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

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

In Re: K-DUR ANTITRUST LITIGATION

ON APPEAL FROM A FINAL ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY GRANTING DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

BRIEF OF THE FEDERAL TRADE COMMISSION AS *AMICUS CURIAE* SUPPORTING APPELLANTS AND URGING REVERSAL

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INTEREST OF THE FEDERAL TRADE COMMISSION

The Federal Trade Commission (the "Commission" or "FTC") is an independent federal agency, charged with promoting a free and competitive marketplace and protecting consumer interests. *See* 15 U.S.C. §§ 41 *et seq.* The Commission has substantial experience concerning the balance between antitrust and intellectual property laws,[1] the "Hatch-Waxman Act,"[2] and the types of agreements at issue here.[3] Indeed, it is currently litigating a challenge to a drug maker's use of exclusion payments, in another district court in this Circuit. *See King Drug Co. of Florence, Inc. v. Cephalon,*

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[1] *See, e.g.*, Federal Trade Commission, *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition* (2011) (http://www.ftc.gov/os/2011/03/110307patentreport.pdf); U.S. Department of Justice & Federal Trade Commission, *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition* (2007) (http://www.ftc.gov/reports/innovation/P040101PromotingInnovationand CompetitionrptO704.pdf); Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003) (www.ftc.gov/os/2003/10/innovationrpt.pdf); U.S. Department of Justice & Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995) (www.usdoj.gov/atr/public/guidelines/0558.htm).

[2] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (codified at various sections of Titles 15, 21 and 35 of the U.S. Code).

[3] *See, e.g., FTC v. Watson Pharm., Inc.*, 687 F. Supp. 2d 1371 (N.D. Ga. 2010), *appeal docketed*, No. 10-12729-DD (11th Cir., argued May 13, 2011); *In re Bristol-Myers Squibb Co.*, FTC Dkt. No. C-4076 (April 14, 2003); *In re Hoechst Marion Roussel, Inc.*, FTC Dkt. No. 9293 (May 8, 2001).

Inc., 702 F. Supp. 2d 514 (E.D. Pa. 2010) (denying motion to dismiss).[4] The Commission has also gathered empirical evidence regarding exclusion-payment agreements: in 2002, the Commission conducted a comprehensive study of generic drug entry,[5] and since January 2004, has reviewed drug patent settlements filed pursuant to the 2003 amendments to the Hatch-Waxman Act,[6] and has reported those results annually. *See* notes 17-19, *infra*.

The Commission files this brief pursuant to Fed. R. App. P. 29 and 3d Cir. LAR 29, in support of appellants, urging reversal.

STATEMENT OF THE CASE

The legality of exclusion payments in pharmaceutical patent settlements is a question of first impression in this Circuit but is already the subject of active debate among judges in other circuits. This Court's resolution of the question will have a profound impact on American consumers' ability to receive the benefits of generic

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[4] The Commission is also familiar with the particular agreements at issue here, having challenged those agreements in an administrative proceeding. *See In re Schering-Plough Corp.*, 136 F.T.C. 956 (2003), *vacated & set aside, Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

[5] *See* Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* (July 2002) (www.ftc.gov/os/2002/07/genericdrugstudy.pdf) (hereinafter "*FTC Generic Drug Study*").

[6] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, § 1112 (codified at 21 U.S.C. § 355 note).

drugs: according to an FTC staff analysis published in January 2010, exclusion-payment settlements are costing consumers about $3.5 billion per year.[7]

A. Pharmaceutical Patents

The patent laws grant inventors the exclusive right to practice an invention for a limited time. 35 U.S.C. §§ 154, 271(a). In the case of pharmaceuticals, some patents may claim the chemical compound itself, while others claim particular features of a drug product, such as coatings or other characteristics that affect how its active ingredient is released into the body.[8] Patents on drug product characteristics may prolong exclusivity well beyond expiration of the compound patent, but they can often be "invented around." For example, the time-release profile achieved through a patented time-release mechanism might be achievable through another, non-infringing, mechanism.[9] In addition, the mere fact that a patent has been issued by the Patent and

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[7] Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, (2010) (http://www.ftc.gov/os/2010/01/100112 payfordelayrpt. pdf).

[8] *See* Martin A. Voet, THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA & PHARMACEUTICAL LIFE-CYCLE MANAGEMENT 59 (3d ed. 2011) (describing pharmaceutical patent categories); 21 C.F.R. § 314.53 (noting categories of patents that may be listed in the Orange Book, including active ingredient patents, formulation and composition patents, and method-of-use patents).

[9] *See, e.g., Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348, 1357 (Fed. Cir. 2004) (finding non-infringement where the defendant was able to design around patent claim regarding time release); *see also* Voet, *supra*, at 62-63 (explaining that "[a] formulation patent offers the least desirable patent protection because

Trademark Office does not mean that it is valid; alleged infringers frequently prevail in litigation by demonstrating that the patent is invalid.[10]

The antitrust laws have long recognized that patents are an important incentive for innovation.[11] However, "'[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 * * * .'" *Lear, Inc. v. Adkins*, 395 U.S. 653, 663-64 (1969) (quoting *Pope Mfg Co. v. Gormully*, 144 U.S. 224, 234 (1892)).

B. The Hatch-Waxman Act

The Hatch-Waxman Act's purpose is to foster entry of low-cost generic drugs into the market while safeguarding brand-name drug patent rights.[12] The Act allows

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typically it can be avoided by using a different formulation"); Elizabeth H. Dickinson, *FDA's Role in Making Exclusivity Determinations*, 54 Food & Drug L.J. 195, 197 (1999) ("With the listing of formulation patents in the Orange Book, the assertion that the patent will not be infringed is very common, because competitor companies have been able to design around the patented formulation").

[10] *See* John Allison & Mark Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998) (examining all written, final validity decisions by either district courts or the Federal Circuit from 1989 through 1996 and finding that 46% of litigated patents were declared invalid).

[11] *See, e.g., Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990) ("the aims and objectives of patent and antitrust laws may seem, at first glance, wholly at odds. However, the two bodies of law are actually complementary, as both are aimed at encouraging innovation, industry and competition.").

[12] *See, e.g.*, H.R. Rep. No. 98-857, Pt. 1, at 14-17 (1984); *id*. Pt. 2, at 5-6.

for accelerated approval of a generic drug by the Food and Drug Administration ("FDA") through an Abbreviated New Drug Application ("ANDA"), upon a showing that the new (generic) drug is "bioequivalent" to one already approved. 21 U.S.C. § 355(j). Patent holders benefit from an extension of the patent term that compensates for patent life lost through the time required for FDA approval. 35 U.S.C. § 156.

The Act contains a detailed structure designed to facilitate challenges to patents that are either invalid or too narrow to legitimately prevent the entry of generic drugs. The branded drug company submits to the FDA a list of patents that it claims cover its drug. 21 U.S.C. § 355(b)(1). A generic firm submitting an ANDA must make a certification regarding each listed patent. Most pertinent here, a "Paragraph IV certification" must state that the patent is either invalid or not infringed. 21 U.S.C. § 355(j)(2)(A)(vii) (IV). Once a generic makes a Paragraph IV certification, a special procedure permits the patent holder to bring suit immediately, before the generic applicant even markets its product, so as to allow speedy resolution of the patent claim. 35 U.S.C. § 271(e)(2); *see Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). During the first 30 months of the patent litigation, FDA normally cannot approve the generic product. 21 U.S.C. § 355(j)(5)(B)(iii).

The Act also encourages generic competitors to challenge patents: it rewards the first filer of a "Paragraph IV-ANDA" with 180 days of marketing exclusivity,

during which time subsequent ANDA applicants must stand in line and await FDA approval. 21 U.S.C. § 355(j)(5)(B)(iv). No parallel economic incentive is provided for ANDA filings that do not challenge the branded drug's patent. *See* James T. O'Reilly, *Prescription Pricing & Monopoly Extension: Elderly Drug Users Lose the Shell Game of Post-Patent Exclusivity*, 29 N. Ky. L. Rev. 413, 414 (2002) (Congress provided the 180-day generic exclusivity period as "a reward for challenging monopolists' abuse of weak patents").

Hatch-Waxman has brought great benefits to consumers. As acknowledged by a former president of the Generic Pharmaceutical Association — an organization of generic drug firms, some of which have benefitted financially from pay-for-delay deals — successful challenges to patents involving the "blockbuster" drugs Prozac, Zantac, Taxol, and Plantinol alone are estimated to have saved consumers more than $9 billion.[13]

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[13] *Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before Senate Commerce Comm.*, 107th Cong., 2d Sess. 56, 61 (2002) (Statement of Kathleen D. Jaeger, Pres. & CEO, Generic Pharma. Ass'n). For a more recent estimate on savings from generic drugs, *see Paying off Generics to Prevent Competition with Brand Name Drugs: Should it Be Prohibited?: Hearing Before Senate Judiciary Comm.*, 110th Cong., 1st Sess. 164, 166 (2007) (Statement of Michael Wroblewski, Project Director, Consumers Union) (consumer savings in 2006 from generic competition to Zocor, Pravachol, Zoloft, Wellbutrin, and Flonase are estimated at $6.6 billion).

Experience has also borne out Congress's premise that many patents purportedly standing in the way of generic entry will not withstand challenge. The Commission studied all patent litigations initiated between 1992 and 2000 between branded drug manufacturers and Paragraph IV generic challengers, and found that generics prevailed with respect to73% of the drug products that were the subject of patent litigation that resulted in a court decision. *FTC Generic Drug Study, supra* note 5, at 19-20. A later analysis similarly concluded that, of the 2002-2004 Federal Circuit decisions with a final ruling on a drug patent claim, accused infringers had a 75% success rate. *See* Paul Janicke & Lilan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 5 (2006).

C. Exclusion-Payment Patent Settlements

The pernicious impact of exclusion-payment settlements is that, by delaying the marketing of potentially noninfringing generic drugs, they deprive consumers of the economic benefits that normally attend the introduction of generic drugs. Typically, a branded manufacturer loses about 90% of its unit sales after generic products enter the market. *See* note 7, *supra*. While generic entrants gain that unit volume, they do not gain most of the revenues lost by the branded manufacturer because, as generic competition sets in, the price for generics falls, on average, by about 85% — *i.e.*, to about 15% of what the branded manufacturer was charging. *Pay-for-Delay*, note 7, supra, at 8. As

a result, the vast majority of the benefit of generic entry goes not to the generic sellers, but to the public, in the form of lower prices.[14] Both branded and generic companies thus have strong incentives to enter into exclusion-payment settlements, which allow them to share a continuing stream of monopoly profits while depriving the public of the benefits of early generic entry.

D. The 2003 Medicare Modernization Act

Prompted by concern over the anticompetitive effects of agreements such as those at issue here, Congress amended Hatch-Waxman as part of the 2003 Medicare Amendments, *supra* note 6. Those amendments sought in part to stamp out the "abuse of the Hatch-Waxman law" 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. 107-167, at 4 (2002).[15] Among the corrective

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[14] For example, if a branded 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.

[15] In the words of Rep. Waxman, "[t]he law has been turned on its head. * * * We were trying to encourage more generics and through different business arrangements, the reverse has happened." Cheryl Gay Stolberg *et al*., *Keeping Down the Competition: How Companies Stall Generics and Keep Themselves Healthy*, The New York Times, July 23, 2000, at A11 (quoting Rep. Waxman). Similarly, Senator Hatch characterized such agreements as "appalling." 148 Cong. Rec. S7566 (daily ed. July 30, 2002).

measures to address such abuses, the amendments require branded and generic companies who enter into patent litigation settlements to file those settlement agreements with the Commission and the Department of Justice for antitrust review. Pub. L. No. 108-173, §§ 1111-1118.

E. Trends in Exclusion-Payment Patent Settlements

From 2000 through 2003, the Commission initiated a number of enforcement actions involving exclusion-payment patent settlements, most of which resulted in consent orders.[16] Following those actions, drug makers apparently refrained from entering into settlements with substantial exclusion payments, and litigants instead reached settlements in other ways. For example, in the first year following Congress's filing requirement, fourteen agreements resolving patent infringement actions were reported, and not one involved an exclusion payment.[17] In contrast, during the following reporting year (during which the Eleventh Circuit handed down its decision in *Schering*, note 4, *supra*), there were eleven final settlements of brand-generic patent litigation, of which three (27%) included both compensation to the generic and a

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[16] *See, e.g., In re Abbott Labs.*, FTC Dkt. No. C-3945 (May 22, 2000); *In re Geneva Pharm., Inc.*, FTC Dkt. No. C-3946 (May 22, 2000); *In re Hoechst Marion Roussel, Inc.*, FTC Dkt. No. 9293 (May 8, 2001).

[17] Federal Trade Commission, Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004* (www.ftc.gov/os/2005/01/050107medicareactrpt.pdf) 1-2 (2005).

restriction on its entry.[18] In the most recent report, the number of patent settlements that included both compensation to the generic and a restriction on entry increased 60%, from 19 in FY 2009 to 31 in FY 2010.[19]

F. The K-Dur Settlements

Schering marketed K-Dur 20, a potassium supplement used to treat high blood pressure. The active ingredient of K-Dur 20 was not patentable, but Schering held a patent on the drug's time-release formulation. That patent expired in September 2006.

In 1995, both Upsher and ESI filed ANDAs with Paragraph IV certifications seeking approval for generic versions of K-Dur 20. Schering sued them both. In 1997, on the eve of trial, Schering entered into a settlement with Upsher. Schering agreed to pay Upsher $60 million, and Upsher agreed to abandon its challenge and forgo entry until 2001. Upsher also agreed to grant Schering a bundle of licenses, for which Schering would make conventional milestone and royalty payments. In 1998, Schering also entered into an agreement with ESI. A portion of this settlement covered a side

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[18] Federal Trade Commission, Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005* (www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf) 3-4 (2006).

[19] Federal Trade Commission, Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2010* (http://www.ftc.gov/os/2011/05/1105mmaagreements.pdf) 2 (2011).

deal, but Schering separately agreed to pay ESI up to $15 million in exchange for ESI's agreeing not to market its generic version of K-Dur until January 2004.

G. The Commission's Litigation

In March 2001, the Commission issued an administrative complaint charging that Schering's agreements with Upsher and ESI violated Section 5 of the FTC Act, 15 U.S.C. § 45. *In re Schering*, 136 F.T.C. at 1076-91. In 2003, the Commission held that both agreements violated Section 5, but the Eleventh Circuit set aside that decision. *See* note 4, *supra*.

H. The Present Litigation

In this case, purchasers of K-Dur 20 allege that Schering's settlement agreements with Upsher and ESI violated the Sherman Act, and the district court granted defendants' motions for summary judgment. A-9-10. The district court adopted a Special Master's Report that concluded that, absent a showing that the patent infringement suit was "objectively baseless," there could be no antitrust challenge unless the settlement restrained competition beyond "the scope of Schering's patent." A-56. The Report deemed the agreements "well within" the patent's scope because the entry dates that the parties agreed to were before the patent expired and no products other than the generic products at issue in the litigation were delayed by the agreements. *Id.*

SUMMARY OF ARGUMENT

This appeal presents a legal issue on which a number of federal courts have taken varying approaches, none of which has succeeded in balancing the competing interests. The court below followed rulings from the Second and Federal Circuits, which have adopted an extremely permissive attitude toward exclusion-payment settlements, condoning them unless they involve "sham" claims of patent infringement, or extend to items not even arguably within the patent's scope. Those rulings have been controversial, prompting disagreement among the judges of the Second Circuit. (Part I.A.)

Other courts have taken different approaches. Rulings of the Sixth and D.C. Circuits suggest that these settlements may be subject to per se condemnation under the antitrust laws, at least in some circumstances. (Part I.B.) Still other courts — including another district court within this Circuit — have suggested the need for further inquiry into the strength of the asserted patent claims in order to assess the reasonableness of such settlements for the purpose of antitrust analysis. (Part I.C.)

The decision below is problematic in that it conflicts not only with basic antitrust principles, but with patent law and the policies of the Hatch-Waxman Act. Agreements made by patent holders are subject to antitrust scrutiny, particularly where, as here, they eliminate potential competition by splitting monopoly rents with would-be competitors. The district court's rule — which allows such agreements as long as the patent infringe-

ment claim rises above the level of a "sham" — is especially inappropriate in light of the policies of Hatch-Waxman, in which Congress expressly sought to encourage challenges to weak or narrow patents, and thereby spur early generic entry. The court's rule would negate such challenges by allowing a branded company simply to pay generic filers to stay out of the market until the patent expires. Economic realities make such deals irresistible as long as they are condoned by the courts. (Part II.A.)

Patent settlement agreements should be assessed under the antitrust rule of reason — a rule that, as recent Supreme Court teachings make clear, is flexible enough both to take into account the patent context and to recognize a presumption of illegality for types of agreements whose likely anticompetitive impact is clear. Parties may settle patent disputes in a variety of ways, and many settlements — *e.g.*, those in which the parties compromise on an entry date, without payment by the patent holder — pose little competitive problem. On the other hand, where a settlement includes a substantial payment, that payment must be a *quid pro quo* for something; if the challenger is offering a commitment to stay out of the market for a specified time, it follows that the payment is to secure exclusion of a potential competitor. Because such an agreement closely parallels market allocation arrangements universally recognized as unlawful, a presumption of antitrust illegality is justified. Such a presumption is bolstered by the policies of Hatch-Waxman and by experience that shows the vulnerability of many

pharmaceutical patents, the weakest of which will be the most likely to result in exclusion-payment settlements. (Part II.B.)

ARGUMENT

This appeal poses a question of both doctrinal and practical importance. The ruling below would condone, in the vast majority of cases, exclusionary deals that are profitable for both the branded and generic companies, but deprive consumers of the benefits of competition, by allowing branded companies to pay the generic to stay out of the market until patent expiration. Such agreements are already proliferating, in the shadow of similarly lenient rulings — delaying generic entry and costing consumers billions of dollars a year.

At the same time, resolution of the legal issue presented — which lies at the intersection of the patent laws, the Hatch-Waxman Act, and the antitrust laws — has proven elusive. The courts that have considered it have taken a variety of approaches, yet none has achieved a satisfactory accommodation of the interests at stake, which must recognize the likely anticompetitive nature of such agreements, yet afford an opportunity to defend settlements that benefit or do not harm competition. This case presents an opportunity for this Court to untangle this problem.

I. The Variety of Approaches to the Exclusion Payment Problem

A. Per Se Lawfulness and the Disagreement Within the Second Circuit

The Second and Federal Circuits, as well as the court below, treat exclusion-payment settlements as lawful so long as the exclusionary terms of the agreement are nominally within the patent's scope, regardless of the strength or weakness of that patent or the patent-holder's claims of infringement.[20] In the Second Circuit, however, that position was not adopted without controversy. After a divided panel of that court adopted that rule in *Tamoxifen*, another panel, considering the appeal in *CA2 Cipro*, unanimously stated that, while it was bound by the decision in *Tamoxifen*, it "believe[d] there [were] 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." 604 F.3d at 110. The plaintiff-appellants filed a petition for rehearing *en banc*, but it was denied. Judge Pooler dissented from the denial, stating that "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." 625 F.3d at 781.

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[20] *See Ark. Carpenters Health & Welfare Fund v. Bayer AG ("CA2 Cipro")*, 604 F.3d 98 (2d Cir.), *on pet. for rehearing*, 625 F.3d 779 (2d Cir. 2010); *In re Ciprofloxacin Hydrochloride Antitrust Litig. ("CAFC Cipro")*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *see also Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003).

B. Per Se Unlawfulness Under Some Circumstances

The Sixth Circuit has held exclusion-payment settlements to be per se unlawful, at least under some circumstances. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003). Although the reach of that holding remains subject to debate,[21] the court's opinion contains broad language condemning such settlements:

> There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* restraint of trade.

Id. at 909. Accordingly, some observers – including the *CA2 Cipro* panel — have characterized the Sixth Circuit position as one of per se illegality. *See* 604 F.3d at 105.

An earlier ruling of the D.C. Circuit also recognized the anticompetitive nature of exclusion-payment settlements, and suggested that at least some such agreements could be unlawful per se. *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001), involved a claim by a subsequent generic filer that a settlement agreement between a branded company and the first generic filer, which delayed

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[21] In advising the Supreme Court not to grant *certiorari* in that case, the Solicitor General (joined by the Commission) stated that the Sixth Circuit's holding appeared to be limited to situations in which part of the agreement goes beyond the literal scope of the patent grant, and that it involved an interim settlement that did not even yield finality as to the patent dispute. *See* Brief for the United States as Amicus Curiae, *Andrx Pharms., Inc. v. Kroger Co.*, No. 03-779, filed July 2004, at 11-17.

generic entry, was anticompetitive. Although the court of appeals affirmed dismissal on the pleadings, it directed that the dismissal be without prejudice, because the second generic could have a valid antitrust claim based on such an agreement. *See* 256 F.3d at 807-12. In so doing, the court expressed doubt that the restraint could be justified as "ancillary," but "rather could reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions" — language that clearly suggests the availability of per se treatment. *See id*. at 811; *see generally Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49 (1990) (market allocation is per se unlawful). The *Biovail* court also recognized, more generally, that

> "[a] payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties entering the agreement and the rent-preserving effect of that agreement."

Id. at 809 (quoting D. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 Food & Drug L. J. 321, 335 (2000)).

C. Decisions Considering the Strength of the Patent

Other courts — including another district court within this Circuit — have issued rulings suggesting the need for an inquiry into the strength of the underlying patent claims when analyzing exclusion-payment settlements. In *King Drug*, *supra*, the court denied a motion to dismiss a case in which the FTC, among other plaintiffs, is

challenging a series of settlements with generic drug makers.[22] That court articulated a "scope of patent framework." The *King Drug* court noted respects in which its ruling was consonant with those in *Tamoxifen* and *CAFC Cipro*, 702 F. Supp. 2d at 528-29, but the details of its ruling show that it contemplates a broader inquiry into the strength of the relevant patent. In particular, and in contrast to the approach adopted by the lower court here, the *King Drug* court makes clear that one way plaintiffs may satisfy the scope of the patent test is by establishing "non-infringement" or "patent invalidity." *Id.* at 533. Litigation in that case is ongoing.

King Drug relied substantially on two rulings from the Eleventh Circuit, *Schering, supra*, and *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294 (2003). *See* 702 F. Supp. 2d at 534-35. As that court pointed out, *Valley Drug* involved a remand for evidentiary proceedings. *Id.* Those proceedings included a factual inquiry into the "protection afforded by the patent," based on "the likelihood of [the patentee's] obtaining such protections," as viewed at the time of the agreements. *See* 344 F.3d at

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[22] The Commission's complaint alleges that Cephalon had a narrow patent that would not prevent generic competition to its branded product; that Cephalon, the generic companies, and Wall Street observers expected generic entry in 2006; that it paid each of the four generic companies (more than $200 million collectively) to abandon their patent challenges and forgo entry until 2012; and that it thereby blocked competition by any other potential generic entrant as well. The result, as described by Cephalon's then chief executive, was dramatic: "We were able to get six more years of patent protection. That's $4 billion in sales that no one expected." *See* J. George, "Hurdles ahead for Cephalon," Philadelphia Bus. J., Mar. 20, 2006 (http://assets.bizjournals.com/philadelphia/stories/2006/03/20/story1.html).

1312. And the *Schering* ruling was based, in part, on the fact that the FTC "had not raised allegations that the patent itself was invalid * * * ." 702 F. Supp. 2d at 535; *see Schering*, 402 F.3d at 1068. The *Schering* court also expressly "underscore[d] the need to evaluate the strength of the patent." *Id*. at 1076. Although there has been disagreement regarding the meaning of the Eleventh Circuit's test,[23] it appears to provide for an inquiry based on the strength of the patent and the patent-holder's claims of infringement. *See also Andrx Pharms. v. Elan Corp*., 421 F.3d 1227, 1236 (2005) (reversing dismissal on the pleadings in a case challenging a patent settlement agreement, noting the "fact-intensive" nature of antitrust cases).

II. Legal and Policy Analysis of Exclusion-Payment Settlements

A. The Decision Below Conflicts With Fundamental Antitrust and Patent Principles and the Policies of the Hatch-Waxman Act

The decision below follows the permissive approach adopted by the Second and Federal Circuits, condoning an agreement between potential rivals to share monopoly

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[23] In petitioning for *certiorari* in *Schering*, the FTC expressed its concern that the Eleventh Circuit's rulings could be interpreted as effectively imposing a "sham" standard. *See* Petition for Certiorari, *FTC v. Schering-Plough Corp.*, No. 05-273, at 14-15 (Aug. 2005). Others, however, have disagreed with that reading. Notably, the Solicitor General differed in his brief in *Schering*, in which he concluded that "[n]either *Valley Drug* nor [*Schering*] holds * * * that evidence of invalidity or non-infringement available at the time of settlement would be irrelevant in assessing the permissibility of an exclusion-payment." Brief for the United States as Amicus Curiae, at 17-18 (May 2006). In any event, the Eleventh Circuit will have an opportunity to clarify its standard in a pending appeal, for which argument was held recently. *See FTC v. Watson Pharmaceutical*, note 3, *supra*.

profits instead of competing. In the absence of countervailing considerations, such an agreement is a plain violation of the antitrust laws. *See Palmer*, 498 U.S. at 49-50. The court below erred in supposing that such an agreement is somehow justified by virtue of Schering's patent rights. On the contrary, the result below is inconsistent with the Supreme Court's patent jurisprudence and the specific congressional policies embodied in the Hatch Waxman Act, as well as with basic antitrust principles.

Agreements among competitors are not exempt from scrutiny under the Sherman Act just because a patent is involved. *See, e.g., United States v. Masonite Corp.*, 316 U.S. 265 (1942) (patent agency agreements held to violate the antitrust laws); *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948) ("holder of the patents cannot escape the prohibitions of the Sherman Act" by "aggregating patents" in pooling arrangement). 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 (1963) (White, J., concurring) (competitors' collusive termination of patent interference proceeding 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 Supreme Court concluded that this arrangement

amounted to price-fixing, because Masonite had eliminated potential competition 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.

Schering has likewise managed to divide the market with potential competitors by sharing monopoly profits. As in *Masonite*, it is no answer to say that Schering's patent rights might have enabled it to exclude Upsher and ESI from the market entirely by prevailing in litigation. That is not what it did. Instead, it avoided the risks of litigation by entering into agreements that allowed the companies effectively to divide the market. Exclusion payments exclude competition no matter how weak or narrow a patent claim is — an opportunity *not* provided by the patent system itself, under which weak patents can be invalidated and narrow patents can be declared not infringed. *See* 35 U.S.C. § 282, ¶ 2 (1)-(3).

Moreover, through Hatch-Waxman, Congress created a special incentive for generic drug companies to challenge weak patents. As described above (at 5-6), Congress provided a specific incentive, in the form of the 180-day exclusivity, to encourage generic firms to challenge weak or narrow patents that interfere with generic

entry. The ruling below would render this careful plan an exercise in futility, however, by allowing exclusion-payment settlements whenever a patent-holder can make non-sham arguments that its patent is valid and infringed.

The economic realities of the pharmaceutical industry, moreover, make these deals irresistable if they are condoned. Given the large gap between branded and generic prices, a branded manufacturer can pay the generic firm more than the generic could hope to earn even if it entered the market, and still have a great deal of monopoly profits left over. *See* note 14, *supra*, and accompanying text. Even the weakest patents can be protected. *See Tamoxifen*, 466 F.3d at 211. Hatch-Waxman would thus yield consequences that Congress plainly did not intend: frequent payments from branded firms to generics, but less benefit to consumers. A trend toward settlements with compensation to the generic along with an agreement to defer entry indeed appears to have established itself in the wake of court decisions permitting such settlements. See *supra* at 9-10 & nn. 17-19.

B. Exclusion-Payment Settlements Should Be Treated as Presumptively Unlawful

How, then, should exclusion-payment settlements be treated under the antitrust laws? Although the settlements that Schering entered into are a form of market allocation, they should not be condemned as per se antitrust violations. Rather, they should be evaluated under the rule of reason — which embraces a range of analyses,

from full market analysis to abbreviated "quick look" scrutiny. *See generally California Dental Ass'n v. FTC*, 526 U.S. 756 (1999). The rule of reason is sufficiently flexible to take full account of patent interests and the Hatch-Waxman context.[24]

The essential task in such a rule of reason analysis is to distinguish between exclusion that results from the strength of the patent and any additional exclusion that results from a private agreement. Many pharmaceutical patent cases have been settled by the parties' agreement on an entry date prior to the patent's expiration, but without payments by the patent holder.[25] Such settlements can be defended on the ground that any exclusion simply reflects the strength of the patent as understood by the parties. These settlements are thus unlikely to raise serious antitrust concerns, as the Commission has recognized. *Schering*, 136 F.T.C. at 987.

When, however, settlements of such patent litigation *do* include substantial payments from the patent holder to the challenger — instead of vice-versa, which is the way that most patent disputes are settled outside of the Hatch-Waxman context — one

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[24] 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 (2004) (taking regulatory context into account in Section 2 analysis).

[25] From FY2004 to FY2009, drug companies filed 218 final settlements involving brand-name and generic companies, and 70% of those agreements did not involve compensation to the generic and deferred entry. *Pay-for-Delay*, note 7, supra, at 4.

must ask, what is the *quid pro quo* for those payments?[26] In the absence of another explanation, the patent holder is evidently buying a greater degree of exclusion than it could have achieved otherwise — as compared either with a hypothetical settlement that does not entail payment, or with the expected outcome of litigation.[27] Accordingly, courts and commentators have recognized the inference of anticompetitive purpose and effect that can be drawn from such payments. *See Andrx Pharm.*, 256 F.3d at 809; XII Herbert Hovenkamp, ANTITRUST LAW ¶ 2046, at 327 (2d ed. 2005).

In such cases, antitrust and patent-law principles, evidentiary considerations, and the policies of Hatch-Waxman all support a presumption that settlements involving both payment (in any form) by the patent holder and forbearance from entry by the

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[26] 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" are frequently used as subterfuges to mask payments for delay. Straightforward payments have "given way to more complex arrangements," making it more difficult for an antitrust plaintiff to demonstrate a net flow of consideration to the generic firm. *See* S. Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 663-66 (2009). 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.

[27] Although in some cases, a settlement without payment may not be achievable, this analysis does *not* presume the possibility of such settlements. *Cf. Schering*, 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 an average "expected value" of the outcome of litigation.

challenger are anticompetitive, thus shifting the burden to the parties to justify the agreement. The Supreme Court has long recognized that an agreement effecting a "naked restraint on price and output requires some competitive justification" to avoid condemnation. *NCAA v. Bd. of Regents of Univ. of Oklahoma*, 468 U.S. 85, 110 (1984). Payments that, on their face, appear to be in exchange for market exclusion are similar to the agreements the Supreme Court condemned as per se unlawful in *Palmer*. 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." *Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 36-37 (D.C. Cir. 2005); *see N. Tex. 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." Herbert Hovenkamp, 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 was for something *other than* delay. Evidence of other reasons for the payment, if it exists, is far more likely to be in the

settlement parties' hands than in the hands of one challenging the agreement. The parties may, alternatively, be able to establish that their agreement achieves beneficial efficiencies. *See Schering*, 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 35-36. But the parties' superior access to any such evidence further supports use of a burden-shifting presumption.

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. *See* p. 7, *supra*. This evidence suggests that exclusion-payment agreements are likely to involve brand-name patents that could not withstand the very type of legal challenges that Hatch-Waxman sought to encourage. In other words, exclusion payments are most likely to be used to protect the weakest patents. *See, e.g.*, *Tamoxifen*, 466 F.3d at 212 (acknowledging that such settlements can protect patents that are "fatally weak").

Use of such a presumption also has the benefit of obviating a detailed factual inquiry into the underlying patent claims. As discussed above, some courts have suggested that such an inquiry into the strength of the patent is needed to resolve antitrust claims. *See* pp. 17-19, *supra*. Although such an approach is certainly preferable to a rule that protects agreements that perpetuate exclusion based on the weakest patents, as

the Second and Federal Circuits have adopted, it nevertheless requires that courts and litigants must revisit patent issues the parties previously sought to resolve without litigation.[28] Such an inquiry is unnecessary if the courts draw the straightforward inference that — in the absence of an explanation to the contrary — a substantial payment from a patent holder to a challenger, accompanied by the challenger's commitment to refrain from market entry for a specified period of time, reflects an improper agreement to restrict market competition.

Perhaps most important, recognition of this presumption — that agreements containing both payments to patent challengers and commitments 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. Exclusion payment settlements most commonly appear in the context of pharmaceuticals subject to Hatch-Waxman,[29] and the policies of that law underscore the need for a rule that protects consumers from collusive agreements to stifle generic entry. The most reliable way to effectuate those policies is to recognize a rule of presumptive illegality.

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[28] The Commission, and a number of courts, have recognized the difficulties posed by such inquiries. *See, e.g.*, *Schering*, 136 F.T.C. at 992-98; *Tamoxifen*, 466 F.3d at 203-04.

[29] *See*, *e.g.*, *Tamoxifen*, 466 F.3d at 206; Herbert Hovenkamp, et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1751 (2003).

Accordingly, the Commission submits that the lessons of economics, the teachings of experience, and an appropriate balancing of important congressional objectives 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 make a showing of how and why their agreement is not anticompetitive. If the parties meet their burden, the burden of showing that the agreement is nevertheless anticompetitive would shift back to the plaintiff.

CONCLUSION

For the foregoing reasons, this Court should reverse the district court's ruling, and remand for consideration of the issues according to the standard set forth herein.

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COMBINED CERTIFICATIONS

1) Bar membership – Because this brief is filed on behalf of an administrative agency of the United States, there is no bar membership requirement.

2) Word count – I certify that this brief complies with Fed. R. App. P. 29(d) and Fed. R. App. P. 32(a)(7). It contains 6555 words, as counted by the WordPerfect word processing program.

3) Typeface and type style – This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6). It was prepared using the WordPerfect word processing program in a 14-point proportionally-spaced Times New Roman typeface.

4) Service upon counsel – I hereby certify that on May 18, 2011, I served ten copies of the Brief of the Federal Trade Commission as *Amicus Curiae* Supporting Appellants and Urging Reversal on this Court by express overnight delivery. On the same day, I used this Court's CM/ECF system to serve this brief on the following counsel, who represent all the parties to this matter:

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