the *Inwood Labs* decision. *See* Abbreviated New Drug Application Regulations; Patent and Exclusivity Provision, 59 Fed. Reg. 50338 (Oct. 3, 1994). The established law at the time of the agreement precluded Barr from retaining a right to exclusivity.

See Cipro II, 261 F. Supp. 2d at 243;[16] *cf. Tamoxifen*, 466 F.3d at 218-19 (rejecting a claim that Barr manipulated the 180-day exclusivity period based on similar analysis).

Finally, plaintiffs argue that Barr and HMR unlawfully agreed to refrain from filing ANDA-IVs even after the Cipro patent expired. The agreement states that Barr and HMR are "not to . . . file any [ANDA] relating to Cipro with . . . a certification made pursuant to Paragraph IV of the Act." The district court reasonably interpreted the agreement to mean that Barr and HMR would not file any ANDA-IV certifications challenging the validity of the Cipro patent. *See Cipro II*, 261 F. Supp. 2d at 253. This reading was consistent with Barr's concession of validity and with the fact that there could not be an ANDA-IV certification for a non-infringing version of the drug since Bayer had a compound patent.

Plaintiffs contend that *Tamoxifen* is distinguishable because, by relying on the district court's *Cipro III*

16. Plaintiffs contend that the district court erred in *Cipro III* when it admitted that, based on its ruling in *Cipro II*, it need not consider this claim "anew." *See* 363 F. Supp. 2d at 540 (citing *Cipro II*, 261 F. Supp. 2d at 243-47). *Cipro II* considered the claim in the context of plaintiffs' motion for partial summary judgment. When addressing defendants' motion for summary judgment in *Cipro III*, the district court was required to view the evidence in plaintiffs' favor. Because the district court's analysis is consistent with *Tamoxifen*, which was decided at the 12(b)(6) stage, the district court did not err by incorporating its analysis from *Cipro II*.

decision, *Tamoxifen* adopted an erroneous view of the facts of this case *i.e.22*, *Tamoxifen* was based on an erroneous view of the facts of *Cipro*. This argument is not persuasive. *Tamoxifen* relied on *Cipro III* not for its facts, but rather for its legal and policy analysis. The *Tamoxifen* majority urged against addressing the probability that a patent was invalid and deferred to a patent holder's desire to settle patent challenges, concluding that a patent holder could reasonably decide to pay money, even more than a generic manufacturer would make on the market, to guarantee protection of its patent. *See Tamoxifen*, 466 F.3d at 210 ("[A] rule [limiting the amount of exclusion payments] would . . . fail to give sufficient consideration to the patent holder's incentive to settle . . . .").

Plaintiffs and amici also argue that *Tamoxifen* runs afoul of the purpose of the Hatch-Waxman Act. The purpose of the Hatch-Waxman Act, 21 U.S.C. § 355, was "to make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647. The Act sought to accomplish this objective by providing an incentive through the ANDA-IV certification procedure for generic manufacturers to challenge presumptively valid patents, which, if successful, would result in exclusivity for the first successful challenger and the entry of generic drugs into the market. The market entry of generic drugs arising from successful Hatch-Waxman challenges can result in significant savings to consumers. *See* Brief for AARP as Amicus at 8-9 (discussing generic manufacturers' challenges to the Prozac patent and

Paxil patent where generic entry resulted in $2.5 and $2 billion in consumer savings, respectively).[17]

These policy arguments cannot be addressed here. As defendants note, this panel is bound by *Tamoxifen* "absent a change in law by higher authority or by way of an in banc proceeding." *United States v. Snow*, 462 F.3d 55, 65 n.11 (2d Cir. 2006). However, there are several reasons why this case might be appropriate for reexamination by our full Court.

First, the United States has itself urged us to repudiate *Tamoxifen*, arguing that *Tamoxifen* adopted an improper standard that fails to subject reverse exclusionary payment settlements to appropriate antitrust scrutiny. Brief for the United States as Amicus at 6, 14-15;[18] *see also* Brief for the United States as Amicus in *Joblove v. Barr Labs., Inc.*, No. 06-830, 2007 WL 1511527, at *1 (U.S. May 23, 2007) (describing the *Tamoxifen* standard as "incorrect"). In the pending case, the United States argues:

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17. One study found that generic manufacturers prevailed in 73% of the Hatch-Waxman lawsuits that were tried to verdict. *See* Brief for American Antitrust Institute ("AAI") as Amicus at 3 (citing *Generic Drug Entry Prior to Patent Expiration*, at vii (2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf).

18. The Department of Justice provided a brief at the request of the panel. Though the United States argues that our *Tamoxifen* decision was wrongly decided, it "takes no position on the ultimate merits of this appeal." Brief for the United States as Amicus at 9.

Appendix B

> This Court's *Tamoxifen* standard inappropriately permits patent holders to contract their way out of the statutorily imposed risk that patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract. . . . [T]his standard effectively bars considering whether the agreement might violate the antitrust laws, and so offers no protection to the public interest in eliminating undeserved patents.

Brief for the United States as Amicus at 14-15.[19] While acknowledging that patent-holders are entitled to settle disputes over the validity of their patent, the United States proposes that excessive reverse payment settlements be deemed presumptively unlawful unless a patent-holder can show that settlement payments do not greatly exceed anticipated litigation costs. *Id.* at 27-32.

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19. Amici similarly argue that the *Tamoxifen* court's permissive approach to reverse payments offers protection to patent holders beyond that envisioned by patent law, is inconsistent with the principle that antitrust cases be decided "based upon demonstrable economic effect rather than . . . formalistic line drawing," Brief for AAI as Amicus at 5, (quoting *Continental T.V., Inc. v. GTE Sylvania, Inc.,* 433 U.S. 36 (1977)), and did not give sufficient consideration to the public interest in "authoritative testing of patent validity." Brief for Nat'l Assoc. of Chain Drug Stores, Inc. as Amicus at 20 (quoting *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971)).

Second, there is evidence that the practice of entering into reverse exclusionary payment settlements has increased since we decided *Tamoxifen*. Prior to our *Tamoxifen* decision, there were fourteen settlements of Hatch-Waxman lawsuits, none of which involved reverse payments to a generic manufacturer. Brief for American Antitrust Institute as Amicus at 3 (citing Fed. Trade Comm'n, *Generic Drug Entry: Prior to Patent Expiration* 31-32, 34 (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf). After *Tamoxifen*, however, plaintiffs represent that twenty of twenty-seven Hatch-Waxman settlements have involved reverse payments.

Third, after *Tamoxifen* was decided, a principal drafter of the Hatch-Waxman Act criticized the settlement practice at issue here. *See* 148 Cong. Rec. S7565 (July 30, 2002) (remarks of Sen. Hatch) ("As coauthor of the [Hatch-Waxman Act], I can tell you that I find these type[s] of reverse payment collusive arrangements appalling"); see also 146 Cong. Rec. E1538-02 (Sept 20, 2000) (remarks of Rep. Waxman) ("[R]equir[ing] companies seeking to reach secret, anticompetitive agreements to disclose them to the FTC . . . . [would] ensure that existing antitrust and drug approval laws are enforced to the letter.").[20]

20. We are not insensitive to "the oft-repeated warning that the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 117 (1980) (quotation marks omitted). However, remarks by an Act's author do not trigger the typical concern about post-enactment legislative history, namely that "the losers in the legislative arena hope to persuade the courts to give them the victory after all." Richard A. Posner, *How Judges Think* 344 (2008).

Fourth and finally, the *Tamoxifen* panel appears to have relied on erroneous characterization of the Hatch-Waxman Act. *Tamoxifen* was based in no small part on the panel majority's statement that reverse exclusionary settlements "open[ ] the [relevant] patent to immediate challenge by other potential generic manufacturers which did indeed follow – spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit..." 466 F.3d at 214. If understood as a legal conclusion that the statutory exclusivity period cedes to the first ANDA filer to successfully defend, was erroneous. *See* Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1583-86 (2006); *cf.* 21 C.F.R. § 314.107(c)(1)-(2) (only first-filer eligible for exclusivity period); 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873 (Aug. 6, 1999) (revisiting and re-endorsing FDA interpretation of exclusivity provisions); 21 U.S.C. § 355(j)(5)(D)(iii) (codifying FDA interpretation).[21]

In addition, unlike *Tamoxifen*, which was decided at the 12(b)(6) stage, this case involves a summary judgment decision based on a full record. This case could

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21. Although the panel majority might conceivably be understood to have described only the *beliefs* of ANDA filers before 2003, we think that the above-quoted language is more naturally read as a legal characterization of the Hatch-Waxman Act's exclusivity provisions.

provide our full Court with an opportunity to revisit the issues in play in *Tamoxifen* and to analyze the competing interests that underlie antitrust challenges to reverse payment settlements in light of the full record and the arguments of the parties and amici, including the United States, that have been raised in this appeal. We therefore invite plaintiffs-appellants to petition for in banc rehearing.

CONCLUSION

In sum, as long as *Tamoxifen* is controlling law, plaintiffs' claims cannot survive. Accordingly, we AFFIRM the judgment of the district court. However, we believe there are compelling reasons to revisit *Tamoxifen* with the benefit of the full Court's consideration of the difficult questions at issue and the important interests at stake. We therefore invite the plaintiffs-appellants to petition for rehearing in banc.

APPENDIX C — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT, EASTERN DISTRICT OF NEW YORK DATED MARCH 31, 2005

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

1:00-MDL-1383
(DGT)

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION

MEMORANDUM AND ORDER

TRAGER, J.

This action involves agreements between the brand-name manufacturer of the widely used antibiotic ciprofloxacin hydrochloride ("Cipro") and potential generic manufacturers of Cipro. The brand-name manufacturer, Bayer AG, a German company, and its American subsidiary, Bayer Corporation (collectively, "Bayer") and the generics, Barr Laboratories, Inc. ("Barr"); The Rugby Group, Inc. ("Rugby"); Hoechst Marion Roussel, Inc. ("HMR"); and Watson Pharmaceuticals, Inc. ("Watson") (collectively, "generic defendants")[1] entered into agreements that Direct

1. Barr and Rugby are in the business of, *inter alia*, manufacturing and marketing generic drugs. Rugby was the U.S. generic drug subsidiary of HMR until February 1998, when Rugby was acquired by Watson, a company that produces and distributes generic and brand-name drugs. Watson is not a signatory to any of the allegedly unlawful agreements.

Appendix C

Purchaser Plaintiffs ("direct plaintiffs") and Indirect Purchaser Class Plaintiffs ("indirect plaintiffs") allege prevented competition in the market for Cipro in violation of federal and state antitrust laws.[2] Plaintiffs previously filed motions for partial summary judgment seeking a determination that these agreements were *per se* unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1 (and various state antitrust and consumer protection laws), which were denied. Subsequently, indirect plaintiffs amended their complaint to add a new count, Count V, alleging *Walker Process*-type[3] and sham litigation antitrust violations under state law.

Bayer and generic defendants have now each filed motions for summary judgment asserting that these agreements do not violate Section 1 of the Sherman Act because they had no anti-competitive effects beyond the

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2. The generic defendants, together with Bayer, will be referred to as the "defendants," while direct plaintiffs and indirect plaintiffs will be referred to as "plaintiffs."

3. In *Walker Process Equipment, Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 177, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965), the Supreme Court first recognized an antitrust cause of action based on assertion of a patent known to have been obtained by fraud on the United States Patent and Trademark Office ("PTO"), provided that the other elements of a Sherman Act claim are present. Such claims are commonly referred to as *Walker Process* claims. Because indirect plaintiffs are asserting their claims under state law and because they have pointed to no state law explicitly recognizing an antitrust claim for assertion of a patent obtained by fraud, their claim is referred to as a *Walker Process*-type claim.

scope of Bayer's patent on ciprofloxacin, while direct plaintiffs have filed a motion for partial summary judgment arguing that the agreements meet the "anti-competitive conduct" requirement of Section 1 of the Sherman Act and the "antitrust injury" requirement of the Section 4 of the Clayton Act. Bayer has also filed two motions relating to Count V of indirect plaintiffs' second amended complaint ("Count V"). The first, a motion to dismiss Count V, is made on the grounds that indirect plaintiffs' state law *Walker Process*-type claim is preempted by federal patent law and is barred by the statute of limitations. The second, filed in the event Count V is not dismissed, is a motion for summary judgment on Count V on the grounds that indirect plaintiffs have failed to demonstrate that any misrepresentations or omissions made by Bayer in prosecuting its patent were so highly material that the patent would not have issued but for the alleged deceptions and that plaintiffs' sham litigation claim fails as a matter of law. Finally, HMR and Rugby have filed a motion for summary judgment that indirect plaintiffs' claims against them are barred by the doctrine of *Illinois Brick*[4] and that any rights assigned to indirect plaintiffs do not include claims against HMR.

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4. Under *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977), indirect purchasers are barred from recovering damages for monopolistic overcharges under federal antitrust law.

Appendix C

Background

The statutory and regulatory background, as well as the circumstances of this case, were fully described in the court's initial opinion, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740 (E.D.N.Y. 2001) ("*Cipro I*") (granting certain plaintiffs' motions to remand to state court). The developments in the case were further discussed and analyzed in a second opinion, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003) ("*Cipro II*") (granting in part and denying in part defendants' motions to dismiss, and denying plaintiffs' motion for partial summary judgment asserting that the agreements constituted *per se* violations of the antitrust laws). Familiarity with those decisions is presumed, and what follows is a summary of only those facts necessary for the resolution of the pending motions.

Bayer is the assignee of U.S. Patent No. 4,670,444 ("the '444 Patent"), a compound patent which claims the chemical entity that is the active ingredient in Cipro – ciprofloxacin hydrochloride—and all its generic equivalents. *See Cipro II*, 261 F. Supp. 2d at 249 ("A patent on a compound that is the only active ingredient in a drug covers all generic versions of that drug . . . . regardless of how formulated, processed or delivered . . . ."). The '444 Patent issued on June 2, 1987 from patent application Ser. No. 614,923 ("the '923 application"), which was filed on May 29, 1984. The '923 application was filed as a continuation-in-part[5] of Ser.

5. A continuation-in-part application is an application that claims priority to and includes the subject matter of at least part of an earlier-filed application.

No. 292,560 ("the '560 application"), which was filed on August 13, 1981, and Ser. No. 436,112 ("the '112 application"), which was filed on October 22, 1982. *See* App. to Aff. of Paul J. Skiermont in Support of Bayer's Mot. for Partial Summ. J. on Count V of the Indir. Pls.' Proposed Second Am. Consol. Class Action Compl. ("Bayer Count V App."), Ex. 1.

In October 1987, Bayer's predecessor, Miles, Inc., obtained FDA approval to market Cipro in the United States. *Cipro II*, 261 F. Supp. 2d at 194. From 1987 until 2004, Bayer was the only producer of Cipro in the United States. *Id.* On October 22, 1991, Barr filed Abbreviated New Drug Application ("ANDA") 74-124 for permission to market a generic version of Cipro, and included a Paragraph IV certification, seeking permission to market its generic drug before expiration of the '444 Patent on the grounds that the patent was invalid and unenforceable. *Id.* Because the '444 Patent claims the active ingredient in Cipro and because Barr was required in its ANDA to certify that its generic version of Cipro was bioequivalent to Bayer's Cipro, there is no dispute that Barr's product would have infringed Bayer's patent. *Cipro II*, at 249; *see also* App. to Aff. of Paul J. Skiermont in Support of Bayer's Mot. for Partial Summ. J. on Pls. Claims Under the Sherman Act and Corr. State Law Claims ("Bayer Sherman Act App."), Tab 5 (Stipulation and Order (Barr's stipulation that it infringed the '444 Patent)).

Pursuant to the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355,

on December 6, 1991, Barr notified Bayer of its ANDA IV filing, and on January 16, 1992, Bayer sued Barr for patent infringement in the Southern District of New York, where the case was assigned to Judge Whitman Knapp. *Cipro II*, 261 F. Supp. 2d at 194. In January 1996, Bayer and Barr filed cross-motions for partial summary judgment, which Judge Knapp denied in an order and opinion dated June 5, 1996. *Id.* at 195. In March 1996, while these cross-motions were *sub judice*, Barr agreed to share equally any profits from the eventual marketing and/or distribution of Cipro with Rugby, which was then a subsidiary of HMR, and, in return, Rugby agreed to finance a portion of the costs and expenses of the patent litigation against Bayer. *Id.*

On January 8, 1997, just weeks before trial was scheduled to begin, Bayer and Barr reached a settlement of the patent litigation, with Bayer entering into three separate agreements with Barr, HMR and Rugby, and Bernard Sherman and Apotex, Inc. (collectively, the "Settlement Agreements") and a supply agreement with Barr and HMR (the "Supply Agreement") (collectively with the Settlement Agreements, the "Agreements"), the terms of which give rise to the plaintiffs' claims of Sherman Act violations. *Id.* at 195-96. Under the Barr Settlement Agreement, Bayer paid Barr $49.1 million and, in return, required Barr to amend its ANDA from a Paragraph IV certification to a Paragraph III certification, which would permit it to market a generic form of Cipro only upon the expiration of the '444 Patent. *Id.* at 196. However, the Barr Settlement Agreement preserved the option

for Barr to re-amend to a Paragraph IV certification (for the purpose of reclaiming the 180-day exclusivity period that is awarded to a first-filer of an ANDA IV) in the event the '444 Patent were subsequently declared invalid or unenforceable by a court of competent jurisdiction. Bayer Sherman Act App., Ex. 16 ¶ 5(a); *see Cipro II*, 261 F. Supp. 2d at 243-47.

Under the terms of the Supply Agreement, Barr and HMR agreed not to manufacture or have manufactured a generic form of Cipro in the United States. *Cipro II*, 261 F. Supp. 2d at 196. The Supply Agreement further provides that Bayer will either supply Bayer-manufactured Cipro to Barr, HMR and Rugby for distribution in the United States, or make quarterly payments to Barr from January 1998 through December 2003, at which time the '444 Patent was due to expire. *Id*. Bayer opted to make the payments, which, by December 2003, when added to the initial $49.1 million payment, totaled approximately $398 million. *Id*.

Bayer and Barr also entered into a Consent Judgment, terminating the litigation, in which Barr affirmed the validity and enforceability of the '444 Patent and admitted infringement. *Id*. at 196; Bayer Sherman Act App., Ex. 18. The Consent Judgment was signed by Judge Knapp, but made no mention of any payments from Bayer to Barr. *Id*.

Six months after settling with Barr, in July 1997, Bayer submitted the '444 Patent to the Patent and Trademark Office ("PTO") for reexamination. During

the reexamination, Bayer amended certain of the claims of the '444 Patent and cancelled others, after which the PTO reaffirmed the patent's validity, including the validity of claim 12, which was not substantively amended and which all parties agree covers ciprofloxacin hydrochloride. *Id.* at 197; Bayer's Reply Mem. in Supp. of Its Mot. for Partial Summ. J. on Count V of the Indirect Purchaser Class Pls.' Proposed Second Am. Consolidated Class Action Compl. ("Bayer's Count V Reply Mem.") at 19; Bayer Sherman Act App., Ex. 5; App. to Aff. of Paul J. Skiermont in Support of Bayer's Mot. for Partial Summ. J. on Count V of the Indir. Pls.' Proposed Second Am. Consol. Class Action Compl. ("Bayer Count V S. J. App."), Ex. 9. Thereafter, four other generic companies - Schein, Mylan, Carlsbad and Ranbaxy - each challenged the reexamined '444 Patent by filing ANDA IVs for Cipro. *Cipro II*, 261 F. Supp. 2d at 197. Bayer defeated Schein and Mylan's validity challenges on summary judgment, and those decisions were upheld by the Court of Appeals for the Federal Circuit. *Id.* at 201. The Carlsbad case proceeded to a nine-day bench trial, after which the judge rejected Carlsbad's invalidity argument and upheld the validity of the '444 Patent. *See* Bayer Count V App., Exs. 15 and 16 (*Bayer AG v. Carlsbad Tech., Inc.*, No. 01-cv-0867-B, slip op. at 5-13 (S.D. Cal. June 7, 2002 and Aug. 7, 2002)). Ranbaxy's challenge was dismissed as moot after Ranbaxy withdrew its Paragraph IV certification. *Cipro II*, 261 F. Supp. 2d at 197.

Appendix C

Discussion

(1)

Sherman Act Motions for Summary Judgment

The *Cipro II* decision made clear that Barr's agreement with Bayer not to sell ciprofloxacin in exchange for the exclusion payments, also commonly known as reverse or exit payments,[6] did not constitute a *per se* violation of the Sherman Act because the exclusionary effect of the Agreements was within the scope of the '444 Patent. Direct plaintiffs now move for summary judgment that the exclusion-payment scheme meets the "anti-competitive conduct" requirement of Section 1 of the Sherman Act under a rule of reason analysis, while both Bayer and generic defendants move for summary judgment that the Agreements had no anti-competitive effects that are actionable under the Sherman Act because they were within the scope of the '444 Patent. Resolution of this issue requires a close look at the intersection of patent and antitrust laws.

The rule of reason analysis involves a three-step process. First, the plaintiff must prove that "the challenged action has had an *actual* adverse effect on

6. In briefing these motions, the parties have sometimes referred to these payments as "reverse" payments. Adoption herein of the "exclusion payments" nomenclature is made for ease of reference, and in recognition that the payments, whatever they are called, are made in exchange for a competitor's exit or exclusion from the relevant market.

competition as a whole in the relevant market." *K.M.B. Warehouse Distributors, Inc. v. Walker Mfg. Co.*, 61 F. 3d 123, 127 (2d Cir. 1995) (emphasis in original) (quoting *Capital Imaging Assocs. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 543 (2d Cir.), *cert. denied*, 510 U.S. 947, 114 S.Ct. 388, 126 L.Ed.2d 337 (1993)). Next, "the burden shifts to the defendant to establish the 'pro-competitive redeeming virtues' of the action." *Id.* If the defendant succeeds, the burden shifts back to the plaintiff to "show that the same procompetitive effect could be achieved through an alternative means that is less restrictive of competition." *Id.*[7], [8]

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7. Summary judgment is appropriate only in those cases where there is no genuine issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Here, Bayer, generic defendants and direct plaintiffs have each filed motions for summary judgment on the issue of whether the Bayer/Barr settlement agreements had an anti-competitive effect. The burden of proving anti-competitive effects lies with the plaintiffs in the first instance, and, as discussed *infra*, plaintiffs have shown no anti-competitive effects beyond the scope of the '444 Patent. The analysis with respect to those anti-competitive effects that are within the scope of the '444 Patent (and which all parties agree were present) constitutes a pure discussion of law without regard to burdens of proof.

8. A recent decision by the Eleventh Circuit questions the appropriateness of the *per se* versus rule of reason approach for claims of antitrust violations involving patents. *See Schering-Plough v. Federal Trade Comm'n*, __ F.3d __ , __ , 2005 WL 528439, at *7 (11th Cir. Mar. 8, 2005). The Eleventh Circuit's opinion can fairly be read as breaking the first step of a rule of reason analysis – assessing the actual adverse effects on competition – (Cont'd)

a. Relevant market

Taking these steps one at a time, the first question is whether plaintiffs have shown that the Agreements had an actual adverse effect on competition in the relevant market. Traditionally, the starting point of an antitrust inquiry is the definition of the relevant market. *See*, *e.g.*, *Geneva Pharma. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) ("Evaluating market power begins with defining the relevant market."). The purpose of this inquiry is to determine whether defendants possess market power, *i.e.*, the ability to lessen or destroy competition, which, while not the *sine qua non* of a violation of Section 1 of the Sherman Act, is "a highly relevant factor in rule of reason analysis because market power bears a particularly strong relationship to a party's ability to injure competition." *Capital Imaging*, 996 F.2d at 546. The parties dispute whether the relevant market comprises only ciprofloxacin, as plaintiffs have asserted in their complaint, *see* Indir. Pls.' Second Am. Consol. Class

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(Cont'd)

into three steps to determine whether there are any anti-competitive effects that exceed the scope of the patent. Regardless of whether the Eleventh Circuit intended to jettison the rule of reason analysis in the patent context or simply refine the analysis, the case at bar will be considered under this court's prior opinion adopting the rule of reason mode of analysis. *See Cipro II*, 261 F. Supp. 2d at 256-57. It would be inappropriate not to address the issue accordingly, not least because the parties have briefed the issue in light of that analysis. In any event, the same result would be reached under either analytical approach.

Action Compl. ¶ 34, or includes other drugs in the same molecular family as ciprofloxacin (flouroquinolones), which Bayer contends compete with ciprofloxacin in the U.S. antibiotic market, *see* Bayer Defs. ' Mem. of Law in Opp'n to Direct Purchaser Pls.' Mot. for Partial Summ. J. ("Bayer's Opp. Mem."), at 26-29.

Plaintiffs assert that it is unnecessary to show a relevant market in this case because there exists direct evidence of anti-competitive effects. Mem. in Support of Direct Purchaser Pls.' Mot. for Partial Summ. J. ("Dir. Pls.' Mem."), at 25. In general, to sidestep the traditional relevant market analysis, a plaintiff must show by direct evidence "an actual adverse effect on competition, such as reduced output." *Geneva v. Barr*, 386 F.3d at 509 ("If plaintiff can demonstrate an actual adverse effect on competition, such as reduced output, . . . there is no need to show market power in addition.") (citing *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460-61, 106 S.Ct. 2009, 2019, 90 L.Ed.2d 445 (1986); *K.M.B. Warehouse*, 61 F.3d at 128-29). The reason for permitting this alternative showing is simply that the purpose of an inquiry into market power "is to determine whether an arrangement has the potential for genuine adverse effects on competition." *FTC v. Indiana Fed'n of Dentists*, 476 U.S. at 460, 106 S.Ct. at 2019. In effect, market power is "but a 'surrogate for detrimental effects.'" *Id.*, 476 U.S. at 461, 106 S.Ct. at 2019 (quoting 7 P. Areeda, Antitrust Law ¶ 1511, p. 429 (1986)).

For their direct evidence showing, direct plaintiffs point to government and academic studies concluding

that purchasers derive substantial savings from the availability of generic drugs; internal analyses by the brand name and generic manufacturers themselves forecasting significant price reductions once generic drugs become available; and sales data showing the actual effects of competition once generic Cipro was introduced into the market. Dir. Pls.' Mem. at 25-31. In particular, direct plaintiffs rely on a 1998 study by the Congressional Budget Office comparing brand-name and generic prices for twenty-one different drugs that faced generic competition between 1991 and 1993, which found that the average retail price of a prescription for a generic drug in 1994 was less than half the average brand-name drug price. App. in Support of Decl. of Monica L. Rebuck for Dir. Pls. I Mot. for Partial Summ. J. (Dir. Pls. I Summ. J. App.), Tab 5 (Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, at 28-31 (July 1998) ("CBO Study")). Another study cited by ,direct plaintiffs found that by 2000, the average brand-name prescription cost 340 percent more than its generic equivalent ($65.29 versus $19.33). Dir. Pls. Summ. J. App., Tab 20 (Kirkling et al., *Economics and Structure of the Generic Pharmaceutical Industry*, 41 J. Amer. Pharm. Assoc. 578, 579 (2001)).

These studies notwithstanding, the significant price differences actually suggest a finding contrary to the one implied by plaintiffs. Namely, brand-name pharmaceuticals and their generic counterparts might not always compete in the same markets at all because,

based on the higher prices of the brand-name drugs, there is less cross-elasticity of demand than one might expect. (If there were, the prices for brand-name drug prices should fall and be closer to that of generics). Indeed, the CBO Study cited by plaintiffs indicates that prices for brand-name drugs continue to rise faster than inflation even after generic competition begins. CBO Study at 30-31. The Second Circuit recently relied on similar price differential data to reach a particularly narrow market definition in *Geneva v. Barr*, 386 F.3d at 496-500. In that case, the court, relying on the factors set forth in *Brown Shoe Co. v. United States*, 370 U.S. 294, 325, 82 S.Ct. 1502, 1524, 8 L.Ed. 1264 (1956), defined the market as limited to *generic* warfarin sodium. *Id.*; *see also Asahi Glass Co., Ltd. v. Pentech Pharma., Inc.*, 289 F. Supp. 2d 986, 995-96 (N.D. Ill. 2003) (Posner, J., sitting by designation) (noting that paroxetine, the active ingredient in Paxil, competes with molecules that are the basis for other antidepressant drugs such as Prozac and Zoloft, but reserving the possibility that paroxetine might still warrant treatment as a separate market).

Despite the fact that brand-name pharmaceuticals are apparently able to maintain significantly higher prices even after generic entry, the parties' internal analyses prepared at the time the Agreements were entered into confirm that both Bayer and Barr expected Bayer to lose significant sales once generic competition began, with Bayer estimating losses of between $510 million and $826 million in Cipro sales during the first two years of generic competition, depending on the

number of generic manufacturers entering the market. Dir. Pls.' Summ. J. App., Tab 47A, at BCP4630078. Another contemporaneous internal Bayer document estimated Bayer's losses due to a potential adverse judgment in the '444 Patent litigation at $1.679 billion net present value. Dir. Pls.' Summ. J. App., Tab 47D at BCP-P-0001572-004(2). Barr, similarly, projected that it and other generic manufacturers would capture a large percentage of the market for ciprofloxacin within the first two years of generic competition, and would enter the market at a 30 percent discount off Bayer's price. Dir. Pls.' Summ. J. App., Tab 36A at BLI-003560.

Finally, direct plaintiffs point to post-generic entry data showing that Barr in fact did capture more than 50 percent of Bayer's Cipro sales soon after entering the market, and that it initially priced its generic ciprofloxacin at only 8 percent below Bayer's Cipro product. Dir. Pls.' Summ. J. App., Tab 35 (Expert Report of Jeffrey J. Leitzinger, Ph.D., at 38 n.93). Direct plaintiffs also note that the Amended and Restated Supply Agreement between Bayer and Barr, dated August 28, 2003, which provides for Bayer to continue supplying ciprofloxacin to Barr for resale after expiration of the pediatric marketing exclusivity extension that Bayer obtained pursuant to 21 U.S.C. § 355a, sets drastically reduced prices for Cipro after the commencement of open generic competition. Dir. Pls.' Summ. J. App., Tab 43A at BCP4660023. For example, a 100-pill bottle of oral, 500-mg ciprofloxacin that cost Barr $321.96 before the beginning of open generic competition would cost only $14.30 after the expiration

of Bayer's pediatric exclusivity, a 95 percent difference in price. *Id*. Bayer has admitted that the purpose of the price drop was to allow Barr to compete with additional generic manufacturers who would then be entering the market. Dir. Pls.' Summ. J. App., Tab 80 at 112.

Bayer discounts the import of these facts, insisting instead that Cipro competes in the larger market of flouroquinolones, which includes other drugs such as Levaquin, Floxin and Noroxin, within which Cipro has been losing market share, from 75 percent in 1996 to 43 percent in 2001. Bayer's Opp. Mem. at 28-29. Bayer maintains that a properly defined market must include all quinolone antibiotics and that defendants did not possess enough market power to control prices or exclude competition within that larger market. *Id*. at 29.

Although evidence that Bayer charged high prices for Cipro "may of course be indicative of monopoly power," it is not necessarily conclusive in the absence of any analysis of Bayer's costs. *See, e.g., Geneva v. Barr*, 386 F.3d at 500. Plaintiffs have provided neither evidence of Bayer's costs nor any direct evidence that defendants restricted output. However, the pricing strategy encompassed in the Amended and Restated Supply Agreement compels an inference that Bayer was reaping an abnormally high price-cost margin, given the 95 percent price drop that was to occur almost a full year in the future for an identical quantity of an identical strength of the identical drug. Dir. Pls.' Summ. J. App., Tab 43A at BCP4660023. Given Bayer's obvious ability

to control prices, and its admission that it did not anticipate a commensurate drop in its own production costs for Cipro,[9] it is reasonable to accept plaintiffs' contention and conclude both that the relevant market is for ciprofloxacin and that Bayer had market power within that market.

b. Adverse effect on competition

The ultimate question - and this is the crux of the matter - is not whether Bayer and Barr had the power to adversely affect competition for ciprofloxacin as a whole, but whether any adverse effects on competition stemming from the Agreements were outside the exclusionary zone of the '444 Patent. It goes without saying that patents have adverse effects on competition. *See Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 816, 65 S.Ct. 993, 998, 89 L.Ed. 1381 (1945) (A patent "is an exception to the general rule against monopolies and to the right to access to a free and open market."); *Schering-Plough*, ____F.3d____ at, 2005 WL 528439, at *7 ("By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive

9. Bayer admitted at oral argument that its estimated costs of production did not change after the exclusivity period, but contends that its marketing costs were projected to drop sharply after generic entry. It is understandable that Bayer would choose to spend less to promote Cipro at a time when its marketing efforts would not redound exclusively to its own benefit, but a drop in such discretionary spending only further illustrates the degree to which Bayer controlled its own profit margin.

effect is already present."). However, any adverse effects within the scope of a patent cannot be redressed by antitrust law. *See United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1127 (D.C. Cir. 1981) ("[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by the patent and is otherwise legal."); *see also United States v. General Electric Co.*, 272 U.S. 476, 485, 47 S.Ct. 192, 195, 71 L.Ed. 362 (1926); *E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70, 91, 22 S.Ct. 747, 755, 46 L.Ed. 1058 (1902). The '444 Patent gave Bayer the right to exclude competition entirely for ciprofloxacin for the term of the patent, and any conduct within the scope of the patent is exempt from antitrust scrutiny. *See Cipro II*, 261 F. Supp. 2d at 248 ("[A] patent holder does not run afoul of the Sherman Act unless the patent holder acts beyond the confines of the patent monopoly."). Defendants argue that a determination that the Agreements do not restrict competition beyond the scope of the claims of the '444 Patent ends the inquiry as to anti-competitive effects. Plaintiffs, on the other hand, argue that the exclusionary power of the patent for purposes of the anti-competitive effects analysis should be tempered by its potential invalidity.

i. The validity inquiry

While there have been to date only a handful of cases discussing the legality of patent settlement exclusion payments, some courts and commentators have dealt with the questions of whether and to what extent the validity of the patent should be a factor in appraising

the legality of an exclusion payment, and what sort of inquiry into validity an antitrust court should make. The Second Circuit has not yet addressed these issues, but two federal circuits, two district courts (including one on which Judge Posner sat by designation) and the Federal Trade Commission ("FTC") have considered them. Although those courts have come to different conclusions regarding the legality of exclusion payments at issue in those cases, they have generally agreed that an antitrust court need not make an independent assessment of the underlying patent's validity.

The Eleventh Circuit's approach in *Valley Drug*

The Eleventh Circuit in *Valley Drug Co. v. Geneva Pharma., Inc*., 344 F.3d 1294 (11th Cir. 2003), held that to the extent the effects of the subject settlement agreements are within the scope of the exclusionary potential of the patent, such effects are not subject to *per se* (or rule of reason) antitrust condemnation, even where the patent is later held invalid. *Valley Drug*, 344 F.3d at 1311. The two agreements at issue in that case were between Abbott, manufacturer of the pioneer drug Hytrin, and two of its generic competitors - Geneva and Zenith. *Id*. at 1296. Abbott held multiple patents on Hytrin, a drug containing terazosin hydrochloride, which is used to treat hypertension and enlarged prostate, and Geneva filed several ANDA IVs on Hytrin over a period of years. *Id*. at 1298. Zenith, meanwhile, had also filed an ANDA IV on Hytrin, which was pending when two additional patents relating to the active ingredient in Hytrin were issued to Abbott. *Id*. Abbott

listed the new patent information with the FDA, which then required Zenith to make a certification with respect to the newly-issued patents. *Id.* Rather than comply, Zenith filed suit against Abbott to force Abbott to delist the new patents, alleging that Abbott listed them with the knowledge that they were not applicable to Hytrin. *Id.*

On March 31, 1998, Abbott and Zenith entered an agreement settling their delisting and infringement dispute, under which Zenith agreed not to sell or distribute any generic terazosin hydrochloride product until a third party entered the market or until one of Abbott's patents expired, in exchange for payments by Abbott of $6 million every three months. *Id.* at 1300. The next day, Abbott entered a similar agreement with Geneva whereby Geneva agreed not to sell or distribute any generic terazosin hydrochloride product until one of Abbott's patents expired, a third party entered the market or Geneva obtained a final court judgment from which no further appeal could be taken that its terazosin products did not infringe on of Abbott's patents or that the patent was invalid. *Id.* In exchange, Abbott agreed to pay Geneva $4.5 million per month. *Id.* Geneva subsequently prevailed in the patent infringement suit Abbott had filed against it, obtaining a judgment on September 1, 1998 that the patent at issue in that case was invalid. *Id.* at 1301.

The district court concluded that Abbott's agreements with Zenith and Geneva were *per se* violations of Section 1 of the Sherman Act, holding that

the exclusionary effect of the agreements constituted an allocation of the market between horizontal competitors. *Id.* at 1304. The Eleventh Circuit reversed, however, rejecting the argument "that the agreements by Geneva and Zenith not to produce infringing products are subject) to *per se* condemnation and treble-damages liability merely because the '207 patent was subsequently declared invalid." *Id.* at 1306. The court ruled that "the mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis." *Id.* at 1306-07. The court invoked the rationale of Justice Harlan's concurrence in *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 179-80, 86 S.Ct. 347, 351-52, 15 L.Ed.2d 247 (1965): "[T]o hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits." *Id.* at 1307. The court accordingly reserved any *post hoc* validity analysis for those cases in which the patent was procured by fraud or known by the patentee to be invalid. *Id.* at 1307.

The court concluded that " [p]atent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the

mere invalidity of the patent." *Id.* at 1308. The court held open the possibility that the size of the payment to refrain from competing could be evidence of a lack of faith in the validity of the patent or evidence that the patent was obtained by fraud but, citing this court's decision in *Cipro II*, noted that the asymmetries of risk inherent in a Hatch-Waxman patent litigation and the high profits at stake could induce even a confident patentee to pay a substantial sum in settlement. *Id.* at 1309-10.

The *Valley Drug* court thus took the position that an antitrust court need not consider the potential invalidity of the patent in an exclusion-payment settlement, except in those extreme cases involving fraud on the Patent Office or assertion of a patent known to be invalid, *i.e.,* in circumstances giving rise to an allegation of *Walker Process* fraud or sham litigation. However, the court went on to direct the district court on remand to evaluate the defendants' claim that the exclusionary effects of the patent and the agreements were coextensive because certain provisions of the agreements were analogous to a consensual preliminary injunction and stay of judgment pending appeal. *Id.* at 1312. The court instructed that this evaluation should include a comparison between "the provisions of the agreement and the protections afforded by the preliminary injunction and stay mechanisms," and, furthermore, that the "likelihood of Abbott's obtaining such protections" should be considered. *Id.*

On remand, the district court interpreted the Eleventh Circuit's instructions as requiring an analysis

of the likelihood that Abbott would have won a preliminary injunction at the time the agreements were executed, which it construed as requiring an analysis of whether Abbott would have been able to show that its patent was likely valid, rather than an analysis simply of whether the patent claims covered Abbott's product. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1295 (S.D. Fl. 2005). The district court proceeded to determine the likely validity of the patent at the time the agreements were entered, employing the standards applicable to a preliminary injunction analysis. *Id.* at 1303-07. The district court ultimately concluded that Abbott would likely not have been able to show that its patent was likely valid at the preliminary injunction stage of its suit against Geneva and, therefore, held that the Geneva agreement went beyond the exclusionary zone of the patent and was a *per se* violation of the Sherman Act.

It is not certain that the district court correctly interpreted the Eleventh Circuit's opinion, and, indeed, the Eleventh Circuit seems to have expressed some doubt on that point in an unrelated opinion. *See Schering-Plough*, ____F.3d____ at 2005 WL 528439, at *7 n.14 ("On remand, the district court in *Valley Drug* still applied a *per se* analysis . . . ."). In any event, the implication of the district court's reasoning conflicts with the proposition already rejected in *Cipro, II* - that the legality of the Agreements is contingent on Barr's chances of having won at trial. *See Cipro II,* 261 F. Supp. 2d at 202 ("[P]laintiffs cannot avoid dismissal based on a claim of injury-in-fact that relies on the hope that Barr would have prevailed in its suit against Bayer.").

Appendix C

The Sixth Circuit's approach in *Cardizem*

The Sixth Circuit, in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), also eschewed an analysis of the patent's validity in analyzing the anti-competitive effects of an exclusion-payment patent settlement agreement, although that court, unlike this one, concluded that such a settlement was a *per se* violation of the Sherman Act without considering the scope of the underlying patent right. The agreement at issue in that case, however, contained provisions that clearly exceeded any competitive restrictions accruing to the defendants under patent law, particularly because the settling generic manufacturer, Andrx, did not relinquish its claim to 180 days of generic marketing exclusivity under the Hatch-Waxman Act. That is, a term of the agreement required that Andrx maintain its status as first-filer of an ANDA IV even after entering the agreement with the brand-name manufacturer. *In re Cardizem*, 332 F.3d at 902. Andrx's refusal to amend its ANDA to give up the exclusivity claim resulted in a market bottleneck since no other generic manufacturer could come to market until at least 180 days after Andrx began marketing the drug, a trigger that was postponed indefinitely by the settlement. *Id.* at 907. Thus, the brand-name manufacturer used the agreement to effectively bar third parties from mounting challenges to its patent - a power clearly not within the exclusionary power of a patent. Therefore, although the Sixth Circuit arrived at a different conclusion regarding *per se* liability, its approach was consistent with the position

taken by this court in *Cipro II* - namely, that a patent holder cannot exploit the Hatch-Waxman provisions to create a bottleneck that indefinitely excludes subsequent generic challengers from the market. It is also clear that the Sixth Circuit did not engage in an after-the-fact analysis of the patent's likely validity in reaching its determination.

Judge Posner's approach in *Asahi Glass*

Judge Posner, sitting by designation for the Northern District of Illinois, adopted similar reasoning to that of the Eleventh Circuit in *Valley Drug* in analyzing the merits of an antitrust action brought by a supplier to a generic pharmaceutical company that was shut out of the market for paroxetine hydrochloride (sold as the antidepressent Paxil) by a settlement agreement between the generic and the brand-name manufacturer. *Asahi Glass*, 289 F. Supp. 2d at 992-93. The agreement settled a Hatch-Waxman patent litigation and stipulated that the brand-name manufacturer would provide the finished drug product free of charge to the generic company, which would then sell it as an unbranded version of Paxil and pay a sizeable royalty to the brand-name manufacturer. The plaintiff, which had previously anticipated selling the active ingredient for the drug to the generic manufacturer, found itself without a customer, since the generic manufacturer had no incentive to pay for that which it was already getting for free from the brand-name drug maker. The plaintiff sued both parties to the agreement, alleging that the

agreement violated Section 1 of the Sherman Act. Judge Posner dismissed the complaint on the ground that the agreement was a legitimate settlement of a patent infringement suit. *Id.* at 991.

Commenting on the hesitation of an antitrust court to delve into the merits of a predicate patent suit and its potential effect on a settlement agreement, Judge Posner noted:

> [T]he private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case. A firm that has received a patent from the patent office (and not by fraud. . .), and thus enjoys the presumption of validity that attaches to an issued patent, 35 U.S.C. § 282, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment.

Id. at 992-93. Although *Asahi Glass* did not involve an exclusion-payment settlement, Judge Posner employed a similar approach to that of the Eleventh Circuit in *Valley Drug* in declining to independently assess the

likely validity of the patent unless it was almost certainly invalid or obtained by fraud.[10, 11]

The district court's approach in *Tamoxifen*

This district has also previously adjudicated the legality of a settlement of a patent litigation in which the validity of the patent was less than certain, without engaging in a *post hoc* analysis of the patent's validity. *See In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003) (Glasser, J.). In that case, the brand-name manufacturer, Zeneca, settled with the first generic challenger - coincidentally, Barr - after Barr had obtained a district court judgment, at that time on appeal, that the patent was invalid and unenforceable. *Id.* at 125. Under the settlement, Zeneca paid Barr $21 million and licensed Barr to sell tamoxifen manufactured by Zeneca for a royalty in exchange for Barr's withdrawal of its challenge to the validity to the patent and agreement not to market its generic version of tamoxifen until the patent expired. *Id.* Barr and Zeneca jointly moved the appeals court to dismiss the appeal as moot in light of the settlement and to vacate the judgment below, which motions were granted. *Id.* Three

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10. Neither the Eleventh Circuit nor Judge Posner furnished any examples of or provide further guidance regarding patents that were so blatantly invalid.

11. It happens that Judge Posner did in fact decide the validity of the patent in a related patent infringement case that was decided prior to *Asahi Glass. See Asahi Glass*, 289 F. Supp. 2d at 992. In that case he found the patent to be valid. *Id.*

additional generic manufacturers subsequently challenged Zeneca's patent for tamoxifen, and the patent was upheld in each instance, despite an attempt by one of the challengers to invoke collateral estoppel based on Barr's earlier vacated district court judgment. *Id.* at 126-27.

The district court dismissed the subsequent antitrust action brought by consumers, third-party payors and consumer advocacy groups alleging that they were forced to pay higher prices for tamoxifen as a result of the Zeneca/Barr settlement agreement. The court reasoned: "The lack of competition was not the result of any anti-competitive conduct by Zeneca or Barr, but rather the result of the existence of the '516 patent and the decision by the patent holder to enforce it." *Id.* at 138. In reaching this conclusion, the court did not independently assess the probable validity of the patent, even in light of the earlier district court's finding of invalidity and unenforceability, although it did note the traditional *Walker Process*-type exceptions for patent antitrust liability where the patent is fraudulently procured or the infringement action was a sham. *Id.* at 136.

The Federal Trade Commission's approach in *Schering-Plough*

In a decision heavily relied on by plaintiffs for its holding that exclusion payments exceeding litigation costs up to $2 million are prohibited under the Federal Trade Commission Act, the FTC also "question[ed] the

utility of a rule that would give decisive weight to an after-the-fact inquiry into the merits of the patent issues in a settled case."[12] *In re Schering-Plough Corp*, No. 04-10688, 2003 WL 22989651 (FTC Dec. 8, 2003) ("*Schering-Plough I*"), s*et aside and vacated*, *Schering-Plough Corp. v. Federal Trade Comm'n*, __ F.3d __ , 2005 WL 528439 (11th Cir. Mar. 8, 2005) ("*Schering-Plough II*").

The facts of that case involved two settlement agreements - one between Schering-Plough, the brand-name manufacturer of two extended-release microencapsulated potassium chloride products, K-Dur 20 and K-Dur 10, and Upsher, a generic manufacturer, and one between Schering-Plough and American Home Products ("AHp"), another generic manufacturer. *Id*. at *7. The Schering/Upsher agreement, entered on the eve of the parties' Hatch-Waxman patent infringement trial, called for Schering to make payments totaling $60 million to Upsher in exchange for, *inter alia*, Upsher's agreement not to enter the market with any generic version of K-Dur 20 for over four years. The Schering/AHP settlement, which also ended a Hatch-Waxman patent infringement trial, required Schering-Plough to make payments totaling $30 million in exchange for AHP's agreement not to market any generic version of K-Dur 20 for at least six years. *Id*. After rejecting Schering-Plough's argument that it had received any other consideration for its payments than Upsher's and

12. The ruling was recently set aside and vacated by the Eleventh Circuit on other grounds (*i.e.,* not on the issue of the propriety of *post hoc* evaluations of a patent's validity).

AHP's agreements to delay marketing (both agreements included ancillary licenses), the FTC condemned the agreements as anti-competitive, but not on the basis of a *post hoc* review of the patents' validity.

The FTC provided a pragmatic reason for its refusal to assess validity, which had not been previously articulated by courts considering the issue:

> An after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be particularly helpful, but also likely to be unreliable. As a general matter, tribunals decide patent issues in the context of a true adversary proceeding, and their opinions are informed by the arguments of opposing counsel. Once a case settles, however, the interests of the formerly contending parties are aligned. A generic competitor that has agreed to delay its entry no longer has an incentive to attack vigorously the validity of the patent in issue or a claim of infringement.

Schering-Plough I, 2003 WL 22989651, at *19.[13]

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13. Plaintiffs here have raised a similar argument, suggesting that Barr's attorneys had developed a particularly strong attack on the '444 Patent that no subsequent challenger was capable of replicating. Indir. Pls.' Mem. of Law in Opp'n to Bayer's Mot. for Partial Summ. J. on Count V ("Indir. Pls.' Count V Opp'n"), at 2-4; Indir. Pls.' Mem. of Law in Opp'n to Generic Defs.' Mot. for Summ. J. and Bayer's Mot. for Partial Summ. J. on Pls.' Claims Under the (Cont'd)

Although the Eleventh Circuit heavily criticized the FTC for other aspects of its decision, it had no quarrel with the FTC's rejection of a *post hoc* analysis of patent validity, as its own analysis took no account of the potential invalidity of the patent. *Schering-Plough II*, ____F.3d____, 2005 WL 528439.

This survey of the case law reveals that, with the possible exception of the Eleventh Circuit's instructions to the district court on remand in the *Valley Drug* case (*see* discussion *supra*), courts assessing the legality of patent settlement agreements have not engaged in a *post hoc* determination of the potential validity of the underlying patent (except in cases of *Walker Process* or sham litigation claims) when deciding whether an agreement concerning the patent violates antitrust law. These authorities are persuasive.

Above all, making the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court's assessment of the patent's validity might chill patent settlements altogether. Moreover, as explained *infra*, such an approach would undermine the presumption of validity of patents in all cases, as it could not logically be limited to drug patents, and would work a revolution in patent law.

(Cont'd)

Sherman Act and Corresponding State Law Claims ("Indir. Pls.' Sherman Opp'n"), at 13. Barr's patent counsel are undoubtedly fine attorneys, but it strains credulity to maintain that only one competitor's well-funded legal team could construct such a compelling case against the patent.

In any event, although "the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into," *Valley Drug*, 344 F.3d at 1306, a *post hoc* assessment of the validity of the ciprofloxacin patent it would likely do plaintiffs little good. After all, the '444 Patent has withstood multiple subsequent challenges and its validity has been affirmed by the Federal Circuit.[14] At oral argument, plaintiffs asserted that the court should give little weight to these subsequent failed attacks because none of them raised what plaintiffs believe to be the most forceful attack on the '444 Patent - namely, inequitable conduct. Plaintiffs argue that this defense required extensive discovery and would take a long period of time to prepare and try, and that this explains why none of the subsequent challengers raised this issue.

But this argument is not very convincing in light of the fact that one of the challenges - Carlsbad's, on the ground of obviousness - also required extensive discovery and resulted in a nine-day bench trial. It is difficult to accept the notion that Carlsbad abandoned a stronger argument because it would have presumably required a greater effort, especially since Barr had already done most of the preparatory work on the inequitable conduct issue.

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14. Indeed, there is something anomalous about the notion that plaintiffs could collect treble damages for settlement of a litigation involving a patent that has been subsequently upheld by the Federal Circuit. Even the FTC's decision in *Schering-Plough* outlawing exclusion payments provided for prospective relief only. *Schering-Plough I*, 2003 WL 22989651, at *43.

Plaintiffs further argue that the '444 Patent that emerged from reexamination in the PTO after Bayer's settlement with Barr was much changed from the '444 Patent that Barr had challenged, insinuating that the allegedly strong inequitable conduct defense that Barr had developed would be weaker, or possibly even unavailable, in the hands of challengers of the reexamined '444 Patent. Indir. Pls.' Count V Opp'n, at 3. This is clearly wrong, since the defense of inequitable conduct was available for all the '444 Patent's post-reexamination challengers. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995) (affirming a finding of inequitable conduct, notwithstanding that the withheld reference was later cited during reexamination and the claims were allowed to issue). Thus, the ability of the patent to withstand the subsequent challenges is persuasive, and that there is little likelihood that plaintiffs here would prevail in a *post hoc* attack on the patent.

In sum, it is inappropriate for an antitrust court, in determining the reasonableness of a patent settlement agreement, to conduct an after-the-fact inquiry into the validity of the underlying patent. Such an inquiry would undermine any certainty for patent litigants seeking to settle their disputes. In addition, exposing the parties to a patent settlement agreement to treble antitrust damages simply because the patent is later found to be invalid would overstep the bright-line rule adopted by the Supreme Court in *Walker Process*, first elaborated upon by Justice Harlan in his concurrence and relied

upon by the patent bar for the past forty years. *Walker Process*, 382 U.S. at 179-80, 86 S.Ct. at 351-52 (1965).[15]

ii. The effect of the possible invalidity of the patent on the legality of the Agreements

Having resolved that the validity of the '444 Patent should not be independently assessed, the next question that needs to be addressed is how the *possibility* that the patent is invalid should affect the legality of an exclusion payment. The heart of plaintiffs' argument is that there was at least a chance that the '444 Patent was invalid and, therefore, the Agreements violated antitrust law because the patent rights they enforce derive from a potentially invalid patent. They argue that the potential invalidity of the patent translates into a potential for open competition (and, hence, lower prices), and that the possibility of realizing such open competition was unfairly foreclosed by the Agreements.

Although plaintiffs do not attempt to litigate the validity of the '444 Patent in their motion for summary judgment, or in their opposition to defendants' motions for summary judgment, they do argue that the patent's potential invalidity should be taken into account when assessing whether the anti-competitive effects of the Agreements exceed the exclusionary scope of the

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15. Indirect plaintiffs have added Count V to their complaint, alleging a state law *Walker-Process*-type claim, namely that Bayer obtained the '444 Patent through fraud and that its suit against Barr was a sham litigation. These allegations are discussed more fully in connection with Bayer's motion to dismiss, *see infra* Part 3.

patent. These arguments, plaintiffs assert, do not depend on an analysis of the '444 Patent's validity. In that regard, plaintiffs advance the reasoning of the FTC in *Schering-Plough*, now rejected by the Eleventh Circuit, and the views of several academics.

The starting point of the FTC's analysis whether the exclusion payments in that case were anti-competitive was to compare the amount of competition that occurred under the exclusion payment to "the amount of competition that was likely to occur had it not been for the payment. . . ." *Schering-Plough I*, 2003 WL 22989651, at *16. The FTC then examined and rejected Schering's defense that the restraint on trade due to the exclusion payment was ancillary to the legitimate settlement of a patent dispute, reasoning that the amount of the payment ($60 million) was too high to be "a reasonably necessary element of a settlement that is procompetitive overall." *Id.* at 21. The FTC also rejected as implausible Schering's separate justification for the payment, that it was in exchange for some licenses. *Id.* at 40. The FTC concluded that the payment was made in exchange for delayed entry, and was therefore an agreement that "unreasonably restrains commerce." *Id.*

Plaintiffs note that the FTC relied on the economic analysis advocated by Professor Carl Shapiro in his article *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391 (2003), *see* Dir. Pls.' Summ. J. App., Tab 16, in which he states that, like litigants to a patent infringement suit, consumers have an "expected" gain

from the patent challenge that equals their actual gains if the patent is invalidated, discounted by the probability of its being upheld. Dir. Pls.' Mem. at 14. The parties to the litigation, Professor Shapiro argues, should not be allowed to bargain away this assumed consumer surplus in reaching their settlement. Shapiro, 34 Rand J. of Econ. at 396 ("[A] patent settlement cannot lead to lower expected consumer surplus than would have arisen from ongoing litigation. Effectively, consumers have a 'property right' to the level of competition that would have prevailed, on average, had the two parties litigated the patent dispute to a resolution in the courts.").

This concept of a public property right in the outcome of private lawsuits does not translate well into the realities of litigation, and there is no support in the law for such a right. There is simply no legal basis for restricting the rights of patentees to choose their enforcement vehicle (*i.e.,* settlement versus litigation). Equally important, there is no duty to use patent-derived market power in a way that imposes the lowest monopoly rents on the consumer. *See, e.g., E. Bement & Sons*, 186 U.S. at 91, 22 S.Ct. at 755; *Studiengesellschaft Kohle*, 670 F.2d at 1127. Requiring parties to a lawsuit either to litigate or negotiate a settlement in the public interest, at the risk of treble damages is, as a practical matter, tantamount to establishing a rule requiring litigants "to continue to litigate when they would prefer to settle" and "to act as unwilling private attorneys general and to bear the various costs and risks of litigation." *Nestle Co., Inc. v. Chester's Market, Inc.*, 756 F.2d 280, 284 (2d Cir. 1985); *see also Times Mirror*

Magazines, Inc. v. Field & Stream Licenses Co., 103 F. Supp. 2d 711, 741 (S.D.N.Y. 2000) ("Insisting that a court review a settlement [of a trademark suit] to assure that no public confusion will result would make such agreements of little value to the parties. . . . Parties would sensibly conclude that they might better litigate the issue of confusion to conclusion rather than reach a settlement which might later be found to be unenforceable.") (quoting *T & T Mfg. Co. v. A.T. Cross Co.*, 449 F. Supp. 813, 827 (D.R.I.), *aff'd*, 587 F.2d 533 (1st Cir. 1978), *cert. denied*, 441 U.S. 908, 99 S.Ct. 2000, 60 L.Ed.2d 377 (1979)); Gen Defs. Opp. Mem. at 16 ("Plaintiffs' rule that any of these settlements can be challenged by a third party claiming 'property rights' in some litigation outcome would increase the costs of litigation and of settlement by imbuing the entire process with an additional layer of uncertainty. Litigants would fear third-party challenges to settlements based on unknowable conceptions of what 'consumer surplus' might have occurred had litigation continued."). Although plaintiffs would no doubt argue that litigation is to be preferred in these drug patent cases, as pointed out in *Cipro II*, there is no support for the view that Hatch-Waxman intended to thwart settlements. *Cipro II*, 261 F. Supp. 2d at 256.

Furthermore, even assuming some consumer surplus that the parties are bound to respect in settlement negotiations, such an interest would first have to be quantified. In seeking to calculate this consumer surplus, plaintiffs first couch their analysis in probabilistic terms, acknowledging this court's earlier

admonishment that antitrust liability cannot be predicated on the possible outcome of litigation. Dir. Pls.' Mem. at 12-23; *Cipro II*, 261 F. Supp. 2d at 202; *Schering-Plough I*, 2003 WL 22989651, at *16. In particular, plaintiffs argue that every patent has a chance of being held invalid, which should inure to the public's benefit. Dir. Pls.' Mem. at 12-23 (citing Shapiro, 34 Rand J. of Econ. at 395 ("[A] patent is best viewed as a *probabilistic* property right. What the patent grant actually gives the patent holder is the right to sue to prevent others from infringing the patent. Nothing in the patent grant guarantees that the patent will be declared valid, or that the defendant in the patent suit will be found to have infringed. ") (emphasis in original)).

To support this approach, plaintiffs resort to generalized statements about how patents fare in the courts. Dir. Pls.' Mem. at 18 ("Defendants themselves have admitted that, except in the rarest of cases, no patent stands a greater than 70% chance of being found to be valid."). This argument has some facial appeal, as it is common knowledge that many patents, once challenged, are ultimately held invalid and/or unenforceable. *See, e.g.,* Dir. Pls.' Summ. J. App., Tab 15 (John R. Allison and Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998) (showing that nearly half of all litigated patents are found to be invalid)).

Ultimately, however, this argument proves too much. To begin with the premise, as characterized by generic defendants, that every patent is "a little bit invalid,"

results in undermining the presumption of validity that Congress has afforded patents. 35 U.S.C. § 282 ("A patent shall be presumed valid."); *see* Generic Defs.' Mem. in Opp'n to Direct Purchaser Pls.' Mot. for Partial Summ. J., at 9. Moreover, this premise could have far-reaching effects on everyday patent transactions. *See Schering-Plough II*, __F.3d at __, 2005 WL 528439, at *8 ("Indeed, application of antitrust law to markets affected by the exclusionary statutes set forth in patent law cannot discount the rights of the patent holder.") (citing *Simpson v. Union Oil Co.*, 377 U.S. 13, 14, 84 S.Ct. 1051, 12 L.Ed.2d 98 (1964)). For example, whenever a patentee and accused infringer enter a settlement (usually a license agreement), the accused infringer always either explicitly or implicitly acknowledges the patent's validity, and in many cases must pay the patentee a royalty if it wishes to continue selling the infringing goods.

Although plaintiffs contend that entry with a license is preferable to no entry at all, unless the license is royalty-free, the royalty itself is a barrier to entry, anathema to unfettered competition and, depending on the royalty rate, may offer minimal benefit to the public. If the settlement with a payment to a generic is to be subject to antitrust liability, even though it does not exceed the scope of the patent, the next antitrust challenge to a patent settlement might well take place in the context of a license with royalty, a result that even Professor Shapiro would presumably disfavor. *See, e.g.*, Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. of Econ. at 395 ("[A] prohibition on settling

patent disputes cannot make sense: as noted earlier, virtually every patent license can be viewed as the settlement of a patent dispute, and settlements generally can provide many benefits not only to the settling parties but to consumers as well."). To open royalty-bearing patent license agreements to antitrust scrutiny simply because patents are often held invalid when tested in litigation would undermine the settled expectations of patentees and potential infringers/licensees across countless industries. *See In re Tamoxifen*, 277 F. Supp. 2d at 137 ("No antitrust injury can flow from the prices at which Zeneca licensed tamoxifen to Barr."); *see also Studiengesellschaft Kohle*, 670 F.2d at 1127.

Plaintiffs argue, as an alternative to the probabilistic method described above, that the potential invalidity of the patent can be inferred from the parties' behavior. Plaintiffs suggest that the settlement amount is evidence of the patent's fallibility because its value exceeds the litigation costs of fending off a challenge. Mem. of Dir. Pls. in Opp'n to Defs.' Mots. for Summ. J. at 45. Plaintiffs make the sensible argument that the higher the patentee's expectation of invalidity, the more it will be willing to pay a generic challenger to concede validity and stay out of the market. Thus, the very amount of the exclusion payment is evidence of the probable invalidity of the patent. Indeed, Bayer's own documents bear this theory out: a presentation slide prepared by Bayer's chief negotiator of the Bayer/Barr settlement contains the title, "The maximum settlement amount we should consider paying increases as the risk of losing

increases." Dir. Pls.' Summ. J. App., Tab 47B, at BCP-P-0001668A-004. It is worth mentioning that the presentation slide in question includes a graph plotting Bayer's perceived risk of losing against various dollar amounts and that the amount Bayer ultimately paid Barr (approximately $398 million) is at the 20-25 percent risk-of-loss mark.[16]

However, although direct plaintiffs contend that the amount of the exclusion payment in this case - $398 million - corresponds to a perceived chance of losing of about 50 percent, in absolute numbers Bayer's perceived chance of losing would appear to be much lower. How direct plaintiffs calculated this number is difficult to fathom,[17] especially since they cite Professor Hovenkamp's explanation of expected gains and losses in analyzing the anti-competitive effects of exclusion payments, who states: "[I]f the patentee has a 25% chance of losing, it is willing to pay up to 25% of the value of its monopoly to exclude its competitors without a trial." Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1759 (2003). Applying this model to Bayer's situation - plaintiffs submit that Bayer stood to lose more than $1.5 billion in profits if the '444 Patent was

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16. In fact, once the $398 million is converted to the then-net present value, the corresponding perceived risk of losing is even lower.

17. As their expert candidly admits, "[t] he formulae underlying these calculations are complex." Dir. Pls.' Summ. J. App., Tab 33 (Expert Rep. of Keith B. Leffler, Ph.D., at 34 n. 85).

invalidated - reveals that Bayer's payment of $398 million translates to a perceived chance of losing of 26.5 percent. Of course, Bayer's payment to Barr was likely also constrained by the maximum amount Bayer expected Barr to make if it won the lawsuit, but applying a straight "expectation" economic analysis to these facts would indicate that Bayer was relatively confident of its chances of winning at trial.[18]

Plaintiffs' point is well-taken that the greater the chance a court would hold the patent invalid, the higher the likelihood that the patentee will seek to salvage a patent by settling with an exclusion payment. If courts do not discount the exclusionary power of the patent by the probability of the patent's being held invalid, then

18. This absolute numbers "expectation" model is interesting, particularly in that it happens to line up with the graph on Bayer's presentation slide, but there is no reason to rely upon it for an analysis of the legality of Bayer's payment to Barr. Moreover, this model may be overly simplistic, in that it does not account for other factors underlying the parties' negotiations, such as the possibility that subsequent challengers might enter the market for generic Cipro. In addition, both the indirect plaintiffs and the generic defendants asserted at oral argument that such a model should not be used in assessing the legality of the payment in this case. Indirect plaintiffs argue that a better measure of Bayer's perceived chances of winning the litigation against Barr could be extrapolated from a comparison of the actual payment to Barr's anticipated profit had it won the litigation. Generic defendants, on the other hand, accept that the expectation model could be used to approximate Bayer's perceived chances of success, but assert that the legality of the payment depends not on Bayer's subjective perception of its chances, but rather only on whether the patent litigation was a sham.

the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity. This concern, on its face, is quite powerful. But the answer to this concern lies in the fact that, while the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid. *See, e.g.,* Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. Rev. 11, 25 (2004) ("In a world in which there are numerous firms willing and able to enter the market, an exit payment to one particular infringement defendant need not have significant anticompetitive effects. If there is good reason for believing the patent invalid others will try the same thing."). Moreover, it is unlikely that the holder of a weak patent could stave off all possible challengers with exclusion payments because the economics simply would not justify it. *Cf. id.* at 25 n.54 (noting "ample history of litigation among large numbers of rivals being settled with a comprehensive licensing agreement," but acknowledging that those settlements "typically did not involve exit payments, but rather cross-licenses"). It could, therefore, be expected that the market would correct for any bolstering of flagrantly invalid patents by way of exclusion payments.[19]

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19. A similar argument could be constructed for situations, unlike the one here, where infringement is the dominant issue in the underlying patent litigation. If the scope of the claims is in dispute, but arguably narrow enough that not every bioequivalent

(Cont'd)

See, e.g., Andrx Pharma., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 814 (D.C. Cir. 2001) ("Antitrust law looks at entry into the market as one mechanism to limit and deter exploitation of market power by those who may temporarily possess it. 'Existing firms know that if they collude or exercise market power to charge supracompetitive prices, entry by firms currently not competing in the market becomes likely, thereby increasing the pressure on them to act competitively.'") (quoting *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 717 n.13 (D.C. Cir. 2001)).

Plaintiffs counter that such a market correction would have no impact on the injury to the market in the period before a subsequent challenger successfully invalidates the patent. But that is true in the case of all patents, not just pharmaceutical patents. Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent. *Cf. Schering- Plough II*, __F.3d at__ , 2005 WL 528439, at *8 ("By virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products . . . did not infringe Schering's

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generic drug would infringe the patent, it could be expected that additional generic challengers would be spurred to design around the patent and file their own ANDA IVs based on non-infringement.

patent."). More significantly, this type of delay is entirely within the control of the would-be subsequent challengers, who alone decide when they will challenge the patent by filing an ANDA IV.[20]

Plaintiffs further argue that the very fact that Bayer made an exclusion payment evidences the anti-competitive nature of the Agreements because a brand-name manufacturer's exclusion payments "eliminate its expected losses under litigation - and therefore eliminate consumers' expected gains under litigation . . . ." Dir Pls.' Mem. at 17. Plaintiffs again point to the FTC's decision:

> If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.

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20. Barr filed its ANDA IV on the first day it was permitted to do so under 21 U.S.C. § 355 (j) (5) (D) (ii). *See Cipro II*, 261 F. Supp. 2d at 194. There was no legal bar to other generics filing ANOA IVs that same day or any day thereafter, although pragmatic and economic considerations may have influenced their decision to wait at least until Barr's challenge had concluded before launching their own attacks on the '444 Patent. This is because if Barr were successful, the marketing approval for other generics would be withheld until Barr's 180-day exclusivity period expired.

Schering-Plough I, 2003 WL 22989651, at *16. The problem with this argument is that, due to the disparity between the brand-name manufacturer's and generic challenger's expected profits, there might not be any date that represents a reasonable litigation compromise for early (pre-patent expiration) entry by the generic challenger. The FTC acknowledges that "[t]he anticipated profits of the patent holder in the absence of generic competition are greater than the sum of its profits and the profits of the generic entrant when the two compete." *Id.* Thus, for each day of early (royalty-free) entry by the generic challenger, the brand-name manufacturer will lose many times more in expected profits than the generic challenger will gain. This is, of course, the reason why brand-name manufacturers make exclusion payments rather than granting a license. There simply is no otherwise reasonable litigation compromise.

Moreover, plaintiffs' assertion that Bayer's payment to Barr is anti-competitive because, without it, Bayer and Barr would have agreed on an earlier entry date for Barr or would have otherwise fashioned a more pro-competitive agreement must also fail. This assertion ignores the fact that, if defendants were within their rights (more specifically, the patent right) in reaching the settlement they did, consumers have no right to second-guess whether some different agreement would have been more palatable. *See, e.g., Verizon Comm'n Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16, 124 S.Ct. 872, 883, 157 L.Ed.2d 823 (2004) ("The Sherman Act . . . does not give judges carte

blanche to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition."). In sum, Bayer and Barr cannot be penalized just because plaintiffs can imagine a more pro-competitive settlement, if the agreement they did reach does not adversely affect competition beyond the scope of the '444 Patent.[21]

Finally, plaintiffs argue that Congress granted only a rebuttable presumption of validity, not a conclusive

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21. Candor requires that I recognize that this conclusion is, to some extent, inconsistent with the view expressed in *Cipro I* regarding the motions to remand, where the opinion stated:

> A review of [plaintiffs'] allegations makes plain that plaintiffs have asserted at least one theory by which they may establish state antitrust violations without resorting to a determination of patent law. Plaintiffs' complaints allege there would have been generic competition in the market for ciprofloxacin prior to the expiration of Bayer's patent if Bayer had not reached an unreasonably anticompetitive agreement with Barr, HMR, and Rugby . . . [Plaintiffs] asserted that, as a matter of fact, Bayer would have authorized Barr to distribute ciprofloxacin by granting Barr a license, or by other means, had Barr not agreed to drop its challenge to the validity of the '444 patent in exchange for large cash payments.

Cipro I at 748.

Upon further reflection, I have concluded that patent law imposes no such restriction against cash payments by a patent holder, and, accordingly, antitrust law does not impose such a restriction.

presumption, and that by making a payment, Bayer is buying that which Congress declined to grant. This argument was explicitly rejected by the Eleventh Circuit in *Valley Drug*:

> We cannot conclude that the exclusionary effects of the Agreements not to enter the market were necessarily greater than the exclusionary effects of the '207 patent merely because Abbott paid Geneva and Zenith in return for their respective agreements. If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. The failure to produce the competing terazosin drug, rather than the payment of money, is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.

Valley Drug, 344 F.3d at 1309.

The FTC held that the Schering-Plough exclusion-payment patent settlements violated Section 5 of the Federal Trade Commission Act, *Schering-Plough I*, 2003 WL 22989651, at *43, but specifically exempted from antitrust scrutiny settlements involving only an early entry date. *Id.* at 19 ("Under the standard we adopt here, if the parties simply compromise on the entry date, standing alone, they do not need to worry about a later

antitrust attack."). The difficulty with this approach is that it is not clear that consumers would benefit more from such an arrangement than from an exclusion-payment settlement like the one here. Presumably, the parties to a Hatch-Waxman patent litigation could settle on an early entry date with a license calibrated to achieve a similar financial result to the parties as an exclusion payment. In response to questions on this point at oral argument, indirect plaintiffs and generic defendants agreed that some sort of license, such as an exclusive license for a limited geographic area, "theoretically" could have been negotiated that would, as between the parties, approximate the effect of an exclusion payment. Indir. Pls.' Resp. to the Court's Questions, at 3; Gen. Defs.' Resp. to the Court's Feb. 22, 2005 Questions, at 4. Bayer and Barr, however, focused as they were on defeating plaintiffs' theory that, absent the payment, Bayer and Barr would have agreed on an earlier entry date, were reluctant to concede the point. As Professor Hovenkamp points out,

> In a perfectly functioning market without transaction costs, a monopoly producer would be indifferent between producing everything itself and simply 'licensing' another to make part of its production. The license fee would be the monopoly markup, output would remain at the monopoly level as it would in any perfect cartel agreement, and the monopolist would earn the same profits, although part of them would be paid as license fees rather than as markup on goods that it

> produced. If all parties were completely certain that a patent was valid and infringed, a patentee would have precisely the same set of incentives. It would either produce all output under the patent itself, or else it would license some output to a rival, earning the monopoly profits as royalties. Assuming zero transaction costs, however, a firm in that position would have no incentive whatsoever to pay another firm to stay out of the market. It could exclude without paying anything at all.

Hovenkamp, 87 Minn. L. Rev. at 1750-51.

Assuming the soundness of Professor Hovenkamp's analysis (and it is hard to see how it can be contested), if the monopolist's profit margins are extraordinarily high, the royalty on an early-entry license could be so high that the generic company's prices would be no lower than the brand-name manufacturer's. In this case, given Bayer's projected price drop of 95 percent a year in the future, it is reasonable to infer that Bayer's profit margin for Cipro was in excess of 95 percent.[22] In fact, plaintiffs concede that the terms of Bayer's six-month license to Barr called for an 85 percent royalty, but they complain that the license did not benefit consumers

22. Indirect plaintiffs also allege in their pleadings that Bayer maintained an exceptional profit margin for Cipro: "Bayer's 1999 United States gross sales of Cipro were approximately $1.04 billion and its net sales (or profits) were in excess of $920 million." Indir. Pls.' Second Am. Consol. Class Action Compl. ¶ 70.

because the royalty was so high. Indir. Pls.' Sherman Opp'n, at 26. Indeed, indirect plaintiffs argue that a drug can only be considered "generic" if it is priced at least at a ten percent discount to its branded counterpart at the end-payer level, a standard that was not met by Barr's selling price under the six-month license from Barr, because the 85 percent royalty was paid at the wholesale, not retail, level. Thus, outlawing exclusion payment settlements in favor of early-entry licenses would not necessarily result in a public benefit or satisfy plaintiffs, unless royalty rates are also constrained. Such constraints on patent holders are, of course, impermissible. *See, e.g., E. Bement & Sons*, 186 U.S. at 91, 22 S.Ct. at 755 ("[T]he general rule is absolute freedom in the use or sale of rights under the patent laws of the United States. . . . The fact that the conditions in the contracts [for patent licenses] keep up the monopoly or fix prices does not render them illegal."); *Studiengesellschaft Kohle*, 670 F.2d at 1127 ("A patentee has the right to exclude others from profiting from the patented invention. This includes the right to suppress the invention while continuing to prevent all others from using it, to license others, or to refuse to license, and to charge such royalty as the leverage of the patent monopoly permits.") (citations omitted).

And even if royalty rates were suppressed so as to preserve some consumer benefit, at some point the interests of the patent holder and the generic would diverge so that settlement would be impossible and continued litigation the only viable course. While plaintiffs may view this as a desirable outcome, as noted,

the Eleventh Circuit vacated and set aside the FTC's opinion in *Schering-Plough* as inconsistent with the Eleventh Circuit's holding in *Valley Drug* that "[s]imply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law," unless the "exclusionary effects of the agreement" exceed the "scope of the patent's protection." *Schering-Plough*, __F.3d at__ , 2005 WL 528439, at *17.

A significant issue before the FTC was Schering's affirmative defense that the agreements to delay entry were ancillary to the legitimate settlement of a patent dispute. *Schering-Plough I*, 2003 WL 22989651, at *9, 20. Before measuring the anti-competitive impact of the agreements against the scope of the patent, the Eleventh Circuit reviewed the FTC's determination that Schering's payments to the generic companies were not *bona fide* royalty payments under the licenses Schering obtained from the generics, noting that "[t]he FTC concedes that its position fails if it cannot prove a direct causal link between the payments and the delay [in the generics entering the market]." *Id.*, __F.3d at__ , 2005 WL 528439, at *10. After rejecting the FTC's determination as "not supported by law or logic," the Eleventh Circuit then characterized the aspect of the agreements dealing with the delay in generic marketing as "ancillary restraints" which are "secondary and collateral to an independent and legitimate transaction." *Id.*, F.3d at 2005 WL 528439, at *14. Noting that such ancillary restraints "are generally permitted if they are reasonably necessary toward the contract's objective of

utility and efficiency," the Eleventh Circuit found that the delay provisions were appropriately narrow, as they reached only products that were covered by Schering's patent. *Id.*

Plaintiffs point to the Eleventh Circuit's lengthy discussion of whether the payments were *bona fide* royalty payments as a disavowal of a rule that any payment from the patent holder for a competitor's exclusion that is within the scope of the patent is exempt from antitrust scrutiny. Letter from Steve D. Shadowen dated 3/15/2005, at 2-3. Instead, plaintiffs view that discussion as expressing agreement with plaintiffs' position that such payments in exchange for delay do in fact exceed the scope of the patent. *Id.* A more plausible explanation for the Eleventh Circuit's in-depth treatment of the bona fide royalty question is that the discussion framed the issue of whether the delay aspects of the agreements were ancillary restraints or not. Indeed, the Eleventh Circuit's endorsement of a rule permitting exclusion payments that do not exceed the scope of the patent could hardly be clearer:

> We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the assymetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement. An exception cannot lie . . . when the issue turns on validity

> (*Valley Drug*) as opposed to infringement (the Schering agreements). The effect is the same: a generic's entry into the market is delayed. What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection. Here, we find that the agreements fell well within the protections of the '743 patent, and were therefore not illegal.

Schering-Plough II, __F.3d at__ , 2005 WL 528349, at *17 (citations and internal quotation marks omitted).

Plaintiffs also argue that the Eleventh Circuit's concluding admonition that there is a need "to evaluate the strength of the patent," *Schering-Plough II*, __F.3d at __, 2005 WL 528349, at *17, bolsters plaintiffs' argument that the potential invalidity of the '444 Patent should be taken into account when measuring the exclusionary scope of the patent. Letter from Joseph Lipofsky dated 3/14/2005, at 1-2. In the context of both the opinion as a whole and the controlling precedent of *Valley Drug*, this admonition is more fairly read as requiring an evaluation of the scope of the patent's claims, and not a *post hoc* analysis of the patent's validity, an approach which, as discussed *supra* at Part (1) (b) (i), has not been endorsed by any court other than the *Valley Drug* district court on remand.

To summarize, it would be inappropriate to engage in an after-the-fact analysis of the patent's likely

validity.[23] Nor is it appropriate to discount the exclusionary power of the patent by any probability that the patent would have been found invalid. Moreover, the FTC's now-vacated rule that exclusion payments beyond litigation costs are always illegal should be rejected because it ignores the justified needs of the patent holder in the face of the risks of litigation, especially in an arena where it is well-known that courts are far from error-free.[24] The test for determining the validity of the so-called reverse or exclusion or exit

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23. Of course, as previously discussed, such an inquiry would hardly redound to plaintiffs' benefit, given that the '444 Patent has already been upheld by the Federal Circuit once, that three other attacks have failed and that only a speculative attack is proposed by the plaintiffs here. *See supra* Part 1(b) (i).

24. At least two commentators have suggested that, "[f] or purposes of antitrust analysis, there are and can be no 'wrong' decisions reached by courts in patent litigation . . . [because] [t]he substantive rights granted by Congress to patent holders are those rights . . . which a federal court determines, through congressionally prescribed process, that the patent holder possesses. Because there are no 'wrong' results generated by the patent litigation process, the patent holder improperly enlarges the innovation reward granted to him by Congress when he buys 'insurance' - in the form of exclusion of a competitor – against a 'wrong' result in the patent litigation." Keith B. Leffler and Cristofer I. Leffler, *Want to Pay a Competitor to Exit the Market? Settle a Patent Infringement Case*, 2 ABA Economics Committee Newsletter 26 (Spring 2002). The fallacy of this argument is that it leads to the inevitable conclusion that it is always improper for a patentee to insure against an unfavorable result by paying for a competitor's exclusion. All hedging by patentees - that is, all patent settlements - are now suspect.

payment and the only question remaining is whether the Agreements constrained competition beyond the scope of the patent claims. Here, the only serious argument plaintiffs have raised in that regard is possible manipulation of the l80-day exclusivity period by Barr. However, the theory was fully briefed and disposed of in the *Cipro II* decision and need not be decided anew here. *Cipro II,* 261 F. Supp. 2d at 243-47. In short, Barr's amendment of its ANDA IV to an ANDA III cleared the way for subsequent generic companies to mount challenges to the '444 Patent, an eventuality that was borne out. At least four generic companies filed ANDA IVs after Bayer and Barr entered the Agreements, so it cannot be reasonably argued that the Agreements created a bottleneck to future generic challenges.

Plaintiffs complain that they have been doubly harmed by the Agreements: first by the exclusion of Barr from the market, and second by Bayer's passing on the cost of the settlement payment in the form of increased prices for Cipro. However, if the Agreements themselves do not exceed the exclusionary power of the '444 Patent, any increased prices resulting from the Agreements are the result of the monopoly inherent in the patent. Indeed, "an exclusion of competitors and charging of supracompetitive prices are at the core of the patentee's rights, and are legitimate rewards of the patent monopoly." *Studiengesellschaft Kohle*, 670 F.2d at 1128 (citing *Brulotte v. Thys Co.*, 379 U.S. 29, 33, 85 S-.Ct. 176, 179, 13 L.Ed.2d 99 (1964) (dictum); *Zenith Radio Corp. v. Hazeltine Research, Inc.,* 395 U.S. 100, 136, 89 S.Ct. 1562, 1583, 23 L.Ed.2d 129 (1969)). Of course,

market forces may impose some limits on the prices a patentee can charge. At some point, additional competitors will be spurred to either challenge the patent or design around it, or consumers will find a more affordable (although perhaps less desirable) alternative. *See, e.g., Andrx v. Biovail,* 256 F.3d at 814.

To conclude, in the absence of any evidence that the Agreements created a bottleneck on challenges to the '444 Patent, or that they otherwise restrained competition beyond the scope of the claims of the '444 Patent, the Agreements have not had any anti-competitive effects on the market for ciprofloxacin beyond that which are permitted under the '444 Patent. The fact that Bayer paid what in absolute numbers is a handsome sum to Barr to settle its lawsuit does not necessarily reflect a lack of confidence in the '444 Patent, but rather the economic realities of what was at risk. There is simply no precedent for plaintiffs' argument that the parties to a settlement are required to preserve the public's interest in lower prices. Such a rule would only result in parties being less likely to reach settlements, aside from undermining well-settled principles of patent law. Finally, to even attempt to quantify the public's interest in a patent settlement between private parties would require devaluing patents across the board, a result that would contravene the presumption of validity afforded by Congress and impact the very way patent licenses are handled in countless daily transactions.

Because plaintiffs have not shown that the Agreements had anti-competitive effects beyond the

scope of the '444 Patent, it is not necessary to address the second and third steps of the rule-of-reason analysis - whether defendants can establish the "pro-competitive redeeming virtues" of the Agreements, and whether plaintiffs can "show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition." *K.M.B. Warehouse*, 61 F.3d at 127.

(2)

Consumer Antitrust Standing

As the law now stands, the validity of a patent may be challenged only by an alleged infringer as an affirmative defense or counterclaim to an infringement action brought by the patentee, or by a declaratory judgment plaintiff, who must show

> (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken by the declaratory judgment plaintiff with the intent to conduct such activity.

Teva Pharma. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1330 (Fed. Cir. 2005). Therefore, at present, non-infringing consumers of patented products who may feel

that they are being charged supracompetitive prices by the patentee have no cause of action to invalidate the patent.

It is also apparent that Congress did not intend to change the standing requirements for actions to invalidate patents when it passed, and still more clearly when it later amended, the Hatch-Waxman Amendments in 2003. *See* Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, entitled "Access to Affordable Pharmaceuticals" ("Medicare Amendments"). Indeed, in the Medicare Amendments, which were passed on December B, 2003, after the issues revolving around exclusion-payment and other settlements between brand-name manufacturers and generics had already surfaced, Congress provided for explicit forfeiture of the 180-day exclusivity period that would otherwise be enjoyed by the first filer of an ANDA IV if the first filer settles its suit with the brand-name manufacturer, but only if the Federal Trade Commission or the Attorney General obtains a final decision from the Federal Trade Commission or a court that the agreement between the first filer and the brand-name manufacturer has violated the antitrust law. *See* 21 U.S.C. 355(j) (5) (D) (i) (V) (Supp. 2004).[25] Notably,

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25. The subsection reads

> **(V) Agreement with another applicant, the listed drug application holder, or a patent owner**
>
> The first applicant [forfeits its 180-day exclusivity period if it] enters into an agreement with another

(Cont'd)

Appendix C

Congress made no provision for loosening the standing requirements for challenging patents or even for forfeiture of the 180-day exclusivity period where the antitrust complaint is brought by consumers.

Given that consumers are often subjected to monopoly prices for invalid patents, it is tempting to suggest that, as a policy matter, a rule should be fashioned giving consumers of drugs - and perhaps patented goods generally - the right to challenge the validity of patents. In other words, plaintiffs should be afforded the opportunity to challenge the exclusion-payment scheme at issue here - and licensing arrangements as well - by folding in a predicate challenge to the underlying patent itself. Under the proposed rule, the consumers would have to show by clear and convincing evidence - as accused infringers must - that the subject patent was invalid. This proposal would have

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> applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2) (A) (vii) (IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

the effect of allowing non-infringing consumers of a patented product to seek to invalidate the patent in order to allow price-reducing competitors to enter the market. The desirability of such a change is a complex issue which is not within the competence of judges. A thorough examination of the consequences of such a change would have to be made. For example, would such a change negatively impact the willingness of drug manufacturers to invest in research and development? Should consumers be permitted to recover punitive damages for the overcharges they have suffered? As Justice Harlan noted, patents are often set aside for any number of technical reasons. *Walker Process*, 382 U.S. at 179-80, 86 S.Ct. at 351-52. Perhaps permitting only declaratory relief, together with attorneys' fees, would solve the problem of unduly punishing those who in good faith sought patents that ultimately were shown to be invalid. Another possible alternative is to limit the consumer recovery to the amount of the monopolistic overcharges. These questions lead to the inevitable conclusion that such a change in public policy should be made by Congress, and not by the courts.

(3)

Bayer's Motion to Dismiss Count V of Indirect Plaintiffs' New Complaint

Recognizing that the ultimate vindication of the '444 Patent might immunize the Agreements from antitrust scrutiny under the rule of reason, indirect plaintiffs amended their complaint to add charges that would strip

Bayer of its patent immunity. Indir. Ps.' Mem. of Law in Opp'n to Bayer's Mot. for Partial Summ. J. on Count V, at 1. Six months after summary judgment motions were decided in *Cipro II*, indirect plaintiffs moved to amend their complaint to add claims that Bayer violated state antitrust and/or consumer protection laws by virtue of alleged inequitable conduct before the PTO in procuring the '444 Patent and alleged sham litigation in enforcing the '444 Patent against Barr. Indir. PIs.' Second Am. Consolo Class Action Compl., ¶¶ 296-308. The substance of this new count of the complaint, Count V, is that Bayer made a series of misrepresentations to the PTO in order to secure issuance of the '444 Patent, and then, with knowledge that the patent was invalid and had been fraudulently procured, asserted the patent against Barr even though no reasonable litigant in Bayer's position "at the time of its settlement with Barr" could have expected to win the litigation. Indir. PIs.' Second Am. Consolo Class Action Compl., ¶ 305. Bayer moves to dismiss Count V on two threshold grounds: that it is preempted by federal patent law and barred by the statute of limitations.

Ordinarily, antitrust claims premised on the enforcement of a fraudulently procured patent are brought by an accused infringer as a counterclaim to the original charge of infringement. *See, e.g.*, *Nobelpharma*, 141 F.3d at 1067 ("[A]n antitrust claim premised on stripping a patentee of its immunity from the antitrust laws is typically raised as a counterclaim by a defendant in a patent infringement suit.") Indirect plaintiffs' claims are unusual, both because they are

brought by indirect purchasers of the patented item and because they are asserted under state law. Whatever the reasons for indirect plaintiffs bringing *Walker Process* and sham litigation claims under state law, those claims are preempted by federal patent law and must, therefore, be dismissed.

28 U.S.C. § 1338(a) grants federal district courts exclusive jurisdiction over "any civil action arising under any Act of Congress relating to patents . . . ." Thus, if indirect plaintiffs' state law *Walker Process* and sham litigation claims "arise under" patent law, they may only be heard in federal court.[26] The Supreme Court elucidated what it means for a claim to "arise under" patent law in *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809-11, 108 S.Ct. 2166, 100 L.Ed.2d 811 (1988). Under the well-pleaded complaint rule, plaintiffs' claim must be judged solely on the face of the complaint, without reference to any anticipated defenses; unless patent law is necessary to each and every theory under the claim, § 1338(a) jurisdiction will not be invoked. *Id.*

Here, indirect plaintiffs' Count V rests entirely on patent law. If indirect plaintiffs cannot prove that Bayer

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26. Although the fact that a state law cause of action may only be heard in federal court does not necessarily mean that it is preempted by federal law, *see Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1334 (Fed. Cir. 1998), *overruled on other grounds by Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1358-59 (Fed. Cir. 1999), the inquiries are closely related and in certain circumstances do overlap.

intentionally withheld or misrepresented material information to the PTO during prosecution of the '444 Patent, their *Walker Process* and sham litigation claims cannot survive. Specifically, "[a] finding of *Walker Process* fraud requires higher threshold showings of both intent and materiality than does a finding of inequitable conduct. . . . [and] must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, *i.e.*, that the patent would not have issued but for the misrepresentation or omission." *Nobelpharma*, 141 F.3d at 1070-71. There is simply no theory for proving a *Walker Process* antitrust violation in this case that would not require a showing of misconduct before the PTO. Furthermore, the Federal Circuit has held that "whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law." *Id*. at 1068 (*en banc* in relevant part). And while sham litigation could theoretically be shown by assertion of a patent known to be valid but not infringed, such a theory is not available in this case, where Barr admitted infringement, not just as part of the post-settlement consent judgment, but in the July 25, 1996 Stipulation and Order, entered long before the Agreements were ever negotiated. *See* Bayer Sherman Act App., Ex. 5 (Stipulation and Order (Barr's stipulation that it infringed the '444 Patent)). Indeed, Barr never contested infringement of the '444 Patent, even in its December 6, 1991 Paragraph IV detailed statement which triggered the Bayer/Barr patent litigation. Bayer Sherman Act App., Ex. 2.

The fact that indirect plaintiffs' Count V not only arises out of patent law, but rests entirely on patent law, leads to two conclusions. First, jurisdiction over Count V lies exclusively in federal court. 28 U.S.C. § 1338(a); *Christianson*, 486 U.S. at 809-11; *cf. Cipro I*, 166 F. Supp. 2d at 750-51 (holding that remand was appropriate where plaintiffs had "pleaded at least one theory under which their claims for relief may be resolved without determining the validity of Bayer's patent"); *but see Williams v. Del Monte Fresh Produce Co.*, 325 F. Supp. 2d 855, 858-60 (M.D. Tenn. 2004) (remanding to state court state law claims predicated on fraudulent procurement and enforcement of a patent, where patentee admitted invalidity of patent, thus obviating the need for the state court to adjudicate the federal question). Second, federal patent law preempts any state antitrust cause of action premised on Bayer's alleged bad faith conduct before the PTO because Count V does not allege any conduct other than conduct before the PTO. In other words, the state law remedies invoked by indirect plaintiffs are directed to allegedly tortious conduct before the PTO, not tortious conduct in the marketplace. *Cf. Hunter Douglas*, 153 F.3d at 1334; *Dow Chem. Co. v. Exxon Corp.*, 139 F.3d 1470, 1477 (Fed. Cir. 1998).

Indirect plaintiffs' Count V allegations parallel the abuse of process counterclaim brought in *Abbott Labs. v. Brennan*, 952 F.2d 1346 (Fed. Cir. 1992). There, the Board of Patent Appeals and Interferences awarded priority of invention in an interference proceeding to Brennan, even though Abbott had first conceived and

reduced the invention to practice because Abbott's attorney had backdated a request for extension of time and falsely averred that the request had been timely made. *Id*. at 1348. Abbott brought a civil action in district court seeking to set aside the award of priority to Brennan, and Brennan counterclaimed for, *inter alia*, the state law tort of abuse of process. The Federal Circuit reversed the judgment of abuse of) process, concluding "that the federal administrative process of examining and issuing patents, including proceedings before the PTO's boards, is not subject to collateral review in terms of the common law tort of abuse of process." *Id*. at 1357. The court reasoned that "[a]n additional state action would be an inappropriate collateral intrusion on the regulatory procedures of the PTO, 'under the guise of a complaint sounding in tort,' and is contrary to Congress' preemptive regulation in the area of patent law." *Id*. (quoting *Gilbert v. Ben-Asher*, 900 F. 2d 1407, 1411 (9th Cir. 1990)).

The allegations of Count V differ from the state law claim for unfair competition that was not preempted by federal law in *Dow*. There, Dow alleged that Exxon had threatened to sue actual and prospective Dow customers for patent infringement, even though Exxon allegedly had no good-faith belief that Dow infringed the patent when Exxon made the threats and had allegedly obtained the patent by inequitable conduct. *Dow*, 139 F.3d at 1472. The court held that the claim was not preempted because the tort claim was "not premised upon bad faith misconduct in the PTO, but rather [was] premised upon bad faith misconduct in the

marketplace." *Id*. at 1477. The marketplace misconduct in Dow was Exxon's threats to Dow's customers, not activity that occurred before the PTO or in the context of a litigation. *Id*. at 1472. Indirect plaintiffs' Count V does not allege any malfeasance in the marketplace such as threats to Barr or its customers, but instead rests entirely upon actions that occurred before the PTO. Because the allegations of Count V are coextensive with patent law, they are preempted by patent law. *See, e.g.*, *Semiconductor Energy Lab. Co., Ltd. v. Samsung Elecs. Co. Ltd*., 204 F.3d 1368, 1382 (Fed. Cir. 2000) (affirming dismissal of state RICO counterclaims that "occupy a field identical in scope with the inequitable conduct defense," and noting that "[a]n additional state cause of action predicated so squarely on the acts of inequitable conduct would be 'contrary to Congress' preemptive regulation in the area of patent law.'") (quoting *Abbott*, 952 F.2d at 1357).[27]

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27. Indirect plaintiffs point to a number of cases in which state law causes of action predicated on bad faith procurement of patents have been allowed to go forward. Those cases do not alter the analysis, as none of them addresses preemption of state law *Walker Process* or sham litigation claims. For example, *In re Relafen Antitrust Litig*., 221 F.R.D. 260 (D. Mass. 2004), deals with class certification issues, and makes only passing reference to one allegation that the defendants "entered the market under the banner of a patent procured by fraud." *Id*. at 266. The court's analysis was limited to a determination of whether the requirements of Rule 23 were met, and it did not consider the merits of the case. *Id*. at 265. In subsequent opinions, the *Relafen* court clarified that the indirect plaintiffs in that case were pursuing their *Walker Process* claims as assignees of the rights of several national wholesalers (*i.e.*,

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Appendix C

The only conduct not directly referable to the PTO that indirect plaintiffs point to as an instance of marketplace "maintenance" of the '444 Patent is Bayer's compulsory listing of the '444 Patent in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," or the "Orange Book," as required under 21 U.S.C. § 355 (b) (1). Indir. Pls.' Second Am. Consolo Class Action Compl., ¶ 243; Indir. Pls.' Responses to the Court's Questions for Oral

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direct purchasers), and their claims were therefore not barred by *Illinois Brick*. *See In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 368 (D. Mass. 2004); *In re Relafen Antitrust Litig.*, 2005 WL 418086, at *17, *21 (D. Mass. Feb. 22, 2005). Significantly, none of the *In re Relafen* opinions discusses whether state law *Walker Process* claims are preempted. In both *Intel Corp. v. Via Techs., Inc.*, 2001 WL 777085, at *6 (N.D. Cal. Mar. 20, 2001) and *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 549 (D.N.J. 2000), district courts allowed state law claims to proceed where the only ground on which the parties moved to dismiss was that the state law claims were dependent on the survival of related federal antitrust claims, which were not dismissed. Similarly, in *FDI, Inc. v. W.R. Grace & Co., Inc.*, 1980 WL 1996, *3-4 (C.D. Cal. Sept. 29, 1980), the court refused to grant summary judgment on portions of plaintiff's federal *Walker Process* antitrust and related unfair competition claim based on the same allegations, although preemption is not discussed in the opinion. Thus, although indirect plaintiffs have cited several cases in which state law claims based at least in part on misconduct before the PTO have been permitted to proceed, they have at least to some extent involved non-PTO conduct. In any event, none of them is binding precedent, and none of them cites any reason why such claims are not preempted by federal patent law.

Argument, 2/28/2005. They cite *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 369-73 (S.D.N.Y. 2002), in support of the proposition that such Orange Book filings can be used as a basis for a state law action. The issue before the court in *Buspirone* was whether the Orange Book filings were protected activity under the *Noerr-Pennington* doctrine. *See Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965). The district court held that the filings were not protected under *Noerr-Pennington*, but did not say one way or the other whether Orange Book listings constitute marketplace activity subjecting patent holders to state law antitrust remedies where the underlying alleged bad-faith conduct occurred before the PTO.

Even were one to assume that the Orange Book filing of the '444 Patent would provide a basis for a state law claim, this would not advance plaintiffs' cause here. There was nothing in the act of listing the '444 Patent in the Orange Book that was itself improper, *cf. In re Buspirone*, 185 F. Supp. 2d at 369-73, and the filing, according to plaintiffs, was only improper because Bayer was using it to maintain an allegedly ill-gotten patent. But this claim in turn depends first on a showing that the '444 Patent was obtained by fraud on the PTO. Plaintiffs cannot by this collateral or backdoor method avoid preemption of their state law claim.[28]

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28. ssuming that the mere listing in the Orange Book constituted marketplace misconduct, it is highly unlikely that (Cont'd)

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indirect plaintiffs would be able to establish a *Walker Process* claim. Initially, *Walker Process* fraud requires a showing that the omission or misrepresentation to the Patent Office was so material that the patent would not have issued but for the omission or misrepresentation (a level of materiality referred to as "but for" materiality); consequently, a patent must be invalid before it can be a candidate for *Walker Process* fraud. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1365 (Fed. Cir. 1998) ("Indeed, since the inventorship issue was not grounds of invalidity, it cannot satisfy the "but for" test of fraud."); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070 (Fed. Cir. 1998) ("Such a misrepresentation or omission must evidence a clear intent to deceive the examiner and thereby cause the PTO to grant an *invalid* patent.") (emphasis added). In contrast, because the patent litigation defense of inequitable conduct does not require so high a level of materiality, it is possible for a patent to be unenforceable for inequitable conduct, but still valid. *See, e.g., Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1237 (Fed. Cir. 2003) (citing *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1322 (Fed. Cir. 2000). Indirect plaintiffs' reliance on *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341 (Fed. Cir. 2004) for the proposition that the materiality requirement for a showing of *Walker Process* fraud is met by simply pointing to the PTO's issuance of a patent is a gross misreading of the law. First, *Unitherm* did not depart from the standard set forth in *Nobelpharma* for showing "but for" materiality, and concluded: "Had the PTO not relied on this fraud, the Examiner would have reached the same conclusion as did the district court and this court . . . that no *valid* patent could issue from [the] application." *Unitherm*, 375 F.3d at 1361 (emphasis added). Second, if plaintiffs' assertion were correct – that simple issuance of a patent is sufficient to prove "but for" materiality - then the standard for proving *Walker Process* fraud materiality would be lower than the showing required for inequitable conduct and would, in fact, be met in every

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Even if plaintiffs had made a sufficient showing of marketplace misconduct by Bayer in enforcing its '444 Patent to create an issue of fact, there is a serious question whether indirect plaintiffs have standing to

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case. Such a conclusion is directly contrary to the Federal Circuit's holding in *Nobelpharma* and is not supported by *Unitherm*.

Furthermore, indirect plaintiffs cite eight instances of improper conduct before the PTO. Some have already been rejected by Judge Brewster as failing to establish invalidity (*see Bayer AG v. Carlsbad Tech., Inc.*, No. 01-cv-0867-B, slip op. at 6-7 (S.D. Cal. June 7, 2002)), some by the PTO during reexamination (Bayer Pat. App. Ex. 9) and others have been conceded as not rising to the level of "but for" materiality. More importantly, indirect plaintiffs did not adduce evidence of "but for" materiality for seven of these instances. The only instance for which their expert opined "but for" materiality was a claim that Bayer's statements regarding the superiority of the "compounds of the invention" to the prior art was misleading, because Bayer withheld data showing that certain of the claimed compounds were not, in fact, superior to the prior art. Lawyer advocacy or puffery is not a basis for granting or denying a patent claim. Superiority is not the issue. What is required instead is a showing of novelty and non-obviousness for a patent to issue, 35 U.S.C. §§ 102, 103, and for that the patent examiner is presumed to have relied on data, not attorney advocacy. *Cf. CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) ("During prosecution, an applicant may submit objective factual evidence to the PTO in the form of patents, technical literature, and declarations. . . . The advantages advocacy in this case does not fit any of these categories and was unaccompanied by and not asserted to be supported by any factual evidence. Therefore, a reasonable examiner would not have found it important in deciding whether to allow the application.")

assert a *Walker Process* claim. In *Asahi Glass*, Judge Posner, in *dicta*, assumed that a *Walker Process* claim is only available to a patentee's competitors. *Asahi Glass*, 289 F. Supp. 2d at 995 ("The claim of fraud on the patent office fails for the reason just given: if patent 723 was obtained by fraud, it was a fraud aimed at competing manufacturers of drugs, not at the suppliers of those manufacturers, and so the fraud claim cannot be pressed as an antitrust claim."). This view was earlier expressed by Judge Markey, later of the Federal Circuit, sitting by designation in *Oetiker v. Jurid Werke GmbH*, 671 F.2d 596, 599 (D.C. Cir. 1982) ("The Supreme Court has established that one guilty of fraudulent procurement and attempted enforcement of the patent thus procured may be liable for treble damages to *competitors* under the anti trust laws.") (citing *Walker Process*, 382 U.S. 172) (emphasis added). *See also In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 529 (D.N.J. 2004) ("*Walker Process* and its progeny involve antitrust counterclaimants who were potential or actual competitors in patent infringement suits. In this case, Plaintiffs, as direct purchasers, neither produced mirtazapine nor would have done so; moreover, Plaintiffs were not party to the initial patent infringement suits. Plaintiffs may not now claim standing to bring a *Walker Process* claim by donning the cloak of a Clayton Act monopolization claim.").

Finally, Bayer moves for summary judgment that Bayer's suits against Barr and the subsequent '444 Patent challengers were not sham litigation as a matter of law. To prove sham litigation, a plaintiff must show

(1) "the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits," and (2) that the litigant's "subjective motivation" for bringing the action was a sham seeking to conceal a knowing attempt to interfere with a competitor. *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61, 113 S.Ct. 1920, 1928, 123 L.Ed.2d 611 (1993). Here, Bayer's success in its litigations against Schein, Mylan and Carlsbad forecloses any argument that its lawsuits were shams. *See id.*, 508 U.S. at 61 n.5, 113 S.Ct. 1928 n.5 ("A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham."). Indirect plaintiffs' argument that Bayer's successes in the post-Barr litigations are immaterial, since the '444 Patent had by then undergone reexamination, is unconvincing. As discussed *supra*, reexamination does not cure inequitable conduct, and the defense was available to all of the generic challengers. *Molins v. Textron*, 48 F.3d at 1182.

In any event, as Bayer's motion to dismiss Count V is granted on the preemption ground, it is not necessary to reach the question of whether indirect plaintiffs' state law *Walker Process*-type claims and sham litigation claim are barred by the statute of limitations.

Appendix C

Conclusion

Applying a rule of reason analysis, the first element antitrust plaintiffs must prove is that the challenged agreements had an actual adverse effect on competition in the relevant market. Here, plaintiffs have failed to demonstrate anti-competitive effects in the market for ciprofloxacin because, although the Agreements undoubtedly restrained competition, they did not do so beyond the scope of the claims of the '444 Patent. The '444 Patent allows a zone of exclusion within the bounds of its claims, and that zone is undiminished by any potential invalidity of the claims. This result is compelled by the presumption of validity Congress accorded patents and the destabilizing effect on patent law that a contrary decision would work. Any readjustment of the competing interests affected by exclusion payments is a matter better addressed by Congress than the courts.

For the foregoing reasons,

- Bayer's Motion for Partial Summary Judgment on Plaintiffs' Claims Under the Sherman Act and Corresponding State Law Claims is granted;

- Generic Defendants' Motion for Summary Judgment is granted;

- Direct Purchaser Plaintiffs' Motion for Partial Summary Judgment is denied;

- Bayer's Motion to Dismiss Count V of the Indirect Purchaser Complaint Based on Threshold Grounds is granted;

- Bayer's Motion for Partial Summary Judgment on Count V of the Indirect Purchaser Class Plaintiffs' Proposed Second Amended Consolidated Class Action Complaint is dismissed as moot;

- HMR and Rugby's motion for summary judgment is dismissed as moot;

- Direct plaintiffs' amended complaints are dismissed;

- Indirect plaintiffs' second amended consolidated class action complaint is dismissed;

- Plaintiffs' motions for class certifications are denied as moot.

The Clerk of the Court is directed to close this case.

Dated: Brooklyn, New York
March 31, 2005

SO ORDERED:

/s/
David G. Trager
United States District Judge

APPENDIX D — PERTINENT TEXT OF RELEVANT STATUTES

SHERMAN ANTITRUST ACT

Section 1: Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 1.

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 ("HATCH-WAXMAN ACT"), AS AMENDED

* * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

* * *

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

* * *

(B) Notice of opinion that patent is invalid or will not be infringed

(i) *Agreement to give notice.* An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) *Timing of notice.* An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) *Recipients of notice.* An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) *Contents of notice.* A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been

submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

* * *

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on-(aa) the date on which the court enters judgment reflecting the decision; or (bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or (bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271 (e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II). In such an

action, each of the parties shall reasonably cooperate in expediting the action.

(iv) *180-day exclusivity period*

(I) *Effectiveness of application.* Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) *Definitions.* In this paragraph:

(aa) *180-day exclusivity period.* The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) *First applicant.* As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) *Substantially complete application.* As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) *Tentative approval*

(AA) *In general*

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) *Limitation*

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) *Civil action to obtain patent certainty*

(i) *Declaratory judgment absent infringement action*

Appendix D

(I) *In general*

No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) *Filing of civil action*

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (1) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against

the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) *Offer of confidential access to application*

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other

terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) *Counterclaim to infringement action*

(I) *In general*

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) *No independent cause of action*

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) *No damages.* An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) *Forfeiture of 180-day exclusivity period*

(i) *Definition of forfeiture event.* In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) *Failure to market.* The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative

approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of *certiorari*) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

(II) *Withdrawal of application.* The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

Appendix D

(III) *Amendment of certification.* The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) *Failure to obtain tentative approval.* The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) *Agreement with another applicant, the listed drug application holder, or a patent owner.* The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of *certiorari*) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

(VI) *Expiration of all patents.* All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) *Forfeiture.* The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) *Subsequent applicant.* If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2) (A) (vii) (IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall

be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The

approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than

bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

* * *

21 U.S.C. § 355(j).

(June 25, 1938, c. 675, § 505, 52 Stat. 1052; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; June 25, 1948, c. 646, § 32(b), 62 Stat. 991; May 24, 1949, c. 139, § 127, 63 Stat. 107; 1953 Reorg. Plan

No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; June 11, 1960, Pub. L. 86-507, § 1 (18),74 Stat. 201; Oct. 10, 1962, Pub. L. 87- 781, Title I, §§ 102(b) to (d), 103(a), (b), 104(a) to (d)(2), 76 Stat. 781-783, 784, 785; Aug. 16, 1972, Pub. L. 92-387, § 4(d), 86 Stat. 562; Sept. 24, 1984, Pub. L. 98-417, Title I, §§ 101, 102(a) to (b)(5), 103, 104, 98 Stat. 1585, 1592, 1593, 1597; May 13, 1992, Pub. L. 102-282, § 5, 106 Stat. 161; Aug. 13, 1993, Pub. L. 103-80, § 3(n), 107 Stat. 777; Nov. 21, 1997, Pub. L. 105-115, Title I, §§ 115(a), (b), 117, 119, 120, 124(a), 111 Stat. 2313, 2315, 2316, 2318, 2324; Nov. 29, 1999, Pub. L. 106-113, Div. B, § 1000(a)(9) [Title IV, § 4732(b)(11)], 113 Stat. 1536, 1501A-584; Jan. 4, 2002, Pub. L. 107-109, § 15(c)(1), 115 Stat. 1420; Dec. 3, 2003, Pub. L. 108-155, § 2(b)(1), 117 Stat. 1941; Dec. 8, 2003, Pub. L. 108-173, Title XI, §§ 1101 (a), (b), 1102(a), 1103(a), 117 Stat. 2448, 2452, 2457, 2460.)

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

SEC. 1112. NOTIFICATION OF AGREEMENTS.

(a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

(1) REQUlREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and a brand name drug company that enter into an agreement described in

paragraph (2) shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between a generic drug applicant and a brand name drug company is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the listed drug in the ANDA involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) AGREEMENT WITH ANOTHER GENERIC DRUG APPLICANT.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior

to the date of the first commercial marketing of either of the generic drugs for which such ANDAs were submitted.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between two generic drug applicants is an agreement regarding the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to the ANDAs with which the agreement is concerned.

(c) FILING.—

(1) AGREEMENT.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that such parties are not required to file an agreement that solely concerns

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text

of any agreements between the parties that are not described in such subsections and are contingent upon, provide a contingent condition for, or are otherwise related to an agreement that is required in subsection (a) or (b) to be filed in accordance with this subsection.

(3) DESCRIPTION.—In the event that any agreement required in subsection (a) or (b) to be filed in accordance with this subsection has not been reduced to text, each of the parties involved shall file written descriptions of such agreement that are sufficient to disclose all the terms and conditions of the agreement.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003).

* * *

THE PATENT ACT

Sec. 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)

(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b) (1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement or unenforceability,

(2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,

(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,

(4) Any other fact or act made a defense by this title.

In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and the name and address of any

person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires. Invalidity of the extension of a patent term or any portion thereof under section 154(b) or 156 of this title because of the material failure--

(1) by the applicant for the extension, or

(2) by the Director,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d) (2) is not subject to review in such an action.

35 U.S.C. § 282.

(July 19, 1952, ch. 950, 66 Stat. 812; Pub. L. 89-83, Sec. 10, July 24, 1965, 79 Stat. 261; Pub. L. 94-131, Sec. 10, Nov. 14, 1975, 89 Stat. 692; Pub. L. 97-164, title I, Sec. 161 (7), Apr. 2, 1982, 96 Stat. 49; Pub. L. 98-417, title II, Sec. 203, Sept. 24, 1984, 98 Stat. 1603; Pub. L. 102-572, title IX, Sec. 902(b) (1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 104-41, Sec. 2, Nov. 1, 1995, 109 Stat. 352; Pub. L. 106-113, div. B, Sec. 1000(a) (9) [title IV, Secs. 4402 (b) (1), 4732 (a) (10) (A)], Nov. 29, 1999, 113 Stat. 1536, 1501A-560, 1501A-582; Pub. L. 107-273, div. C, title III, Sec. 13206(b) (1) (B), (4), Nov. 2, 2002, 116 Stat. 1906.)