**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE ELEVENTH CIRCUIT**

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**NO. 10-12729-DD**

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**FEDERAL TRADE COMMISSION,**
**PLAINTIFF-APPELLANT,**
**v.**
**WATSON PHARMACEUTICALS, INC., ET AL.,**
**DEFENDANTS-APPELLEES,**

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**ON APPEAL FROM**
**THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF GEORGIA**
**Case No. 1:09-cv-00955-TWT**

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# BRIEF FOR PLAINTIFF-APPELLANT FEDERAL TRADE COMMISSION

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**No. 10-12729-DD**
**FEDERAL TRADE COMMISSION v. WATSON PHARMACEUTICALS, INC., ET AL.**

Pursuant to Circuit Rules 26.1-1 and 27-1(9), this is to certify that the following is a complete list of all attorneys, persons, and entities known to have an interest in the outcome of this appeal:

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## STATEMENT OF ORAL ARGUMENT

The Federal Trade Commission believes that oral argument will assist the Court in resolving the issues presented in this case.

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## STATEMENT OF JURISDICTION

The Federal Trade Commission filed its complaint under Sections 5 and 13(b) of the FTC Act, 45 U.S.C. §§ 45(a) and 53(b). R.E. Doc. 114. The District Court had jurisdiction under 28 U.S.C. §§ 1313, 1337(a), 1345, and 15 U.S.C. §§ 45(a), 53(b). That court issued an opinion on February 22, 2010, dismissing the second amended complaint, R.E. Doc. 153, and a separate final judgment, R.E. Doc. 156, was listed on the docket on April 21, R.E. Doc 157. A timely notice of appeal was filed on June 10, 2010. R.E. Doc. 158. This court has jurisdiction under 28 U.S.C. § 1291.

## STATEMENT OF ISSUES

**1**. Whether Eleventh Circuit precedent bars an antitrust complaint challenging an exclusion-payment patent settlement even if, at the time of the settlement, an objective observer likely would have concluded that the patent was invalid or not infringed.

**2**. Whether an exclusion-payment patent settlement should be deemed a presumptively unlawful restraint of trade.

## STATEMENT OF THE CASE

This case involves the dismissal, at the pleading stage, of a complaint alleging that defendants entered into an arrangement that, while cloaked in the settlement of a patent dispute, restrained competition in a way that went beyond the scope of the exclusionary potential of the patent. The court below held that this Court's precedents dictate that, as long as the competition foreclosed by the settlement is no longer than the expiration date of the patent holder's claims and the patent holder's infringement claims do not amount to a "sham," there can be no antitrust liability regardless of any evidence of the patent's weakness. Accordingly, despite allegations that the patent at issue here was unlikely to exclude generic entry for reasons that were evident at the time of the parties' settlement, the court entered a final judgment of dismissal.

In this appeal, we show that this Court's precedents can and should be read to allow a fuller analysis, taking into account facts regarding the strength of the patent, and that, under such an analysis, the complaint was fully adequate to survive a motion to dismiss. In the alternative, we submit that, if the district court correctly understood and applied this Court's precedents, those precedents should be revisited in order to bring Circuit law into conformity with antitrust principles as well as specific congressional policies regarding patent disputes affecting generic drugs.

### A. THE FACTS

AndroGel is a prescription gel used to treat hypogonadism, a medical condition involving underproduction of testosterone. Besins Healthcare, S.A., developed AndroGel and licensed the American marketing rights to defendant Solvay Pharmaceuticals, Inc., in 1995. In February 2000, the Food and Drug Administration (FDA) approved Solvay's New Drug Application (NDA),[1] and Solvay began selling AndroGel soon afterwards. AndroGel has been highly successful, and consistently has accounted for more than 70 percent of transdermal testosterone sales. Second Amended Complaint (hereafter "complaint"), R.E. Doc. 114 ¶¶ 33-37, 104.

Although patents covering synthesized testosterone expired decades ago, R.E. Doc. 114 ¶¶ 31, 38, in August 2000 Solvay filed an application for a patent covering a formulation containing specified amounts of testosterone and certain other ingredients. *Id*. ¶ 39. The Patent and Trademark Office granted the application in January 2003. *Id*. ¶¶ 42-43. Five months later, Solvay requested that the Patent and Trademark Office "correct" many claims of the formulation patent – claims originally requested and advocated by Solvay – by inserting a scientific term that would substantially reduce the amount of one of the components of the formulation and change

[1] A company seeking approval to market a new drug must file an NDA demonstrating the safety and effectiveness of its product. 21 U.S.C. § 355(b).

the coverage of the claims. Nonetheless, Solvay represented that this "correction" would not "alter the substance of the patent in any way that would necessitate reevaluation by an Examiner." The Patent and Trademark Office issued the certificate of correction in December 2003. *Id.* ¶ 42. The Solvay formulation patent will expire in 2021. *Id.* ¶ 43.

In May 2003, defendants Watson Pharmaceuticals, Inc., and Paddock Laboratories, Inc., submitted separate Abbreviated New Drug Applications (ANDAs) to the FDA seeking approval of their generic versions of AndroGel under the terms of the Drug Price Competition and Patent Term Restoration Act, colloquially known as the Hatch-Waxman Act.[2] That statute establishes a regulatory regime designed to foster entry of generic drugs into the market while safeguarding existing brand-name drug patent rights.[3] The principal features of the Hatch-Waxman Act relevant here are the establishment of (1) a less burdensome drug approval procedure for generic versions

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[2] Pub. L. No. 98-417, 98 Stat. 1585 (codified at scattered sections of Titles 15, 21, 28, and 35).

[3] *See, e.g.*, H.R. Rep. No. 857, 98th Cong., 2d Sess, Pt. 1, at 14-17 (1984); *id*. Pt. 2, at 5-6; Ashlee B. Mehl, *The Hatch-Waxman Act and Market Exclusivity for Generic Drug Manufacturers: An Entitlement or an Incentive?*, 81 Chicago-Kent L. Rev. 649, 653 (2006).

of already-approved drugs,[4] and (2) a carefully balanced mechanism for encouraging challenges to weak or narrow patents.

Under the latter mechanism, the branded firm lists with the FDA all patents that the firm claims cover its drug. 21 U.S.C. § 355(b)(1). Such patents might cover the chemical compound, or "new molecular entity" (NME), used in the drug, but often, even after the NME patent has long since expired, the branded firm might assert patents on such things as particle size, method of use, delivery system, or (as here) formulation. The terms of such additional patents can greatly extend the time during which the branded drug is purportedly subject to patent protection.

In submitting an ANDA, the generic applicant must certify why the patent laws will not prohibit it from marketing the drug. One type of certification is the "Paragraph IV certification," which states that the patents are invalid or not infringed. If the ANDA applicant makes such a certification, it must notify the brand-name drug company, and the latter may bring an infringement action on the basis of the Paragraph IV certification. 35 U.S.C. § 271(e)(2). If the patent holder files such a suit within 45 days, FDA approval is stayed automatically for 30 months or, if earlier, until the patent expires or there is a judicial determination that the patent is invalid

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[4] Whereas an NDA must include clinical studies to demonstrate safety and efficacy, under the Hatch-Waxman Act an ANDA applicant need only show that its product is bioequivalent to the brand-name counterpart. 21 U.S.C. § 355(j).

or is not infringed. 21 U.S.C. § 355(j)(5)(B)(iii). The automatic stay affords the patent holder a limited period of protection from generic entry, without its having to make the equitable showing necessary to obtain a preliminary injunction. *Cf. eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 126 S. Ct. 1837 (2006). The first company to submit an ANDA containing a Paragraph IV certification obtains a 180-day exclusivity period, during which time no other firm may obtain FDA approval of a generic version of the same drug. § 355(j)(5)(B)(iii). The purpose of this exclusivity period is to give the generic company an incentive to challenge weak patent claims and to compensate it for undertaking the cost and risk of litigation.[5] No parallel economic incentive is provided for ANDA filings that do not challenge the branded drug's patent.

The Watson and Paddock ANDAs included a Paragraph IV certification based on both invalidity and noninfringement. In August 2003, three months after Watson and Paddock had submitted their ANDAs and two months after seeking to correct its patent application, Solvay sued Watson and Paddock for patent infringement. Another company, Par, entered this dispute by agreeing to share litigation costs with

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[5] *See, e.g.*, *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1074 (D.C. Cir. 1998); FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 7, 57 (July 2002) ("*FTC Generic Drug Study*"); Mehl, 81 Chicago-Kent L. Rev. at 651, 656-57.

Paddock and to promote Paddock's generic version of AndroGel. R.E. Doc. 114 ¶¶ 44-47, 50-51, 86-89. Watson and Par estimated that, when approved, generic AndroGel would sell for as little as 15 or 25 percent of Solvay's price. *Id*.[6]

The patent case proceeded through discovery and summary-judgment briefing for three years. During that time, the Hatch-Waxman Act's 30-month stay on generic approval expired, and the FDA approved Watson's ANDA in January 2006. R.E. Doc. 114 ¶¶ 44-47. Watson planned for commercial manufacturing of AndroGel in late 2006. *Id*. ¶ 55.[7]

Fearing that it would lose approximately 90 percent of its AndroGel sales within a year if generic products were introduced in 2006,[8] Solvay began settlement negotiations with Watson, Paddock, and Par. By this point, according to the complaint, the generic defendants had amassed substantial evidence capable of defeating Solvay's patent claims. First, Watson and Paddock had evidence that because of the ingredients or amounts thereof in their generic products, those

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[6] The 15 percent figure accords with a broad industry study of the impact of generic entry. *See* pp. 34-35 & n.22 below.

[7] Watson filed its ANDA before Paddock, so Watson was eligible for the 180-day exclusivity period.

[8] The 90 percent figure accords with a broad industry study of the impact of generic entry. *See* pp. 34-35 & n.22 below.

products were outside the scope of Solvay's patent. R.E. Doc. 114 ¶ 87. Watson and Paddock also developed evidence that Solvay's patent was invalid on several grounds: (1) under 35 U.S.C. § 102(b) for prior commercial sale or public use, in that Besins offered the invention for sale to Solvay in 1995 – a fact that Solvay withheld from the Patent and Trademark Office; (2) for obviousness, under 35 U.S.C. § 103, because the gel formulations and related methods covered by the patent were obvious variations of existing products and methods; and (3) for certain of the claims, under 35 U.S.C. § 112 for failure to meet the "written description" requirement. *Id.* ¶ 88. In short, according to the complaint, Solvay was not likely to prevail in its patent lawsuits against the generic defendants. *Id.* ¶ 86.

Indeed, in its so-called "Project Tulip Financial Analysis," Solvay evaluated the generic firms' expected return from continuing to litigate and concluded that its litigation position alone was likely insufficient to secure its desired nine-year delay of entry until 2015, and that, to secure such a delay, it would have to pay the generic firms. R.E. Doc. 114 ¶ 57. To secure Watson's agreement to the entry date, Solvay agreed to pay Watson an estimated $15-30 million yearly in profits, ostensibly for Watson to market AndroGel to urologists. Solvay entered into similar agreements for smaller annual amounts with Paddock ($2 million) and Par ($10 million), with

Paddock agreeing to serve as a back-up supplier of AndroGel, and Par agreeing to market the drug to primary care physicians. *Id*.¶¶ 48-80.

The complaint alleges that these arrangements made no commercial sense except as mechanisms to pay the generic firms for delayed entry. R.E. Doc. 114 ¶¶ 81-85. Indeed, according to the complaint, Solvay's internal documents indicated that the co-promotion agreements had little value, but would nonetheless be compensated at more than $300 per sales call, 6 to 10 times the compensation for a previous co-promotion deal, despite the fact that prior co-promotion efforts had been canceled because they had "no significant impact" on sales trends. *Id*.¶¶ 82-83. The back-up manufacturing deal also deviated dramatically from a normal business transaction in a variety of ways, according to the complaint, including a long delay in even applying for the required FDA approval and Solvay's commitment to reimburse capital expenditures even after its internal evaluation had concluded that substantial capital expenditures could not be justified in light of the reliable source of supply Solvay already had. *Id*. ¶ 84.

### B. THE PROCEEDINGS BELOW

FTC staff investigated the settlements for potential antitrust violations,[9] and the Commission brought this action in 2009 in the Central District of California against Solvay, Watson, Paddock, and Par. The Commission alleged that the settlements constituted anticompetitive conduct, in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a). At the request of all defendants, that court transferred the case to the Northern District of Georgia, where an earlier Solvay patent infringement lawsuit had been filed. R.E. Doc. 71. The defendants moved to dismiss under Rule 12(b)(6) for failure to state a claim, and the district court granted the motion. R.E. Doc. 153.[10]

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[9] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), requires parties to a prescription drug patent settlement to inform the FTC of the settlement terms. That law sought to stamp out "abuse" of the Hatch-Waxman Act resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower cost drugs off the market." S. Rep. No. 169, 107th Cong., 2d Sess. 4 (2002).

[10] The state of California joined in the suit when it was filed in California, but dropped out when the case was transferred to Georgia. Private parties, as direct purchasers and indirect purchasers, also sued appellees in Georgia. The disposition of the case as to those parties is not relevant to this appeal.

### C. THE DISTRICT COURT'S OPINION

Relying on this court's decisions in *Valley Drug Co. v. Geneva Pharms*., 344 F.3d 1294 (2003), *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (2005), and *Andrx Pharms. v. Elan Corp*., 421 F.3d 1227 (2005), the district court began by stating that the appropriate analysis requires consideration of three factors: "'(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceeded that scope; and (3) the resulting anticompetitive effects.'" R.E. Doc. 153, at 12 (quoting *Schering-Plough*, 402 F.3d at 1066).

In evaluating the first two factors, the court deemed it unnecessary and inappropriate to consider the strength of the branded drug patent. R.E. Doc. 153, at 13. Instead it defined the "exclusionary potential of the patent" solely by reference to the patent claim — regardless of the strength of the claim — concluding that the first factor militated in the defendants' favor, because "[t]he [Besins] patent claims the gel formulation used in AndroGel and that gel formulation is 'necessary to the manufacture and sale of' generic AndroGel." *Id*. at 12. The court cited no record authority for that conclusion, however, and the FTC had asserted the exact opposite in its complaint, alleging that the generics would *not* have infringed the AndroGel patent because the generics did *not* contain the identical ingredients in the same

amount.[11] The court stated that the second factor also did not count against the defendants, because the exclusion lasted only until August 2015, which was five years less than the period of exclusivity that the branded version of AndroGel would have enjoyed if its patent claims had been upheld in the earlier lawsuit (August 2020). *Id.* at 13. And the third factor did not suggest that the settlement was anticompetitive, the court reasoned, because it kept only Watson, Paddock, and Par from selling AndroGel. *Id.*

The district court also rejected the argument that an "exclusion-payment" settlement should be deemed presumptively anticompetitive. R.E. Doc. 153, at 15.

[11] The complaint alleged that the AndroGel formulation patent was not necessary to manufacture the generic product. *See, e.g.*, R.E. Doc. 114 ¶ 87 ("Watson and Par/Paddock * * * assembled evidence that their generic products did not infringe the patent because their products contained ingredients that the patent did not cover, or amounts of ingredients outside the amounts covered by the patent.").

## STANDARD OF REVIEW

When "'a federal court reviews the sufficiency of a complaint, before the reception of any evidence either by affidavit or admissions, its task is necessarily a limited one. The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.'" *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 511, 122 S. Ct. 992, 997 (2002) (citation omitted). A complaint "does not need detailed factual allegations." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964 (2007). All factual allegations in the complaint must be accepted as true and construed in the light most favorable to the plaintiff. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949-53 (2009); *Twombly*, 550 U.S. at 556, 127 S. Ct. at 1965; *Clark v. Riley*, 595 F.3d 1258, 1264 (11th Cir. 2010). When resolving a Rule 12(b)(6) motion, the only question for the court is whether the plaintiff's claims are "plausible," that is "above the speculative level"; that the plaintiff can prove their truth must be assumed "even if [the allegations are] doubtful in fact * * *." *Twombly*, 550 U.S. at 555-56, 127 S. Ct. at 1965. Claims that are "factually suggestive" of illegality cannot be dismissed on the pleadings. *Id*. at 557 n.5, 127 S. Ct. at 1966, n.5.

This court reviews de novo a district court judgment dismissing a complaint for failing to state a claim under Rule 12(b)(6). *Clark v. Riley*, 595 F.3d 1258, 1264

(11th Cir. 2010); *see Andrx Pharms.*, 421 F.3d at 1234-35 (reversing dismissal on the pleadings in a case challenging a patent settlement agreement under the antitrust laws).

## SUMMARY OF ARGUMENT

**I. A.** In *Valley Drug*, this Court stressed the need to give effect to the policies of the patent laws. Those policies, as well as those of the Hatch-Waxman Act, run contrary to the approach of the district court, which would allow exclusion-payment patent settlements even if, at the time of the settlement, an objective observer would have concluded that the patent was likely invalid or not infringed. The district court's approach also does not comport with *Schering-Plough*. There, this Court underscored "the need to evaluate the strength of the patent" and, in reversing an FTC determination that a particular patent settlement was unlawful, noted that "there has been no allegation that the * * * patent itself is invalid" and that "FTC complaint counsel acknowledged that it could not prove that Upsher and ESI could have entered the market on their own prior to the * * * patent's expiration." 402 F.3d at 1076, 1068.[12]

[12] *See also id.* at 1065 (unfavorably contrasting FTC's approach with that of its Administrative Law Judge).

Although *Valley Drug* cautioned that a subsequent finding of invalidity of a patent would not render prior settlement of a dispute over that patent per se unlawful, no decision of this Court has held, as did the court below, that evidence at the time of settlement regarding the strength of a challenged patent and the likely noninfringement of a competitor generic drug is *irrelevant.* Instead, this Court's decisions state that exclusion-payment settlements are neither lawful nor unlawful per se, that the correct legal analysis requires accommodation of the antitrust and patent laws, and that the relevant facts are critical to the proper antitrust analysis.

One relevant fact is the strength of the patent holder's claims of validity and infringement, as objectively viewed at the time of settlement. This evidence is probative of the extent to which condemning the settlement under the antitrust laws would impinge upon the policies underlying the patent laws and, moreover, gives due weight to the goal that Congress sought to achieve in the Hatch-Waxman Act: viz., spurring rapid entry of generic drugs by winnowing out patents that are invalid or not infringed. This Court's precedents permit a rule that an exclusion payment is unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date. That rule properly balances the goals and policies of both the patent and antitrust laws.

**B**. The Commission's complaint alleged ample facts to survive dismissal under that rule. Those allegations would lead an objective observer at the time of the settlement to conclude that Solvay's patent claims are dubious and that there was a strong prospect of generic entry in 2006 absent this agreement. The challenged agreements postponed that entry until 2015, when Solvay hoped to market a new version of AndroGel, thereby postponing competition for almost a decade and perhaps rendering superfluous whatever competition to the original product came afterwards. The payments to generics made no economic sense other than foreclosing generic competition. Solvay had not been looking for a co-promotion partner before it began settlement negotiations, and Solvay's payments to the generics greatly exceeded the value of services to Solvay. Although Solvay ostensibly obtained the generics' aid in marketing AndroGel or in back-up manufacturing capacity, the complaint alleges that the business arrangements were just a means of disguising payments to forestall generic entry and maintain Solvay's monopoly. There is, accordingly, more than a "plausible" inference, *Twombly*, 550 U.S. at 555-56, 127 S. Ct. at 1964-65, that Solvay traded money for a delay of generic competition.

**II.** If, contrary to the discussion in Part I, the district court correctly construed this Court's precedents, then those precedents should be overruled *en banc*.

**A.** The Supreme Court has ruled that, because a party cannot extend a patent beyond what the patent laws grant, agreements among potential rivals regarding patented products must satisfy both the patent and antitrust laws. *See, e.g.*, *United States v. Masonite Corp.*, 316 U.S. 265, 62 S. Ct. 1070 (1942) (patent agency agreements); *United States v. New Wrinkle Inc.*, 342 U.S. 371, 72 S. Ct. 350 (1952) (patent pooling agreements). The Supreme Court has looked to the practical effect of patent holders' agreements and has rejected the idea that, simply because the patent holder could refuse to license or use his patent at all, he is free to use it in any manner. Moreover, in the pharmaceutical industry, Congress has made its intention crystal-clear that weak patents should be challenged and should not create unwarranted obstacles to generic entry. That intention would be nullified by the district court's interpretation of this Court's precedents.

Had Solvay continued to pursue its statutory patent rights through litigation, it might have achieved exclusion, but it likely would have failed and lost its patent rights entirely. Instead, it opted for the certain exclusion that could be achieved by a private agreement to compensate would-be rivals for foregoing competition. The resulting agreement should be subject to antitrust scrutiny; indeed, the great potential that agreements of this sort have for abuse renders them particularly suspect.

**B.** Exclusion-payment agreements pose sufficient dangers to competition to warrant a presumption of illegality. The Supreme Court has recognized that some agreements adversely affecting price or output require competitive justification. *See NCAA v. Bd. of Regents of Univ. of Oklahoma*, 468 U.S. 85, 110, 104 S. Ct. 2948, 2965 (1984). As Professor Hovenkamp has explained, "if structural evidence makes the practice look suspicious," the law should "force the defendant to show why it should be exonerated." *The Antitrust Enterprise* 146 (2005).

Several factors make exclusion payments suspect. *First*: Drug patent settlements containing exclusion payments bear a close family resemblance to the market-division agreement summarily condemned in *Palmer v. BRG of Georgia*, 498 U.S. 46, 111 S. Ct. 401 (1990). *Second*: Firms have strong incentives to enter into such agreements; the monopoly profits retained by the brand-name drug patent holder typically exceed the total returns that all the companies collectively could earn through competition. *Third*: Patent disputes can be and have been resolved without the use of exclusion payments, and such settlements do not raise the same risk of consumer harm. By contrast, when a patent holder makes substantial payments to a challenger, those payments must be for *something* and, in the absence of a convincing explanation, that something is likely to be abandonment of or delay in generic entry. Defendants in such a case have the opportunity to come forward with an explanation

or reasons why the agreement might have competitive benefits, but their superior access to any such evidence warrants use of the presumption.

This approach is especially appropriate in light of practical considerations and policies of Hatch-Waxman – which is the only context in which exclusion payment settlements arise. In that statute, Congress went to great lengths to encourage challenges to vulnerable patent claims for the purpose of promoting early non-infringing generic entry. Such challenges yield great benefit, especially in light of studies indicating that the majority of litigated pharmaceutical patent infringement claims have been rejected. Agreements that on their face bring such challenges to a halt in return for the sharing of monopoly profits should be recognized as presumptively unlawful.

## ARGUMENT

This is not the first occasion for the Commission to address the issue of exclusion-payment settlements in this Court. In *Schering-Plough*, the Court reversed the Commission's first full adjudication of an exclusion payment case, criticizing the Commission for, among other things, failing to amass evidence regarding "the validity and strength of the patent." 402 F.3d at 1068. The Commission has addressed the *Schering-Plough* decision in a number of ways. Based on a good-faith concern that this Court's rulings could be read as foreclosing liability in virtually all exclusion-payment cases, the Commission petitioned the Supreme Court for *certiorari*.[13] But, both then and subsequently, others have read the Court's precedents differently. In response to the Supreme Court's invitation in *Schering-Plough*, the Solicitor General concluded that "[n]either *Valley Drug* nor [*Schering-Plough*] holds * * * that evidence of invalidity or non-infringement available at the time of settlement would be irrelevant in assessing the permissibility of an exclusion-

[13] The Commission has also cited this Court's *Schering-Plough* decision in testimony before Congress, and in various public fora, in the course of advocating a legislative solution to the exclusion-payment problem. *See, e.g., Prepared Statement of the Federal Trade Commission Before the Subcomm. on Commerce, Trade and Consumer Protection, Comm. on Energy & Commerce, U.S. House of Reps. on Protecting Consumer Access to Generic Drugs* (May 2, 2007), available at: http://www.ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf.

payment." Brief for the United States as Amicus Curiae 17-18, *FTC v. Schering Plough*, No. 05-273 (U.S. May 2006).[14] The Supreme Court denied the Commission's petition. 548 U.S. 919 (2006).

Therefore, our premise in pursuing the present case in this Circuit has been that the more nuanced reading of Eleventh Circuit precedent that others have espoused is correct. As shown in Part I, the Court's precedents can indeed be understood as affording an opportunity for a plaintiff to show that a patent settlement effectively exceeds "the scope of the exclusionary potential of the patent," *Schering-Plough*, 402 F.3d at 1066, based on a showing of the weakness of the branded company's claims of patent protection, as viewed objectively at the time of the settlement. Under such a rule, the court below erred in dismissing the complaint before the Commission had any opportunity to prove its allegations. This Court should, accordingly, reverse the judgment below and remand the case to for further proceedings.

If, however, our initial concerns were well-founded, and this panel were to hold that the Court's prior rulings support the district court's conclusion that, short of "sham" patent claims or exclusion of matters not even claimed to be within the scope

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[14] *See also* Brief Amici Curiae of 54 Intellectual Property Law, Antitrust Law, Economic & Business Professors, et al., *Arkansas Carpenters Health & Welfare Fund v. Bayer, AG*, U.S. S. Ct., No. 08-1194, at 4 (describing this Court as applying "its own modified version of the rule of reason that inquires into the underlying validity of the patent before characterizing the conduct").

of the patent, exclusion-settlement payments cannot violate the antitrust laws, then we must rely on our submission in Point II. There, we set out the Commission's position regarding how exclusion-payment settlements should be analyzed under the antitrust laws. We do so in order to preserve the issue should it be necessary to seek review by the *en banc* Eleventh Circuit or the Supreme Court.

## I. THE COMPLAINT SUFFICIENTLY ALLEGED THAT THESE EXCLUSION-PAYMENT SETTLEMENTS ARE ANTICOMPETITIVE UNDER THIS COURT'S PRECEDENTS

This Court's patent settlement cases have sought to craft principles of law that respect and balance the texts, goals, and policies of both the patent and antitrust laws. Analyzed together and in light of their facts, those cases can be read as recognizing the prospect of antitrust liability in circumstances where the parties have foreclosed competition that would likely have emerged absent an agreement. An exclusion payment would be unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked generic entry (and the agreements otherwise satisfied the elements of an antitrust violation, such as market power and competitive effect). Although the Court has recognized the positive value of the settlement of litigation and has made clear that ultimate defeat of patent claims will not retrospectively condemn every settlement, it has not given patent holders *carte blanche* to buy off potential competitors who might well have the

ability and inclination to introduce generic competition. The complaint contains allegations that readily satisfy such a standard, alleging that the asserted patent was unlikely to prevent generic entry and that the parties' own actions, contemporary with the settlement, showed that entry was likely absent an agreement to stop it. *See*, *e.g.*, R.E. Doc. 114 ¶¶ 3, 52-55. Particularly in light of the generous standard by which a complaint must be assessed at the pleadings stage – demanding only that it state a "plausible" claim for relief "above the speculative level," *Twombly*, 550 U.S. at 555-56, 127 S. Ct. at 1964-65 – the court below clearly erred in granting a motion to dismiss on the pleadings.

### A. THIS COURT'S DECISIONS PERMIT CONSIDERATION OF THE POTENTIAL ANTICOMPETITIVE NATURE OF AN EXCLUSION-PAYMENT SETTLEMENT

#### 1. THE DECISIONS IN *VALLEY DRUG*, *SCHERING-PLOUGH*, AND *ANDRX PHARMS.*

In this Court's first decision in this area, *Valley Drug*, this Court rejected the characterization of an exclusion-payment settlement as per se unlawful because such a characterization failed to give effect to the patent laws. 344 F.3d at 1304. As the court observed:

> A patent grants its owner the lawful right to exclude others. * * * This exclusionary right is granted to allow the patentee to exploit whatever degree of market power it

> might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions.

*Id.* Accordingly,

> [A] patentee's allocation of territories is not always the kind of territorial market allocation that triggers antitrust liability, and this is so because the patent gives its owner a lawful exclusionary right. * * * To the extent that Zenith and Geneva agreed not to market *admittedly infringing products before the '207 patent expired or was held invalid*, the market allocation characterization is inappropriate.

*Id.* at 1305 (emphasis added). At the same time, the Court recognized that "[t]he exclusionary right cannot be exploited in every way – patentees cannot pool their patents and fix the prices at which licensees will sell the patented article, for example * * * ." *Id.* at 1304.

Because of the procedural posture of the case[15] and the substantive issues presented,[16] the Court in *Valley Drug* had no occasion to set out a definitive test for the circumstances under which a patent settlement *would* violate the antitrust laws.

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[15] The case arose "on interlocutory appeal from the district court's order granting partial summary judgment." 344 F.3d at 1295.

[16] The settlement parties made two arguments on appeal: (1) the district court erred in applying a rule of per se illegality, rather than the Rule of Reason, because there are procompetitive justifications for such agreements, and (2) the district court erred in granting summary judgment, because there were disputed factual issues. 344 F.3d at 1303. This Court agreed, concluding that the district court had failed to consider that a patent grants its holder a legal monopoly. *Id*. at 1304-04.

Nevertheless, the Court repeatedly explained that the proper antitrust analysis of an exclusion-payment settlement should balance the policies of both the antitrust and patent laws. On the one hand, the Court recognized that the legitimate exclusionary power conferred by a patent provides an important "incentive to induce investment in innovation and the public disclosure of inventions." 344 F.3d at 1304. Quoting Justice Harlan's concurrence in *Walker Process Equip. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 86 S. Ct. 347 (1965), the Court stated that "the effect of antitrust liability on the incentives for innovation and disclosure created by the patent regime must be taken into account when a court considers whether a patentee is stripped of its immunity from the antitrust laws." *Id.* at 1307.

But the *Valley Drug* Court made equally clear that patent law does not simply displace antitrust law; rather, the goal must be "[a] suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system," in order to further "the complementary objectives of the two." 344 F.3d at 1307. What is required, in other words, is "an analysis of the effects of antitrust liability on the innovation and disclosure incentives created by the patent regime, with the aim of 'achieving a suitable accommodation between the differing policies." *Id.* at 1311 (again quoting Justice Harlan's concurrence in *Walker Process*, 382 U.S. at 179, 86 S. Ct. at 351). The Court also approvingly quoted Professor Hovenkamp

for the proposition that courts must be aware not to endorse mistakenly an anticompetitive settlement. *Id.* at 1312 (quoting 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2024 (2d ed. 2005) ("some care must be taken to ensure that * * * the settlement * * * is not more anticompetitive than a likely outcome of the litigation.")).

The next decision was *Schering-Plough*. *Schering-Plough* set aside a Commission order entered after an evidentiary hearing before an ALJ that the exclusion-payment settlement there was anticompetitive. 402 F.3d at 1076. The Court condemned in no uncertain terms the FTC's refusal to evaluate the evidence of the strength of the patent, noting that the FTC trial staff had "acknowledged that it could not prove" that the generic firms could have entered before expiration of Schering-Plough's patent, and that this fact "reinforces the validity and strength of the patent." 402 F.3d at 1068. The Court added that "there has been no allegation *that the [relevant] patent itself is invalid** * *." *Id*. (emphasis added); *see also id*. at 1076 (stressing "the need to evaluate the strength of the patent"). The Court then undertook a lengthy analysis of the record with respect to whether Schering-Plough's payments to the generic companies were for delay or were (as it asserted) for legitimate side deals. *Id*. at 1068-73. The Court held that the record did not support the FTC's conclusion the brand-name firm had paid the generics for delayed entry.

*Id*. at 1072.

The last decision, *Andrx Pharms.*, like this case, arose from a dismissal on the pleadings in an antitrust suit. This Court reversed the district court's judgment, concluding that the plaintiff adequately had pleaded an antitrust violation. 421 F.3d at 1234-36. Remanding the case for further proceedings, the Court noted the "'fact-intensive'" nature of antitrust cases. *Id*. at 1236 (citation omitted).

**2. THE LESSONS OF THIS COURT'S DECISIONS**

This Court's precedents establish the following:

*First:* Exclusion-payment settlements are neither lawful nor unlawful per se. *Valley Drug* held that such agreements are not per se invalid, but strongly implied that they are not invariably lawful. Otherwise, the Court would not have devoted pages of its decision to discussing the appropriate framework to be applied on remand; the Court would simply have directed the district court to enter judgment for defendants. *Schering-Plough* and *Andrx Pharms.* likewise did not hold that exclusion-payment settlements are invariably lawful. Each decision carefully examined the particular settlement at issue.

In that regard it is important to keep in mind the posture of each of this Court's decisions. *Valley Drug* arose from a grant of summary judgment, and *Schering-Plough* was an appeal from a decision on the merits by the Commission after full litigation of the facts. In each of those two cases, therefore, this Court had the benefit

of a presentation or proffering of the facts substantiating the allegation that each settlement was anticompetitive. Only *Andrx Pharms.* arose from a district court's decision to dismiss on the pleadings a challenge to an exclusion-payment settlement, and this Court *reversed and remanded* the judgment in that case for further proceedings to consider the facts. This Court even went so far as to note that antitrust cases are "'fact-intensive.'" 421 F.3d at 1236 (citation omitted). Accordingly, Eleventh Circuit precedent does not shield all exclusion-payment settlements from challenge. Rather, this Court's cases define the endpoints on a spectrum, discuss how to decide where a particular case falls, and emphasize the importance of development of the facts as part of the antitrust analysis of such agreements.

*Second*: Eleventh Circuit precedent establishes that the proper analysis requires accommodation of two different statutory schemes, antitrust and patent law. *See also*, *e.g.*, *United States v. Masonite Corp.*, 316 U.S. 265, 62 S. Ct. 1070 (1942) (reconciling antitrust and patent laws). *Valley Drug* held that a mechanical application of the rule of reason fails to consider the effect on competition of the monopoly lawfully granted to a patent holder, 344 F.3d 1310-11 & n.27, and devoted the bulk of its opinion to the Court's "observations" and "suggest[ions]" regarding the appropriate antitrust framework to be used to "'achiev[e] a suitable accommodation between the differing policies," *id.* at 1311 (citation omitted).

*Schering-Plough* and *Andrx Pharms.* built on those observations and suggestions. But in none of those cases did this Court have occasion to set down a definitive standard for what a plaintiff must prove to establish that a patent settlement agreement improperly stifled likely competition.

*Third*: This Court's decisions support the proposition that evidence regarding the strength of the patent's validity and the existence of infringement – as objectively viewed at the time of settlement – is highly relevant to the inquiry whether the agreement has exclusionary effects beyond the patent's reasonable potential. *Valley Drug, Schering-Plough* and *Andrx Pharms.* emphasized the importance of considering "the exclusionary potential of the patent" as an element of the proper antitrust analysis. *Valley Drug*, as noted above, implied that validity or invalidity of the patent is a relevant factor. *Schering-Plough* chastised the Commission for not addressing, as a factual matter, the likelihood of success on the patent merits.[17] The complaint here sought to respond to that criticism, but the district court never gave the Commission a chance to prove its case.

The key question in this case is the meaning of the oft-used term "the exclusionary potential of the patent," the first of the three factors identified in *Valley*

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[17] *See* 402 F.3d at 1072 ("The Commission, however, refused to consider the underlying patent litigation, and its certainty to be a bitter and prolonged process.").

*Drug*.[18] The district court and appellees read that term as encompassing the full scope of any non-sham claims made under the patent at issue, through the date of its expiration. In our view, such a narrowly-cabined analysis results in an unduly expansive assessment of "exclusionary potential." Any realistic assessment of the "exclusionary potential of the patent" must take into account evidence that (as viewed at the time of the settlement) the patent was unlikely to effect any exclusion.

That approach — recognizing the relevance of evidence regarding the strength of the patent — is consistent with general principles of both patent and antitrust law, and thus furthers a "suitable accommodation" of their "complementary objectives." *Valley Drug*, 344 F.3d at 1307. On the patent law side, the Supreme Court has observed: "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly * * * ." *Lear, Inc. v. Adkins*, 395 U.S. 653, 663-64, 89 S. Ct. 1902, 1908 (1969) (quoting *Pope Manufacturing Co. v. Gormully*, 144 U.S. 224, 234, 12 S. Ct. 632, 636 (1892)). This observation is in keeping with the

[18] It could be argued that evidence of the strength of patent validity and infringement also (or instead) bears on the second and third *Valley Drug* factors, but we think that the first factor is a better home.

Constitutional design that underlies the patent system.[19] On the antitrust side, the Supreme Court has repeatedly recognized that the government is permitted to challenge the validity of a patent when, as here, a patent is raised as a defense to an antitrust claim. *See United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 93 S. Ct. 861 (1973); *United States v. United States Gypsum Co*, 340 U.S. 76, 71 S. Ct. 160 (1950).[20] And it is well-settled law that it is unlawful to pay off even a *potential* competitor to stay out of a market. *Palmer v. BRG of Georgia*, 498 U.S. at 49-50, 111 S. Ct. at 402-03 (involving an agreement not to compete in connection with an intellectual property license). This principle applies even if successful entry is

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[19] Article I, Section 8 of the U.S. Constitution gives Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

[20] As the Court summarized in *Glaxo*:

> "[D]istrict courts have jurisdiction to entertain and decide antitrust suits brought by the Government and, where a violation is found, to fashion effective relief. This often involves a substantial question as to whether it is necessary to limit the rights normally vested in the owners of patents, which in itself can be a complex and difficult issue. The litigation would usually proceed on the assumption that valid patents are involved, but if this basic assumption is itself challenged, we perceive no good reason, either in terms of the patent system or of judicial administration, for refusing to hear and decide it."

410 U.S. at 59-60, 93 S. Ct. at 866.

uncertain, for "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." 12 Hovenkamp ¶ 2030b, at 213.[21] A rule of law that permits *any* settlement within the scope of non-sham patent claims, and rejects evidence regarding the strength or weakness of those claims, flies in the face of these bedrock antitrust principles.

An appropriate reading of this Court's precedents should recognize that an exclusion payment is unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that, absent the settlement, the generic would enter the market at an earlier time than the settlement permits. Although a remote possibility of entry may be insufficient to condemn a settlement, it is unreasonable to require certainty or near-certainty. If the circumstances at the time of settlement would reasonably inform the parties that entry was probable – either through final resolution of the patent litigation or through entry not stopped by a preliminary injunction – then an exclusion payment must be seen as the branded company's "buying off" of a serious threat of competition.

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[21] *See, e.g.*, *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc) (exclusionary conduct is unlawful when it "is aimed at producers of nascent competitive technologies as well as when it is aimed at producers of established substitutes"); *Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1 (1st Cir. 1979) (holding illegal a non-compete agreement between manufacturer and potential entrant that agreed to be exclusive distributor for incumbent).

### 3. THE HARMFUL CONSEQUENCES OF THE DISTRICT COURT'S RULING

The court below did not heed those lessons from this Court's and the Supreme Court's precedents, and instead adopted a rule that (aside from sham infringement claims) renders altogether irrelevant evidence of invalidity or non-infringement available at the time of settlement in assessing the permissibility of an exclusion-payment settlement. The inevitable consequence of such a rule would be that brand-name and generic drug companies could agree to forgo litigation over patent infringement and split up an ongoing stream of monopoly profits, even in situations in which it is evident that it is more likely than not that the patent would be found invalid or not infringed. To see why this is so, it is necessary to consider the economics of generic drug competition.

According to a study conducted by the FTC of the industry as a whole (validated to a remarkable degree as to defendants' specific situation by the parties' internal documents in this case, *see* R.E. Doc. 114 ¶¶ 49-51, 57-59), a branded manufacturer typically loses about 90 percent of its unit sales over the course of generic entry.[22] While generic entrants gain that unit volume, they do not gain all the revenues lost by the branded manufacturer because, as generic competition sets in,

[22] FTC Staff, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (Jan. 2010).

the price falls, on average, to about 15 percent of what the branded manufacturer was charging. Thus, a branded manufacturer can expect that, if a drug is earning $1 billion a year before generic entry, the manufacturer will only earn about $100 million a year once generic competition has matured, and all the generic companies put together will only earn about $135 million a year (90% x 15% x $1 billion), thus leaving approximately $765 million a year for the public through the benefits of competition.[23] The parties have a strong economic incentive to avoid that result.

Suppose, in the above example, both parties recognize that it is highly likely that the litigation will result in a judgment that the patent is either invalid or not infringed. In a settlement process that is totally unconstrained — *e.g.*, one that freely allows exclusion payments to be made from the patent owner to the alleged infringer — the branded company could pay the generic several times its expected profit from actual entry — say, $300 million — and still retain many times what *it* would have earned in the absence of settlement, while the generic profits by sitting on the sidelines. The loser is the public, which loses the benefit it would derive if patent

[23] Both the generic revenues and the public benefit would likely be somewhat greater, because when the price falls, some patients who would otherwise forgo treatment or take a less appropriate medication would purchase the generic product. But the calculation in text closely approximates the dollar impact of generic entry and demonstrates why, if these types of settlements are permitted, enough funds typically would be available to protect even the weakest patents.

litigation either had run its course or had been resolved without the parties' negotiations being distorted by payments to the generic challenger. Already, despite continuing uncertainty concerning the legality of such settlements, one commentator has estimated that exclusion-payment settlements have cost consumers (and other purchasers) $12 billion in excessive prices. *See* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum L. Rev. 629, 651-53 (2009). The FTC study cited above similarly estimates that exclusion-payment settlements are costing consumers about $3.5 billion per year. *FTC 2010 Pay-for-Delay Study* 2.[24]

Consequently, if — as under the district court's approach — exclusion payment settlements are automatically lawful despite evidence at the time of settlement that the patent was invalid or not infringed, the result would be to render meaningless, in the pharmaceutical industry, the Supreme Court's observation in *Lear, Inc. v.*

[24] Such an estimate is hardly surprising or implausible, in light of the enormous importance that generic drugs have come to have to consumers. Domestic expenditures on prescription drugs have grown dramatically over the last 20 years. In 2008, spending on retail prescription drugs was $234 billion, more than a 450 percent increase from the $40 billion spent in 1990. Center for Medicare and Medicaid Services, Office of the Actuary, *National Health Expenditure Data,* Table 2, *available at* http://www.cms.gov/NationalHealthExpendData/downloads/tables.pdf.

*Adkins* about the importance to the public "that competition should not be repressed by worthless patents." 395 U.S. at 663-64, 89 S. Ct. at 1908.

It would be particularly ironic to reach such a result in this industry because Congress went to great lengths, in both the original Hatch-Waxman Act and the 2003 Medicare Amendments, to encourage challenges to questionable patent claims in order to promote early non-infringing generic drug entry. For example, Congress encouraged the early commencement of patent litigation by defining the filing of an ANDA with a Paragraph IV certification as an act of infringement, 35 U.S.C. § 271(e)(2), and by rewarding the *prompt* filing of an infringement suit with a 30-month stay of regulatory approval. The 180-day exclusivity enjoyed by the first filer of a Paragraph IV ANDA – *i.e.*, the first generic to challenge a patent claim – is a further spur to such challenges. And Congress's 2003 addition of a requirement that Hatch-Waxman settlements be reported to the antitrust enforcement agencies – a requirement that was prompted in part by the type of concerns raised by cases like this one[25] – directly reflects its intent that such agreements be subject to searching antitrust scrutiny. Adoption of the district court's approach would effect a de facto

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[25] *See* S. Rep. No. 167, 107th Cong., 2d Sess. 4 (2002) ("the industry has recently witnessed the creation of pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market. Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law that was intended to promote generic alternatives").

negation of the elaborate Hatch-Waxman scheme for incentivizing and adjudicating such litigation.

The irony would be compounded by the track record of outcomes when patent cases in this industry do proceed to adjudication. The Commission studied litigated decisions in all patent cases initiated between 1992 and 2000 between branded drug manufacturers and Paragraph IV generic challengers, and found that the generics prevailed in cases involving 73 percent of the challenged drug products. *FTC Generic Drug Study* 19-20. Thus, although no one questions the right of holders of legitimate patents to profit from their inventions, the existence of so many vulnerable patents underscores the importance of the congressional policy embodied in Hatch-Waxman.

It is one thing to rule, as *Valley Drug* did, that the parties to an exclusion settlement should not automatically be subject to treble damages liability just because a patent is later held invalid. It is something else to provide the blanket shelter from liability that follows from the way that the court below read this Court's rulings. We submit that the district court erred in dismissing this case at the pleadings stage, refusing to allow the Commission to offer evidence of patent invalidity or noninfringement, as evident at the time of settlement.

### B. THE FTC'S COMPLAINT ALLEGES SUFFICIENT FACTS TO STATE A CLAIM UNDER THIS COURT'S DECISIONS

Viewed in light of the above analysis, the Commission's complaint alleged ample facts to survive dismissal. *See* R.E. Doc. 114 ¶¶ 33, 42-47, 60-99, 103-04. Those allegations give rise to an inference that is at least "plausible," *Twombly*, 550 U.S. at 556, 127 S. Ct. at 1965 – and, in fact, quite strong – that this settlement was an agreement to share monopoly rents, an agreement that is unlawful under any appropriate rule of antitrust law.

The FTC's complaint squarely alleged that the generic versions of AndroGel likely would *not* have infringed the AndroGel patent because the generics did *not* contain the identical ingredients in the same amount found in AndroGel. *See* R.E. Doc. 114 ¶ 87 (quoted at p. 12 note 11 above). The assertion that the generic versions of AndroGel "contained ingredients that the patent did not cover, or amounts of ingredients outside the amounts covered by the patent," *id.*, is a factual allegation, and the district court was required to accept that allegation as true for purposes of ruling on appellees' motion to dismiss, *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009); *Twombly*, 550 U.S. at 555, 127 S. Ct. at 1965 (collecting cases). The district court, however, did not. The court wrote, instead, that "[t]he [Solvay] patent claims the gel formulation used in AndroGel *and that gel formulation is 'necessary to the*

*manufacture and sale of' generic AndroGel*." R.E. Doc. 153, at 12 (citation omitted; emphasis added). The district court's conclusion is flatly contradictory to the FTC's allegation. Rules 8 and 12, Fed. R. Civ. P., and well-settled Supreme Court precedent prohibit a district court from rejecting factual allegations in a complaint when asked to dismiss the complaint for failure to state a claim for relief. Doing so was a simple, straightforward legal error.

That error alone requires the judgment below to be reversed. But there is more.

The sequence of events and the circumstances surrounding the patent showed that an objective observer at the time of the settlement – including the parties – would have known that the validity of Solvay's patent and its claims of infringement were very much in doubt and, accordingly, it was unlikely that the patent effectively would block generic entry.

The PTO issued Solvay a patent in January 2003, and Watson and Paddock filed ANDAs with the FDA four months later. R.E. Doc. 114 ¶¶ 42, 44. The following month Solvay sought leave from the PTO to correct mistakes in its patent application, *id.* ¶ 42 – mistakes that likely were obvious from the ANDAs filed by Watson and Paddock and that would have doomed Solvay infringement claims were Solvay forced to prove them in court. The "plausible" inference is that Solvay knew that its patent was in trouble.

The parties' own contemporaneous assessments confirm that, in the months leading up to the agreement, it was evident that Solvay faced likely generic competition.[26] When Watson received final FDA approval of its product in January 2006, both it and Solvay recognized that generic launch could be imminent, and both Watson and Par/Paddock invested in preparations for such launch. R.E. Doc. 114 ¶¶ 52-55.

It was in the face of such concrete contemporary indications that Solvay's patent was vulnerable and the prospect of generic competition strong that Solvay entered into the challenged agreements, in which Solvay agreed to pay Watson, Paddock, and Par, effectively splitting with them profits from future sales of the original version of AndroGel. In return, the generic defendants dropped their patent challenges; the generic defendants agreed not to compete against AndroGel until 2015. R.E. Doc. 114 ¶¶ 65-67, 76-79. The 2015 date, moreover, was no simple compromise of the patent term, but was geared to Solvay's broader plan of a "line extension" for a more concentrated version of AndroGel, and Solvay considered

[26] AndroGel was highly profitable to Solvay, and Solvay had strong incentives to maintain exclusivity. Solvay sold the product at a considerable markup from what it paid Besins, thus enjoying a substantial profit margin. R.E. Doc. 114 ¶¶ 32, 37. AndroGel's sales from 2000 to 2007 were $1.8 billion, and domestic sales in 2007 alone exceeded $400 million. *Id*. ¶¶ 34-36. AndroGel was Solvay's highest-selling product, *id*. ¶ 36, and it had, accordingly, a strong motivation to safeguard that profit stream.

pulling AndroGel from the market before generics enter in 2015, an action that could kill that market. *Id*. ¶¶ 57-59, 62. All of these allegations further support the conclusion that the broad exclusion of generic entry that Solvay succeeded in effectuating resulted from the agreements, and far exceeded the exclusionary potential of its patent.

The Commission's complaint also contains allegations that the agreements made no economic sense other than by foreclosing generic competition. Although Solvay ostensibly obtained the generics' nominal aid in marketing AndroGel or in providing back-up manufacturing capacity, the complaint alleges that the business arrangements were undertaken to compensate the generics for their agreement to the 2015 entry date. Solvay had not been looking for a co-promotion partner before it began settlement negotiations; Solvay's back-up manufacturing deal was suspect; and the agreed payments to the generics greatly exceeded the value of services that Solvay received in exchange. R.E. Doc. 114 ¶¶ 82-84.[27] The "plausible" inference,

[27] *Solvay's co-promotion deal with Watson and Par*: In the case of other co-promotion deals, Solvay analyzed whether the agreement would increase AndroGel sales. Solvay performed no such analysis of this co-promotion deal. Also, Solvay projected that it would pay Watson more than $19 million annually and Par $10 million annually, or more than $300 per sales call. By contrast, prior Solvay co-promotion deals involving AndroGel projected payments of approximately $30-$45 per call. A Watson executive even stated that $150 per call would be a "ridiculous" rate, yet Watson received double that amount. And unlike other Solvay AndroGel co-promotion deals, Solvay cannot terminate the deals with Watson and Par early if AndroGel sales do not improve. R.E. Doc. 114 ¶ 82.

therefore, is that Solvay traded money for time by delaying entry of generic competitors to AndroGel and by enlisting help from co-conspirators in order to maintain AndroGel's profits until Solvay's new version of AndroGel hit the shelves.

Considered together, appellee's conduct supports the inferences that Solvay's patent was invalid or not infringed, that Solvay sought to settle to retain its monopoly, that via the settlement Solvay assured itself that Watson and Paddock would not offer a generic version of AndroGel until a decade later, when Solvay hoped to convert physicians to prescribe and patients to use a new version of AndroGel as to which there would be no generic substitution. The "plausible" inference is that the parties did exactly what they would have needed and been expected to do if their agreement was designed precisely to split monopoly rents amongst themselves. Thus, the

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*Solvay's back-up manufacturing deal with Paddock*: Solvay performed no diligence of Paddock's manufacturing facilities before entering into the back-up supply agreement with Paddock, and a later site visit showed that Paddock was not able to manufacture AndroGel using Besins' already-FDA-approved process. Also, Solvay has paid Paddock $2 million per year since September 2006 despite the fact that Solvay did not even apply for the required FDA approval for Paddock to serve as a back-up manufacturer until *November 2008*. R.E. Doc. 114 ¶ 84.

Commission's complaint states an antitrust cause of action that can succeed under a proper reading of this Court's precedents, and the court below erred in dismissing it.[28]

## II. AN EXCLUSION-PAYMENT SETTLEMENT SHOULD BE DEEMED PRESUMPTIVELY UNLAWFUL

If this Court reads its decisions as the court below did, then we would urge the full Court to reassess those precedents and replace them with a rule that provides robust protection to consumer welfare under the antitrust laws while respecting the legitimate rights of patent holders.[29] Specifically, we would urge this Circuit to adopt the same standard that the Department of Justice has urged upon the Second Circuit in *Arkansas Carpenters – i.e.*, that settlements involving payments by the patent holder to a patent challenger, accompanied by the challenger's agreement to drop its

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[28] Although other courts, have issued rulings that appear to support the result below, those decisions are erroneous, for the reasons argued in this brief. *See In re Ciproflaxicin Hydrochloride Antitrust Litig*., 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig*., 466 F.3d 187 (2d Cir. 2006). More recently, however, another Second Circuit panel criticized that rule, expressly inviting a petition for *en banc* reconsideration of *Tamoxifen*. See *Arkansas Carpenters Health & Welf. Fund v. Bayer*, 604 F.3d 98 (2d Cir. 2010). Such a petition was filed and supported by a host of *amici*, including both the Commission and the Justice Department. That petition remains pending.

[29] We recognize that a ruling expressly departing from Circuit precedent would require consideration by the Court *en banc*. *See, e.g.*, *United States v. Svete*, 556 F.3d 1157, 1160 (11th Cir. 2009) (en banc). In light of the enormous importance of affordable generic drugs to the health and economic well-being of the American people, we submit that this case clearly "involves a question of exceptional importance." Fed. R. App. P. 35(a)(2).

challenge and stay out of the market for a specified length of time, should be viewed as a presumptively unreasonable restraints of trade. A showing that the settlement parties have entered into such an agreement would shift to them the burden of justifying their agreement by showing that the payment was not for delayed entry or that the settlement otherwise served beneficial goals cognizable under the Rule of Reason. If the defendants carry this burden, the plaintiff can offer evidence to rebut the defendant's showing, such as demonstrating that the defendants' justification is a pretext or that the agreement is on balance anticompetitive. This presumption of illegality and burden-shifting process is a sensible approach and "make[s] an adjustment between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act." *Line Material*, 333 U.S. at 310, 68 S. Ct. at 562.[30]

### A. AGREEMENTS AMONG COMPETITORS TO SETTLE LITIGATION ARE SUBJECT TO ANTITRUST SCRUTINY

Well-settled principles lay the foundation. As this Court recognized in *Valley Drug*, an agreement in which an incumbent in a market pays a *potential* competitor

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[30] *See, e.g., FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 106 S. Ct. 2009 (1986). The burden-shifting approach discussed below is similar to the one used in employment discrimination litigation. *See, e.g., McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 93 S. Ct. 1817 (1973); *Raytheon Co. v. Hernandez*, 540 U.S. 44, 124 S. Ct. 513 (2003).

to stay out is normally a *per se* violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, even if success of the would-be entry is uncertain. *See* 344 F.3d at 1304 (citing, *inter alia*, *Palmer v. BRG of Georgia, Inc*.). This proposition comports with contemporary microeconomic theory and more than a century of antitrust experience, which have shown that such agreements between rivals are generally anticompetitive because they restrict output and raise price. *E.g.*, Dennis W. Carlton & Jeffrey M. Perloff, *Modern Industrial Organization* 123-25 (4th ed. 2005); 12 Hovenkamp ¶ 2030b.

Agreements among competitors are not exempt from Sherman Act § 1 just because a patent is involved. *See, e.g., United States v. Masonite Corp*. (patent agency agreements); *United States v. Line Material Co., United States v. Gypsum Co.*, and *United States v. New Wrinkle Inc*. (patent pooling agreements). The overarching principle, long established by the Supreme Court, is that "[t]he owner of a patent cannot extend his statutory grant by contract or agreement." *Masonite*, 316 U.S. at 277, 62 S. Ct. at 1077. Patent owners, like any other property owners, cannot use their intellectual property for unlawful ends. Accordingly, as *Masonite* went on to explain, "[b]eyond the limited monopoly which is granted, the arrangements by which the patent is *utilized* are subject to the general law." *Id.* This principle remains true even if the agreement takes the form of a litigation settlement. *See United States v.*

*Singer Mfg. Co.*, 374 U.S. 174, 197-200, 83 S. Ct. 1773, 1785-87 (White, J., concurring) (competitors' collusive termination of a patent interference proceeding to help broaden the patent's scope runs afoul of the Sherman Act).

*Masonite* is particularly instructive for it provides a close analogy to the present situation. There, a patent owner sued or threatened to sue its potential competitors for patent infringement, but resolved those disputes by licensing the competing firms to sell its product – at a price it set. The other firms abandoned their competing products. The Supreme Court – while recognizing that a patent holder generally does nothing wrong by licensing its patents and employing agents to sell its products – nevertheless concluded that this arrangement amounted to price-fixing, because Masonite had engineered a means by which it could eliminate potential competition with its product by splitting monopoly rents with would-be competitors:

> Active and vigorous competition then tend[ed] to be impaired, not from any preference of the public for the patented product, but from the preference of the competitors for a mutual arrangement for price-fixing which promises more profit if the parties abandon rather than maintain competition.

316 U.S. at 281, 62 S. Ct. at 1079. The Court also rejected the argument that, because Masonite could have sold its patented product without licensing it at all, it could

therefore wield the "lesser power to license on his own conditions," if those conditions amounted to the creation of a *de facto* cartel. *Id.* at 277, 62 S. Ct. at 1078.

Defendants here have likewise achieved a *de facto* cartel, by ensuring the continued existence of a monopoly and sharing its profits. As in *Masonite*, it is no answer to say that Solvay's patent rights might have enabled it legitimately to have excluded the generics from the market entirely by prevailing on its patent claims. That is not what it did. Instead, it entered into an *agreement* with the generic companies that, in effect, allowed them to *divide* the market by virtue of their receipt of a share in a stream of monopoly profits that was guaranteed by their promise not to enter as competing sellers. They became silent partners in Solvay's monopoly.

This case is illustrative of a fundamental choice patent holders face under the patent laws. Assertion of patent rights through litigation is privileged, but risky. It is privileged because, as long as the patent holder avoids making claims that amount to a "sham," it may do so without fear of antitrust consequences.[31] But it is risky, for the same reason litigation is always risky: the patent holder could lose. A defendant may challenge the validity of the patent, deny that his product infringes, or assert

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[31] *See Professional Real Estate Investors, Inc., v. Columbia Pictures,* 508 U.S. 49, 113 S. Ct. 1920 (1993)*; Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 86 S. Ct. 347 (1965); *Eastern R.R. Presidents Conf. v. Noerr Motor Freight*, 365 U.S. 127, 81 S. Ct. 523 (1961); *UMW v. Pennington*, 381 U.S. 657, 85 S. Ct. 1585 (1965).

other defenses. *See* 35 U.S.C. § 282. If the patent is ruled invalid, the patentee loses the right to exclude not only that defendant but also any other would-be entrant. *See Blonder-Tongue Labs. v .Univ. of Ill. Found.*, 402 U.S. 313, 91 S. Ct. 1434 (1971). Moreover, even a successful patentee faces uncertainty as to the relief he will obtain. Like any other litigant, a patent holder can secure injunctive relief excluding a rival – whether a preliminary or permanent injunction – only if he can show entitlement to such relief under general standards of equity. *See eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 126 S. Ct. 1837 (2006).

A patent holder may choose the certainty of settlement over the risks of litigation, but the price is being subject to antitrust scrutiny. It is true that a patent grants a party a legal right to exclude[32] and that a patent is presumed valid.[33] But that presumption is just that – a procedural rule allocating the burden of proof in litigation.[34] Further, although settlements are encouraged in the law,[35] settlements are

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[32] *E.g.*, 35 U.S.C. § 154(a)(1); *Zenith Radio Corp. v. Hazeltine Research, Inc*., 395 U.S. 100, 135, 89 S. Ct. 1562, 1583 (1969).

[33] 35 U.S.C. § 282.

[34] *See KSR Int'l v. Teleflex* Inc., 550 U.S. 398, 426, 127 S. Ct. 1727 (2007); *Stratoflex, Inc. v Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed . Cir. 1983). The patentee bears the ultimate burden of proving infringement.

[35] *E.g.*, *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215, 114 S. Ct. 1461, 1468 (1994).

contracts which, like all private contracts, are subject to the antitrust laws. Consequently, it does not follow that rivals may use a patent of unknown validity as a shield for antitrust scrutiny of an agreement not to compete. Some such agreements are nothing but a device to obtain "protection from competition which the patent law, unaided by restrictive agreements, does not afford." *Masonite*, 316 U.S. at 279, 62 S. Ct. at 1078. When that is true, the patent laws do not grant the settlement parties refuge from the antitrust laws. The clear opportunity and powerful financial incentive that an exclusion-payment settlement offers potential rivals to split monopoly rents, the history of rivals' using patents as a screen for collusive behavior, and the generous settlement terms that often can be found in them – all those factors strongly counsel in favor of a policy requiring not only rigorous judicial scrutiny of exclusion-payment settlements in order to ensure that they achieve no more than their lawful ends, but also the rule that the settling parties should bear the burden of proving that their own particular agreement is benign. *See* 12 Hovenkamp ¶ 2046, at 334 ("In sum, the combination of a 'large' payment from the patentee to the challenger, plus physical or legal conditions that make it unlikely that third parties can immediately enter the market, creates a strong presumption of unreasonableness.").

## B. THE POLICIES OF BOTH THE ANTITRUST AND PATENT LAWS MILITATE IN FAVOR OF TREATING PATENT SETTLEMENT EXCLUSION AGREEMENTS AS PRESUMPTIVELY UNLAWFUL

Although exclusion-payment settlements are a form of market allocation, the Commission does not seek to condemn them as *per se* antitrust violations. Rather, they should be subject to the Rule of Reason – which embraces a range of analyses, from full market analysis to abbreviated "quick look" scrutiny. *See generally California Dental Association v. FTC*, 526 U.S. 756, 119 S. Ct 1604 (1999). We recognize that this Court has previously forsworn Rule of Reason analysis in this context. *Schering-Plough*, 402 F.3d at 1065-66. But the Rule of Reason is adequately flexible to take full account of the patent context.[36]

The task, then, is to distinguish exclusion that results from the strength of the patent from exclusion that represents an augmentation of the patent's exclusionary power by private agreement. For a court to do so reliably, it is essential that it take into account the inherent uncertainty in patent litigation and the terms of the agreement. Like all contested rights, patent claims are subject to uncertainty, which the parties must deal with in either litigating or settling. Suppose, for example, all

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[36] The Supreme Court has emphasized that antitrust law should give due consideration to whatever the commercial context may be. *See Verizon Communications Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 411-12, 124 S. Ct. 872, 881 (2004) (taking regulatory context into account in Section 2 analysis).

agreed that Solvay's patent claims stood a 50-50 chance of prevailing. The parties might resolve that uncertainty by agreeing on an entry date earlier than the expiration date of the patent. If the settlement consisted solely of such a compromise, it could easily be defended on the ground that any exclusion simply reflected the strength of the patent as understood by the parties. Consumers also reap a benefit from such a settlement, commensurate with the patent's strength.

Such settlements – in which the parties to patent litigation settle by compromising the date of entry but without payments – are thus unlikely to entail any exclusion beyond that provided by the strength of the patent, and indeed may bring consumer benefits. Settlements of this sort have also been common in the pharmaceutical context. From FY2004 to FY2009, drug companies filed 218 final settlements involving brand-name and generic companies, and 70 percent of those agreements did not involve exclusion-payments and delayed entry. *FTC 2010 Pay-for-Delay Study* 4.[37]

When, however, settlements of such patent litigation *do* include substantial payments from the patent holder to the challenger, one must ask what is the *quid pro*

[37] Such payment-free settlements were particularly frequent during the years 2000 through 2005, after the Commission began challenging pay-for-delay settlements. That trend, however, has reversed.

*quo* for those payments?[38] In the absence of another explanation for them, the ready explanation is the patent holder is obtaining a greater degree of exclusion than it could have achieved without the payment – as compared either with a hypothetical settlement that does not entail payment, or with the expected outcome of litigation.[39] Accordingly, courts and commentators have recognized the strong inference of anticompetitive purpose and effect that can be drawn from such "problematic" payments. *See Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001); 12 Hovenkamp ¶ 2046, at 327.

Under these circumstances, antitrust and patent-law principles, evidentiary considerations, and the policies of the Hatch-Waxman Act all support a presumption

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[38] The rule we urge should apply whenever the patent holder provides economic value to the challenger in any form. In recent years, it has become clear that supposed "side deals" between settling parties are frequently used as subterfuges to mask payments for delay. Straightforward payments for delay have "given way to more complex arrangements," making it difficult for an antitrust plaintiff to demonstrate a net flow of consideration to the generic firm. *See* Hemphill, 109 Colum. L. Rev. at 663-66. As Professor Hemphill notes, because of "the absence of brand-generic deals outside of settlement" agreements, "a presumption that the side deal provides disguised payment to the generic firm for delayed entry is appropriate." *Id*. at 668-69.

[39] Although in some cases, a settlement without payment may not be achievable, this argument does *not* presume the possibility of such settlements. *Cf. Schering-Plough*, 402 F.3d at 1066 n.15. Rather, it is based on the recognition that, as compared with delayed entry secured through an exclusion payment, competition and consumers are better off *either* with a payment-free settlement, *or* with a "roll of the dice" on litigation.

that patent settlements involving both payment by the patent holder and forbearance from entry by the challenger are anticompetitive, thus shifting the burden to the parties to justify the agreement. The Supreme Court has long recognized that agreements effecting a "naked restraint on price and output requires some competitive justification." *NCAA*, 468 U.S. at 110, 104 S. Ct. at 2965. Payments that, on their face, appear to be in exchange for market exclusion are very similar to the agreements that the Supreme Court condemned as *per se* unlawful in *Palmer v. BRG of Georgia*. They thus bear a "close family resemblance [to] another practice that already stands convicted in the court of consumer welfare," and can properly be treated as "inherently suspect." *See Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 36-37 (D.C. Cir. 2005); *see also North Texas Specialty Physicians v. FTC*, 528 F.3d 346, 361 (5th Cir. 2008) (upholding the Commission's application of "inherently suspect" analysis, including burden-shifting, as "comport[ing] with the framework provided by the Supreme Court" in *California Dental*). As Professor Hovenkamp has put it, "if structural evidence makes the practice look suspicious," the law should "force the defendant to show why it should be exonerated." *The Antitrust Enterprise* 146 (2005).

General evidentiary principles also support use of a presumption. The principal means by which a court may satisfy itself that a particular settlement is not

competitively harmful is by ascertaining that the payment in question was for something *other than* delay. Evidence of other reasons for the payment, if it exists, is far more likely to be in the defendants' hands than the plaintiff's, and it thus makes sense for them to be required to offer such justifications. *See generally* Simon Greenleaf, *A Treatise on the Law of Evidence* § 14 (1899); 1 David W. Louisell, *Federal Evidence* § 66 (1977); 2 John William Strong, et al., eds. *McCormick on Evidence* §§ 342-44 (4th ed. 1992).

The settlement parties may, for example, be able to come forward with evidence that the payments in question in fact caused no competitive harm because they had a legitimate basis other than delay. Or they might be able to establish that agreement achieves beneficial efficiencies – a possibility that the Commission has acknowledged. *See Schering-Plough*, 136 F.T.C. at 999-1002. The opportunity for such showings of "competitive justification" is typically afforded before an "inherently suspect" practice is condemned. *See Polygram*, 416 F.3d at 36. But the parties' superior access to any such evidence supports use of the presumption.

Recognition of this presumption – that agreements containing both payments to patent challengers and agreements by those challengers to forbear from market entry are anticompetitive unless justified – is especially appropriate in light of the context in which this issue arises. As courts and commentators have recognized, such

"reverse payment" settlements have, as a practical matter, only been seen in the context of pharmaceuticals subject to the Hatch-Waxman law,[40] and the policies of that law underscore the need for a rule of law that protects consumers from collusive agreements to stifle generic entry. Any private agreement in which a branded pharmaceutical company "pays off" a patent challenger to drop or soften the sort of challenge Congress specifically meant to encourage necessarily runs counter to those policies. The most reliable way to effectuate them is to recognize a rule of presumptive illegality.

Practical considerations concerning pharmaceutical patent litigation further demonstrate the propriety of such a rule. Experience shows that a high proportion of brand-name patent holders *lose* patent lawsuits litigated to a decision. After studying patent litigation from 1992 to 2000 between branded drug companies and generic firms (cases that were neither settled nor still pending in district court), the Commission found that the generic firm prevailed on a finding of patent invalidity or non-infringement in cases involving 73 percent of the drug products considered. *FTC Generic Drug Study* 20. That study suggests that many exclusion-payment agreements are likely to involve brand-name patents that could not withstand just the

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[40] *See, e.g.*, Herbert Hovenkamp, et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1751 (2003).

type of legal challenges that the Hatch-Waxman Act sought to encourage generic firms to make. Exclusion payments are most likely to be used to protect the weakest patents. *See, e.g.*, *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 212 (2d Cir. 2006) (acknowledging that permitting settlements in which branded and generic rivals agree to avoid competition and share the resulting profits would protect patents that are "fatally weak"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 534 (E.D.N.Y. 2005) ("the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity"). A later analysis confirms the FTC's finding, concluding that, of the 2002-2004 Federal Circuit decisions with a final ruling on a drug patent claim (validity, infringement, or enforceability), alleged infringers had a 70 percent success rate. *See* Paul Janicke & Lilan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 20 (2006). Deeming exclusion-payment settlements presumptively unlawful is consistent with the evidence.

Accordingly, the Commission submits that the lessons of economics, the teachings of experience, and common sense justify a rule that proof of an exclusion-payment agreement is sufficient to establish a prima facie case of illegality. At that point, the settlement parties should be required to explain how and why their agreement is not anticompetitive.

## CONCLUSION

The judgment should be reversed and the case remanded to the district court for further proceedings.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(b). It is proportionally spaced and contains 13,249 words, as counted by the WordPerfect word processing program.

July 26, 2010

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## CERTIFICATE OF SERVICE

I hereby certify that on July 26, 2010, I electronically filed the foregoing Brief for Plaintiff-Appellant Federal Trade Commission at the Eleventh Circuit Court of Appeal's EDF website. Also on this day an original plus six paper copies of the Brief and Record Excerpts were sent via overnight delivery to the Court and two paper copies sent to each of the following:

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