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

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

IN RE K-DUR ANTITRUST LITIGATION

On Appeal from the March 24, 2010 Order of the
United States District Court for the District of New Jersey,
Judge Joseph A. Greenaway, Presiding by
Designation on the District Court

BRIEF OF AMICI CURIAE AMERICAN ANTITRUST INSTITUTE AND 26 PROFESSORS IN SUPPORT OF APPELLANTS AND REVERSAL

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CORPORATE DISCLOSURE STATEMENT

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STATEMENT OF INTEREST OF AMICI CURIAE

All parties consent to the filing of this brief. The Academic Amici are professors who have collectively written extensively on innovation, intellectual property law, competition, and antitrust law. (A list of signatories is attached as an Appendix). Their sole interest in this case is that patent and antitrust law develop in a way that serves the public interest and public health by promoting both innovation and competition. The American Antitrust Institute ("AAI") is an independent non-profit educational, research, and advocacy organization devoted to advancing the role of competition in the economy, protecting consumers, and sustaining the vitality of the antitrust laws. AAI is managed by its Board of Directors, with the guidance of an Advisory Board that consists of more than 115 prominent antitrust lawyers, law professors, economists, and business leaders. *See* http://www.antitrustinstitute.org. AAI frequently appears as amicus curiae in cases raising important antitrust issues, including, for example, in *Pacific Bell Telephone Co. v. linkLine Communications, Inc.*, 555 U.S. 438 (2009), in which it participated in oral argument before the Supreme Court.

Amici have filed this brief because they believe that the Special Master's economic and legal reasoning below is flawed and the rule adopted by the court seriously threatens to undermine competition in the pharmaceutical industry. If left standing, the opinion would upset a carefully-crafted statutory scheme

designed to prevent weak or narrow patents from blocking the entry of affordable generic drugs. The stakes for consumers are high.

FED. R. APP. P. 29(c)(5) STATEMENT

No counsel for a party has authored this brief in whole or in part, and no party, party's counsel, or any other person or entity—other than the amici or their counsel—has contributed money that was intended to fund preparing or submitting this brief. One member of AAI's Advisory Board is a partner in one of the law firms representing the appellants, but neither he nor the law firm played any role in this filing.

INTRODUCTION AND SUMMARY OF ARGUMENT

Few competition problems are as critical as pay-for-delay settlements such as the one involving K-Dur. These agreements are currently shielding more than $20 billion of branded drugs from generic competition. *See* FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, AN FTC STAFF STUDY 2 (Jan. 2010) [hereinafter FTC, PAY FOR DELAY], *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf; *Oversight of the Federal Trade Commission Bureau of Competition and the Department of Justice Antitrust Division: Hearing Before Subcomm. on Courts & Competition Policy of H. Judiciary Comm.*, 111th Cong. 4-5 (2010) (prepared statement of the FTC), *available at* http://www.ftc.gov/os/testimony/100727antitrustoversight.pdf. The cost of these settlements to consumers and their health plans has been estimated at between $3.5 billion and $12 billion per year. *See* FTC, PAY FOR DELAY, *supra*, at 2; C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 649 (2009). And recently the number of such settlements has increased dramatically. *See* Press Release, FTC, FTC Staff Report Finds 60 Percent Increase in Pharmaceutical Industry Deals That Delay Consumers' Access to Lower-Cost Generic Drugs (May 3, 2011), *available at* http://www.ftc.gov/opa/2011/05/mmareport.shtm.

Beyond the financial costs, these agreements have severe consequences for public health. Artificially inflated drug costs lead to high out-of-pocket costs that force patients to split pills in half or skip taking their medications. Such consumer-coping strategies expose patients to worsening symptoms, escalating medical conditions, and even death. *See* Thomas Rice & Karen Y. Matsuoka, *The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors*, 61 MED. CARE RES. & REV. 415, 420, 427-28 (2004).

Given the anticompetitive effect of these pay-for-delay agreements and the inference of anticompetitive intent when the branded drug pays the generic tens or hundreds of millions of dollars to drop its challenge to the patent, the two federal antitrust agencies and numerous well-respected commentators have advocated that reverse-payment settlements (in excess of litigation-cost savings) should be presumptively unlawful. Such an approach is fully supported by the Hatch-Waxman Act, which sought to encourage generic challenges to drug patents. And it is fully consistent with antitrust law's condemnation of market allocation agreements among competitors and potential competitors as per se illegal. A naked agreement by a patentee to pay a competitor not to challenge its patent obviously would be illegal. That such an agreement is contained in a settlement agreement does not eliminate its anticompetitive effects. Such settlements ought to be at least presumptively unlawful.

The Special Master's reasons for rejecting this standard do not withstand scrutiny. The Special Master determined that as long as the agreement was "within the scope of the patent," it was protected by the Patent Act, but this assumes the very validity and infringement that is at issue in these cases. A rule of presumptive illegality also is not inconsistent with the presumption of patent validity, as this is merely a procedural presumption. Moreover, in this case, infringement was at issue, and there is no presumption of infringement; on the contrary, a patentee has the burden of proving infringement. Finally, the standard of upholding a settlement as long as the underlying litigation is not "objectively baseless" sets a toothless standard that ignores the balance struck by the Hatch-Waxman Act between fostering innovation and promoting competition in the pharmaceutical industry.

ARGUMENT

I. THE HATCH-WAXMAN ACT SUGGESTS A STANDARD OF PRESUMPTIVE ILLEGALITY FOR REVERSE-PAYMENT SETTLEMENTS

As the Supreme Court has made clear, it is appropriate for antitrust courts to "be attuned to the particular structure and circumstances of the industry at issue." *Verizon Commc'ns v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 411 (2004). Determining the appropriate antitrust rule in a regulated industry requires that the analysis "recognize and reflect the distinctive economic and legal setting of the

regulated industry to which it applies." *Id.* As the leading antitrust treatise makes clear, "the presence of regulation in some instances limits the antitrust role and in some instances simply changes it or even enlarges it." 1A PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 240d, at 289 (3d ed. 2006). The regulatory framework here supports a rule of presumptive illegality for reverse-payment settlements.

A. The Hatch-Waxman Act Sought to Promote Generic Competition and Encourage Brand Drug Innovation

In the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act, Congress enacted a complex regulatory regime to solve urgent problems. The marketplace in the early 1980s suffered from sparse generic entry and stifled brand-drug firm innovation. Generic drugs have the same active ingredients and performance as brand drugs. At the time of the Hatch-Waxman Act, however, generic firms needed to undertake lengthy, expensive trials to demonstrate safety and effectiveness. FDA approval took years, and because the required tests constituted infringement, generics could not even begin the process during the patent term. At the time Congress enacted Hatch-Waxman, there was no generic on the market for 150 brand-name drugs whose patents had already expired. H.R. REP. NO. 98-857, pt. 1, at 17 (1984).

The Act's drafters lamented the "practical extension" of the patentee's "monopoly position" beyond expiration of the patent. H.R. REP. NO. 98-857, pt. 2, at 4 (1984). They sought to "make available more low cost generic drugs." H.R. REP. NO. 98-857, pt. 1, at 14. Generic competition would save the federal and state governments many millions of dollars each year. And given that older Americans used nearly 25 percent of prescription drugs, *id.* at 17, competition would "do more to contain the cost of elderly care than perhaps anything else this Congress has passed." 130 CONG. REC. 24427 (Sept. 6, 1984) (statement of Rep. Waxman).

The first tool created to accelerate generic entry was the Abbreviated New Drug Application ("ANDA") process that allowed generic firms to rely on the brand drug's safety and effectiveness studies and avoid the expensive and lengthy new-drug-application process. 21 U.S.C. §§ 355(j)(2)(A), 355(j)(8)(B). Second, Congress resuscitated the experimental use defense. The Act exempted from infringement the manufacture, use, or sale of a patented invention for uses "reasonably related to the development and submission of information" under a federal law regulating the manufacture, use, or sale of drugs. 35 U.S.C. § 271(e)(1). Third, Congress increased competition by (as discussed more fully below) creating a 180-day period of marketing exclusivity, reserved for the first generic to certify that the brand firm's patent was invalid or not infringed.

In addition to promoting generic competition, Hatch-Waxman included several mechanisms to increase incentives for brand-firm innovation. First, Congress increased the effective patent life by extending the patent term, with the extension currently amounting to half the time the drug is in clinical trials plus the period spent awaiting FDA approval after trials. 35 U.S.C. § 156(c). Second, Congress granted an automatic 30-month stay of FDA approval to patent holders who sue Paragraph IV generic filers within 45 days. This period provides an additional exclusionary right benefiting brand firms that—even without obtaining a preliminary injunction or demonstrating entitlement to one—will not face generic competition for a substantial period of time. 21 U.S.C. § 355(j)(5)(B)(iii). Finally, Congress provided for periods of market exclusivity not based on patents, such as the four-year exclusivity period for a drug with a new active ingredient. 21 U.S.C. § 355(j)(5)(F)(ii).

The Act's drafters emphasized the equilibrium between competition and innovation. Representative Henry Waxman underscored the "fundamental balance of the bill." 130 CONG. REC. 24425 (Sept. 6, 1984). The Energy and Commerce Committee Report explained that allowing early generic challenges "fairly balances" the exclusionary rights of patent owners with the "rights of third parties" to contest validity and market products not covered by the patent. H.R. REP. NO. 98-857, pt. 1, at 28 (1984). And the House Judiciary Committee noted that it "has

merely done what the Congress has traditionally done in the area of intellectual property law[:] balance the need to stimulate innovation against the goal of furthering the public interest." H.R. REP. NO. 98-857, pt. 2, at 30 (1984).

A central element of this equilibrium was the 180-day period of marketing exclusivity. This period was reserved for the first generic firm to successfully challenge a patent and introduce competition before the end of the patent term. When the FDA approves a new drug application ("NDA"), it lists the drug and any relevant patents in a publication known as the Orange Book. Before entering the market, a generic applicant must provide one of four certifications for each patent listed in the Orange Book relating to the relevant NDA. The first three certifications—no patent on the drug, an expired patent, and a promise to wait until the patent expires—do not result in periods of exclusivity. Only the "Paragraph IV" certification, by which the generic claims that the patent is invalid or not infringed, leads to exclusivity. 21 U.S.C. § 355(j)(2)(A)(vii). Given the drafters' goals to encourage entry against invalid patents before the end of the patent term, exclusivity limited to Paragraph IV makes sense.

B. Reverse Payments Undermine the Hatch-Waxman Act

To avoid the judicial scrutiny of their patents that the Act seeks to promote, many pharmaceutical patentees have entered into "reverse" or "exclusion" payment settlement agreements. Under these agreements, the generic firm

typically (1) drops its challenge to the validity of the patent or its denial of the patentee's claim of infringement, and (2) agrees not to enter the market until the patent is about to expire. In return, the patentee pays the generic challenger tens or hundreds of millions of dollars.

Such payments frequently occur because the incentives of brands and first-filing generics overlap considerably. Because the brand makes more by keeping the generic out of the market than the two parties would receive by competing in the market, the parties have an incentive to split the monopoly profits, making each better off than if the generic had entered. The brand then can use a portion of these millions, if not billions, of dollars of additional profit from delayed competition to pay the generic. In fact, it could even pay more than the generic would have received from *winning* its patent challenge and *entering* the market.

Such reverse payments are fairly characterized as the purchase by the patentee of the generic firm's agreement to cease or delay its efforts to enter the market and compete against the patented drug. An agreement concerning the generic entry date, without any cash payment, should reflect the odds of the parties' success in patent litigation. A brand is likely to gain additional exclusivity by supplementing the parties' entry-date agreement with a payment to the generic. The *quid pro quo* for the payment would appear to be the generic's agreement to stay out of the market beyond the expected entry date.

In the years since the passage of the Hatch-Waxman Act, the primary drafters of the legislation have expressed their disapproval of reverse-payment settlements. Representative Waxman explained that such agreements "turn[] the . . . legislation on [its] head." Motion & Brief of Representative Henry A. Waxman as *Amicus Curiae* in Support of Petitioner at *1, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2462026. Waxman emphasized that the purpose of the legislation was to promote generic competition, not to allow generics "to exact a portion of a brand-name manufacturer's monopoly profits in return for withholding entry into the market." *Id.* Senator Hatch similarly found such agreements "appalling." And his assessment mirrored that of Waxman in making clear that "[w]e did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition." 148 CONG. REC. S7566 (daily ed. July 30, 2002).

As its drafters have recognized, the effectiveness of the Hatch-Waxman Act has been severely compromised by settlements like the one at issue in this case. Although generic entry has burgeoned in the quarter-century since Congress enacted the law, generics are increasingly not serving their designated function. *See* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 71 (2009); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design*

Problem, 81 N.Y.U. L. REV. 1553, 1616 (2006) [hereinafter Hemphill, *Paying for Delay*]; Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 25-26 (2004).

The 180-day bounty, in particular, has been twisted from an incentive for the generic to challenge patents to a barrier to entry preventing challenge. By settling with the first challenger, the brand firm can significantly delay other generics' entrance into the market. *See* HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 15.3, at 15-45 (2d ed. Supp. 2010). Later generics would be less motivated to pursue a challenge since they would be further behind in the approval process, would not be entitled to the market exclusivity period, and would receive a return dependent on the outcome of the first filer's suit. Hemphill, *Paying for Delay*, *supra*, at 1586; C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 78 ANTITRUST L.J. ___ (forthcoming 2011), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1736822. Such hurdles loom large given the costs of developing generic drugs, receiving FDA approval, and pursuing costly patent litigation.

The Act's drafters encouraged challenges to invalid patents, seeking to obtain earlier market entry and lower prices for consumers. Carrier, *supra*, at 71.

But the Act's carefully balanced regulatory regime is not working as intended to promote competition.

C. An Agreement to Pay a Potential Competitor Not to Enter a Market or to Delay Entry is Inherently Suspect

Of all the types of business activity, agreements by which competitors divide markets threaten the most dangerous anticompetitive effects. Market division restricts *all* competition between the parties on *all* grounds. Even price fixing allows the parties to compete on factors other than price. Settlement agreements by which brands pay generics not to enter the market threaten dangers similar to territorial market allocation. But instead of allocating geographic space, they allocate time, with the brand blocking all competition for a period of time. *See In re Schering-Plough Corp.*, No. 9297, 2003 WL 22989651, at **10-12 (F.T.C. Dec. 8, 2003), *vacated by Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005).

The Supreme Court has held that the antitrust laws protect both actual and potential competition. Thus, the Sherman Act prohibits not only agreements that reduce competition, but also those that restrain potential market entry. *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (agreement between competitor and potential entrant that the potential entrant would not attempt to enter the competitor's market held to unlawfully restrain competition); *United States v. Topco Assocs.*, 405 U.S. 596 (1972) (agreement between competitors not to

attempt to enter each other's market held unlawful). Accordingly, it is plain that a naked agreement by a patent holder to pay a competitor or potential competitor not to challenge its patent would be per se illegal. The fact that such an agreement is contained in a settlement of patent litigation may suggest that procompetitive justifications ought to be entertained, but is hardly a defense in and of itself. On the contrary, if the terms of a patent settlement agreement unreasonably restrain competition, they violate the Sherman Act. *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963) (patent settlement agreement excluding foreign competitors from U.S. market held per se unlawful). As stated by the United States, the Sherman Act does not permit patent holders "to contract their way out of the statutorily imposed risk that the patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract." Brief for the United States in Response to the Court's Invitation at 14, *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010) (No. 05-2851).

D. Reverse Payments Should Be Presumptively Unlawful

Given (1) Congress's careful balance of innovation and competition in the drug industry, (2) the usurpation of that equilibrium by payments for generics to delay entering the market, and (3) the anticompetitive harms of payments for delay, the appropriate standard in this case is far higher than the objectively-baseless standard offered by the Special Master.

Amici believe that, for the reasons described above, the standard should be at least presumptive illegality. As far back as 2003, the FTC argued that "paying a potential competitor to accept an entry date is a payment not to compete and presumptively anticompetitive." Reply Brief of Counsel Supporting the Complaint at 25, *In re Schering-Plough Corp.*, 2003 WL 22989651 (F.T.C. Dec. 8, 2003) (No. 9297). In 2009, the Department of Justice Antitrust Division aligned with the FTC in asserting that "the anticompetitive potential of reverse payments . . . in exchange for the alleged infringer's agreement not to compete and to eschew any challenge to the patent is sufficiently clear that such agreements should be treated as presumptively unlawful." Brief for the United States in Response to the Court's Invitation at 10, *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010) (No. 05-2581).

Many widely respected scholars have also recommended a test of presumptive illegality. Professors Herbert Hovenkamp, Mark Janis, and Mark Lemley contend that reverse payments should be "presumptively unlawful" unless the payment "is no more than the expected value of litigation and collateral costs attending the lawsuit." Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1759 (2003). Carl Shapiro and Mark Lemley, viewing patents as "probabilistic property right[s]," conclude that settlements should not "lead to lower expected consumer surplus than would

have arisen from ongoing litigation," and that reverse payments in excess of avoided litigation costs are "a clear signal that the settlement is likely to be anticompetitive." Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 396, 407 (2003); *see also* Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP., Spring 2005, at 75, 94.

Professor Scott Hemphill suggests a "presumption of illegality" if the settlement "restricts the generic firm's ability to market a competing drug" and also "includes compensation from the innovator to the generic firm." Hemphill, *Paying for Delay*, *supra*, at 1561. And Professor Michael Carrier has explained that "the appropriate default position for reverse-payment settlements should be presumptive illegality" and that a brand is likely to gain exclusivity beyond that provided by the patent "by supplementing the parties' entry-date agreement with a payment to the generic." Carrier, *supra*, at 76.

In short, the government agencies and many respected commentators support an approach of presumptive illegality. As explained above, such an approach makes sense because of Congress's balance of innovation and competition in the industry, the upsetting of that equilibrium by payments for delay, and the severe anticompetitive harms of these agreements. At the same time, presumptive, rather than per se, illegality ensures that if such agreements

have procompetitive benefits in a particular case, they can be considered by the court.[1]

II. DETERMINING WHETHER A SETTLEMENT IS "WITHIN THE SCOPE OF THE PATENT" CANNOT RESOLVE THE ANTITRUST ISSUE

The Special Master concluded that the settlements in this case were not unlawful because they did not "exceed the exclusionary scope" of the patent. *In re K-Dur Antitrust Litig.*, Civ. No. 01-1652, 2009 WL 508869, at *27 (D.N.J. Feb. 6, 2009). The Special Master found that "with respect to the entry dates the parties agreed upon," the settlements "clearly were well within the exclusionary scope of the . . . patent." *Id.*[2] But the Special Master's reliance on the "scope" test to immunize the settlement is not correct. The reason is that a patent that is invalid or not infringed *has no scope whatsoever* in relation to the generic product. In assuming the very validity and infringement at issue, therefore, the concept of

[1] For an example of potential justifications that settling parties could introduce, see Carrier, *supra*, at 76-79 (discussing (1) payments no higher than litigation costs, (2) "cash-strapped generics," (3) parties with asymmetric information, and (4) otherwise reasonable payments).

[2] Curiously, the Master concluded that the agreement fell within the scope of the patent even though Upsher agreed not to market not only its patented drug but also "any other sustained release microencapsulated potassium chloride tablet" on the theory that Upsher had not "developed or planned to develop and market" any other such tablet. *In re K-Dur Antitrust Litig.*, Civ. No. 01-1652, 2009 WL 508869, at *27 (D.N.J. Feb. 6, 2009).

scope used by the Special Master is not an appropriate inquiry. *See* Carrier, *supra*, at 66.[3]

Empirical studies have consistently shown that a significant percentage of granted patents are invalid. Surveys have shown that:

• courts invalidated 46% of patents between 1989 and 1996, John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998);

• the alleged infringer prevailed in 42% of the patent cases that reached trial between 1983 and 1999, Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 385 (2000); and

• in patent cases between 2000 and 2004, courts found 43% of patents invalid and 75% not infringed, University of Houston Law Center, Decisions for

[3] The mere assertion that the patent is valid and infringed is not sufficient to prove these contested points. And, in fact, they are contested. Before the parties settle, generics vigorously claim that the patent is not valid and that its product does not infringe. Of course, after settlement, the generic has every incentive to switch sides and trumpet the patent's validity and infringement. Just to give one example, in the Eleventh Circuit version of this case (brought by the FTC), the generic had initially certified that the brand's patent was invalid or not infringed by its product. After settlement, the generic's views "dramatically changed," with the chief financial officer testifying that because of the risk posed by infringement damages, the company would not market its drug until the litigation was concluded. *In re Schering-Plough*, No. 9297, 2003 WL 22989651, at **19-23 (F.T.C. Dec. 8, 2003), *vacated by Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005).

2000-2004, Issue Codes 01-16, 23, 24, *available at* http://www.patstats.org/2000-04.htm.

In the context of generic challenges to drug patents in particular, the rate of invalidity is even higher. In a study of paragraph IV challenges between 1992 and 2000, the FTC found that the generic prevailed in 73% of the cases. FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 16 (2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

A number of courts considering reverse payments have ignored these data and instead have relied on the presumption of validity contained in Section 282 of the Patent Act, which states that patents "shall be presumed valid." Not knowing the answer to the crucial question of whether a patent is valid, courts have relied on the presumption to conclude that the patent is valid and that the reverse-payment agreement therefore does not harm competition. But the presumption of validity is not entitled to the deference it has received. It is only a procedural presumption governing the order in which proof is presented. It is not substantive evidence of validity. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983); Carrier, *supra*, at 64 (explaining that it is only a procedural presumption, that it "should be entitled to the least amount of deference in situations in which the parties enter agreements that prevent validity from even being challenged," that "the Hatch-Waxman Act's text and legislative history demonstrate the importance

of invalidity challenges," and that "empirical studies have consistently shown that a significant percentage of granted patents are invalid"). In fact, brand firms' payments of millions of dollars to generics so that they do not challenge patents would tend to indicate doubts about validity. *See* Carrier, *supra*, at 75.

Moreover, as the Special Master recognized, there is no presumption of infringement in the Patent Act. To the contrary, on numerous occasions, the Federal Circuit—the appellate court with expertise and experience with patent matters—has been crystal clear that it is the *patentee* who has the burden of proving infringement. As the court has stated:

- "The patentee bears the ultimate burden of proof to demonstrate infringement by a preponderance of the evidence." *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679 (Fed. Cir. 2008).
- "Patent infringement . . . is an issue of fact, which the patentee must prove by a preponderance of the evidence." *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, Nos. 2010-1145, 2010-1177, 2011 WL 651790, at *5 (Fed. Cir. Feb. 24, 2011).
- "To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the patent read on the accused device . . . ." *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310 (Fed. Cir. 2005).

- "The burden remains with the patentee to prove infringement, not on the defendant to disprove it." *Welker Bearing Co. v. PHD, Inc.*, 550 F.3d 1090, 1095 (Fed. Cir. 2008).

In this case, generic Upsher-Smith claimed that its product did not infringe Schering-Plough's patent because the "viscosity of ethyl cellulose" was "outside the range limited by claim 1 of the [] patent" and because its product "does not contain" a derivative of cellulose covered by the patent. *In re K-Dur Antitrust Litig.*, No. 01-1652, 2009 WL 508869, at *6 (D.N.J. Feb. 6, 2009). Upsher also claimed (because of Schering's limiting of its claims in the process of obtaining a patent) that the doctrine of prosecution history estoppel barred Schering from claiming infringement through the doctrine of equivalence. *Id.* The other generic, ESI-Lederle, similarly claimed that its product did not infringe Schering's patent because it lacked the "coating material with different ingredients" covered by the patent. *Id.* at *8. ESI asserted that its tablets "are made by a completely different technology which produces a multi-layered coating with each layer comprised of a separate material having only a single ingredient." *Id.*

All of these claims were more than plausible. Schering's patent did not cover the active ingredient in the potassium chloride supplement. It applied only to a weaker formulation that covered a certain type of tablet with a certain percentage of potassium chloride crystals and certain coating material. *Id.* at *4.

The Special Master conceded that "the key disputed issues in the patent case involved infringement, rather than validity." *Id.* at *25. Nonetheless, he emphasized the "right to exclude" that Schering's patent provided against "infringing competitors." *Id.* And he "decline[d] to discount the exclusionary power of Schering's patent based on the *possibility* that it was not infringed by the Upsher and ESI products" because "[a]lthough there is no presumption of infringement, neither is there a statutory presumption that Schering's patent was not infringed." *Id.* (emphasis in original). This is not correct. Patent law clearly places the burden of proof of infringement on the patentee.[4]

III. THE "OBJECTIVELY BASELESS" STANDARD IS NOT APPROPRIATE FOR COLLUSIVE SETTLEMENTS

The Special Master concluded that the settlements could not be challenged under the antitrust laws unless the underlying patent litigation was "objectively baseless." *Id.* at *27. But if baselessness were the standard, it is difficult to imagine any settlement that would rise to this level.

The test of objective baselessness was developed in a far different setting. The immunity offered by the *Noerr-Pennington* doctrine protects antitrust defendants that engage in petitioning activity but does not extend to sham

[4] The Special Master also found it "inappropriate to conduct an *ex post* inquiry into infringement issues that were resolved by the parties' settlement" even though such settlement involved a payment of $60 million to the allegedly infringing party. 2009 WL 508869, at *25.

litigation, which occurs when a party enforces its patent even though it knows the patent is invalid, unenforceable, or not infringed. *See* HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 11.3a, at 11-20 (2d ed. Supp. 2010). Litigation is a sham if it is "objectively baseless" and it masks an "attempt to interfere directly with the business relationships of a competitor." *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993). The first element requires plaintiffs to show that lawsuits are "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Id.* at 60. In contrast, "if an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized." *Id.*

The high bar of "objective baselessness" may be appropriate for sham litigation claims given the importance of First Amendment policies underlying the *Noerr-Pennington* doctrine. But collusive settlements by which brand firms pay generics to delay entering the market are not entitled to a fraction of this deference. Such settlements, as described above, violate a central purpose of the Hatch-Waxman Act: to promote challenges to invalid patents and lower prices for consumers. Allowing challenges to this worrisome activity only in the rare case of objectively baseless behavior would ensure that numerous anticompetitive agreements to protect weak patents skate untouched through judicial analysis.

Because of the complexities of patent litigation and the standard's lack of teeth, a brand firm's lawsuit is not likely to be found baseless. Indeed, given that the generic firm that initially alleged patent invalidity and non-infringement has now—after receiving millions (if not tens or hundreds of millions) of dollars—changed its tune, it seems particularly unlikely that a court would find the suit to be baseless. Regardless of the exact standard that this court deems appropriate, the objectively-baseless standard applied by the Special Master in this case is excessively deferential to the point of being toothless.

CONCLUSION

For the reasons above, this court should reverse the decision of the district court granting summary judgment for the defendants.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Rules 29(d) and 32(a)(7)(B) of the Federal Rules of Appellate Procedure because this brief contains 5,344 words, excluding the parts of the brief exempted by Rule.

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CERTIFICATE OF SERVICE

I, Ellen Meriwether, hereby certify that counsel for Amici Curiae is a Filing User of the Court's CM/ECF system, and, that this 18th day of May, 2011, this Brief of Amici Curiae American Antitrust Institute and 26 Professors in Support of Appellants and Reversal was served by filing it on the Court's CM/ECF system. I further certify that ten hard copies of this Brief were delivered to the Office of the Clerk for the United States Court of Appeals for the Third Circuit.

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