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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[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 & P

Trademark Office does not mean that it is

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 "bioequiva

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 cha

[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

[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: Summa zatiosettlemenn rto f Abth oseosettlemen(r)-te

[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/ohng,

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 oGbga—at 00491ces

ment claim rises above the level of a "sham" — is especially inappropriate in light of the policies of Hatch-Waxman, in which C

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.*

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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).

[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

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

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

[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

[26] The rule we urge should apply whenever the patent holder provides

settlement parties' hands than in the hands of one challenging the agreement. The

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 ho91(pTD.0019 Tc.11d-23.746c,.000 at 992-98;)]0es the pa

[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.

Respectfully submitted,

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