No. 12-416

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

WATSON PHARMACEUTICALS, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF *AMICI CURIAE* OF 118 LAW, ECONOMICS, AND BUSINESS PROFESSORS AND THE AMERICAN ANTITRUST INSTITUTE IN SUPPORT OF PETITIONERS

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STATEMENT OF INTEREST OF *AMICI CURIAE*

The Academic *Amici* are professors of economics, business, innovation, antitrust law, and intellectual property (IP) law. (A list of signatories is attached as Appendix A.) Their sole interest in this case is to ensure 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 and non-profit education, 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 130 prominent antitrust lawyers, law professors, economists, and business leaders.[1]

Amici have filed this brief because they believe that the ruling of the court below is flawed and seriously threatens to undermine competition in the pharmaceutical industry. If affirmed, the opinion would result in severe anticompetitive harm and would upset a carefully crafted statutory scheme designed to prevent weak or narrow patents from blocking the entry of affordable generic drugs.

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1. No person other than *amici curiae* or their counsel authored this brief in whole or in part or made a monetary contribution intended to fund its preparation or submission. The parties have consented to the filing of this brief and such consents are being lodged herewith. AAI's Board of Directors has approved this filing for AAI. The individual views of Advisory Board members may differ from AAI's positions.

INTRODUCTION AND SUMMARY OF ARGUMENT

Antitrust law protects markets by preventing actual and potential competitors from colluding to harm consumers or exclude rivals. Patent law is designed to encourage innovation by giving inventors a right to exclude others from the patented product. For more than a century, courts have struggled to balance these two interests in the service of a dynamic, competitive economy.

These concerns were at the core of the Hatch-Waxman Act, Congress's framework for balancing patent and antitrust law in the pharmaceutical industry. A central tool in that balance was the encouragement of generic competition by offering a period of exclusivity to the first generic to challenge a brand firm's patent, claiming invalidity or non-infringement. The goal of exclusivity was to encourage generic manufacturers to challenge weak patents and enter the market earlier with cheaper drugs. But this carefully crafted scheme has been upended by brands' payments of millions of dollars to generics to abandon their patent challenges and delay entering the market. These "exclusion payments" or "reverse payments" violate basic antitrust principles, and deprive consumers of low-cost generics, costing billions of dollars a year and ensuring that many Americans are not able to afford necessary medicines.

Exclusion-payment settlements fly in the face of not only antitrust law and the regulatory regime but also patent law. This Court has recognized the important public policy interest served by challenging weak patents. Given the burdens confronting the U.S. Patent and Trademark

Office (PTO) and growing concerns over patent quality, this policy is as critical now as it ever was.

The court of appeals upheld the exclusion-payment settlement in this case by relying on a test based on the "scope of the patent," concluding that any settlement that was within the potential scope of the patent was entirely insulated from antitrust scrutiny. *F.T.C. v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1306 (11th Cir. 2012). This analysis was not appropriate as a matter of either antitrust or patent law. Antitrust law has long forbidden agreements among horizontal competitors to allocate markets, which is the practical result when brands pay generics to drop challenges to weak patents and delay entering the market instead.

And while patent law properly limits competition in some respects, it does so only subject to the limits set forth in the Patent Act. In particular, patent policy not only permits legal challenges to weak patents; it affirmatively encourages those challenges. The court of appeals turned that policy on its head, permitting a patent owner to pay a competitor to avoid the very challenge the law encourages. The scope-of-the-patent test adopted by the court below allows a patentee to convert an initial determination by the PTO to grant a patent into a final, unreviewable conclusion that the patent is necessarily valid, and to do so with no judicial scrutiny whatsoever.

The patent grant itself provides only a presumption of validity. The Eleventh Circuit rule effectively converted that rebuttable (and oft-rebutted) presumption into an irrebuttable one. And it did so in this case in the face of evidence—a large monetary payment by the patentee to

the defendant to drop its validity challenge—that suggests there was good reason for the parties to think at the time they settled the case that this particular patent was invalid or not infringed. Such a rule is inappropriate, as the facts of this case make clear.

In fiscal year 2012, the FTC reported a record forty settlements in which brands paid generics to delay entering the market. Bureau of Competition, FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012*, http://www.ftc.gov/os/2013/01/130117mmareport.pdf. If this Court affirms the decision below, this trend would only accelerate. For all antitrust speed bumps to anticompetitive settlements would be removed, allowing brands to pay generics any amount of money they wish to block generic entry for the entire patent term.

The patents at the heart of exclusion-payment agreements often cause concern. They frequently cover not the drug's active ingredient but narrower aspects like the formulation or method of use that are less innovative and bear more potential for anticompetitive mischief. They are often added late in the game, after the patent on the active ingredient has expired. Indeed, in this case, the patent covered the use of a particular testosterone gel formulation even though pharmaceutical gel products have been available for decades and synthetic testosterone was artificially synthesized as early as 1935.

Commentators have proposed a variety of more suitable approaches to exclusion-payment settlements,

including presumptive illegality. These tests recognize the potentially severe anticompetitive effects of exclusion payments while also allowing the settling parties to offer justifications for their facially anticompetitive agreement.

Amici support reversal of the decision below, which short-circuited analysis of conduct that could be blatantly anticompetitive and that upends important policies at the core of the Hatch-Waxman Act and patent law. *Amici* support a more traditional antitrust framework based on a quick-look analysis that treats exclusion payments as presumptively unlawful.

ARGUMENT

I. THE HATCH-WAXMAN ACT DOES NOT SUPPORT EXCLUSION PAYMENTS

As this 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." *Ibid.* Congress resolved the tension between the patent and antitrust laws in this context by enacting 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. The legislation emphasized the crucial role of generics in challenging invalid and non-infringed patents.

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

In the Hatch-Waxman Act, Congress enacted a complex regulatory regime to foster drug innovation and competition. The pharmaceutical marketplace in the early 1980s suffered from sparse generic entry and stifled brand-drug firm innovation.

Generic drugs have the same active ingredients 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. Approval by the U.S. Food and Drug Administration (FDA) 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. They thus 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 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 the legislature 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, exempting 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 creating a 180-day period of generic marketing exclusivity, reserved for the first generic to certify that the brand firm's patent was invalid or not infringed and enter the market before the patent expired.

In addition to promoting generic competition, the Act included several mechanisms to bolster 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 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. 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. Indeed, just last term this Court discerned in the Hatch-Waxman Act a purpose "[t]o facilitate the approval of generic drugs as soon as patents allow." *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).

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). The purpose of this exclusivity was to encourage challenges to invalid or improperly asserted patents.

B. Exclusion Payments Undermine the Hatch-Waxman Act

In the years since the passage of the Hatch-Waxman Act, the primary drafters of the legislation have expressed their disapproval of exclusion-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." *Ibid.* 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 in this case. Although generic entry has burgeoned in the three decades 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) [Carrier, *Unsettling Settlements*]; C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1616 (2006) [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 generics 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* 1 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); C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 Antitrust L.J. 947 (2011). 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*, at 1586. Such hurdles loom large given the costs of developing generic drugs, receiving FDA approval, and pursuing patent litigation.

The Hatch-Waxman Act encouraged challenges to invalid patents in order to promote earlier generic market entry and lower prices for consumers. But the carefully balanced regulatory regime is not working as intended to promote competition. And exclusion-payment settlements are the reason.

II. EXCLUSION PAYMENTS ARE FACIALLY ANTICOMPETITIVE

Of all the types of business activity subject to the Sherman Act, agreements by which competitors divide markets are the most dangerous. Market division restricts *all* competition between the parties on *all* grounds. Even price fixing (unlawful as it is) allows the parties to compete on factors other than price.

This Court has held that the Sherman Act prohibits not only agreements that reduce competition among existing competitors, but also those that restrain potential market entry. In *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (per curiam), the Court found that an agreement by which rivals "agreed not to compete in the other's territories" was anticompetitive. *See also* Robert H. Bork, *The Antitrust Paradox: A Policy at War with Itself* 269 (1993 ed.). And the leading antitrust treatise makes clear that "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2030b, at 220 (3d ed. 2012).

Brand firms such as Solvay have entered into exclusion-payment settlements with generics. Pursuant to these agreements, the generic firm (1) drops its patent challenge and (2) agrees to delay entering the market. In return, the brand pays the generic millions—sometimes hundreds of millions—of dollars.

These payments are profitable to the settling parties precisely because they eliminate actual or potential competition. Because the brand firm 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 cede the market to the brand firm and split the monopoly profits. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391, 408 (2003) [Shapiro, *Antitrust Limits*]. The brand then can use a portion of this additional profit from delayed competition to pay the generic. In fact, the brand could even pay more than the generic would have received from *winning* its patent challenge and *entering* the market. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (approving exclusion payment of $398 million, more than the generic would have made even if it had won the case and entered).

Exclusion payments are fairly characterized as the brand's purchase of the generic'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, will normally reflect the odds of the parties' success in patent litigation: the more likely the patentee is to win the case, the more it can rely on the patent itself to exclude competition. 1 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). But paying generics to stay out of the market changes that calculus. A brand is likely to gain additional exclusivity by supplementing this 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 resulting from litigation.

Settlements by which brands pay generics not to enter the market pose dangers analogous to territorial market allocation. Instead of allocating geographic space, they allocate time, with the brand blocking *all* competition for a period of time. 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 under *Palmer*. The fact that such an agreement is contained in a settlement of patent litigation may suggest that procompetitive justifications could be entertained, but is hardly a defense in and of itself. On the contrary, if the terms of a patent settlement unreasonably restrain competition, they violate the Sherman Act. *United States v. Singer Mfg. Co.*, 374 U.S. 174, 194-95 (1963) (striking down a patent settlement excluding foreign competitors from the U.S. market).

With an exclusion payment, the brand firm buys assurance that its patent will not be invalidated—something that patent law alone does not give and the Hatch-Waxman Act did not contemplate.

III. THE MERE FACT OF A PATENT CANNOT JUSTIFY ANTICOMPETITIVE EXCLUSION PAYMENTS

The court of appeals concluded that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." 677 F.2d at 1322.[2] The fact that one of the antitrust defendants had a

2. The two prongs of liability not relying on scope are more ephemeral than real, making the Eleventh Circuit's test effectively one of per se *legality*. The test for sham litigation requires an

patent that the law presumed valid, it concluded, meant that any anticompetitive harm must flow from the patent and not from the exclusion-payment settlement. In so concluding, the court below committed a logical fallacy. The fact that a settlement reaching a product *outside* the scope of the patent is per se illegal does not mean that one falling *within* the potential, facial scope of the patent is automatically valid. Michael A. Carrier, *Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem*, 16 Stan. Tech. L. Rev. 1, 5 (2012) [Carrier, *Scope Test*]. In any event, the Eleventh Circuit's scope-of-the-patent test also misunderstands actual patent practice, patent policy, and patent law.

"objective baselessness," *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993), that is extremely difficult to satisfy given the standard's lack of teeth, the complexities of patent litigation, and the fact that a generic that initially alleges patent invalidity and non-infringement later (after receiving millions of dollars) changes its tune. 1 Herbert Hovenkamp et al., *IP and Antitrust* §11.2d (2d ed. 2010). Additionally, the test is grounded in First Amendment protections not relevant when the parties have withdrawn any petition in favor of a private agreement.

The other prong, fraud on the patent office, also sets a high bar not likely to be shown in these cases. *Walker Process Equip. Corp. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965); 1 Herbert Hovenkamp et al., *IP and Antitrust* §11.2f (2d ed. 2010) ("A *Walker Process* claim requires a high burden of proof . . . . Only a few appellate decisions have affirmed a finding of *Walker Process* fraud applying the Federal Circuit's current strict standards.").

A. The Patent Office Frequently Issues Invalid Patents

The grant of a patent reflects an initial judgment by the PTO that an invention is patentable. Such a judgment comes after limited scrutiny with examiners having, on average, less than 20 hours to read an application, search for prior art, evaluate patentability, and reach and write up conclusions. Fed. Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Exec. Summary, at 9-10 (2003).

Because of this limited examination, litigation plays a crucial role in ferreting out invalid patents. It would take "an enormous investment of time and resources" for the PTO to gather the information needed to make appropriate validity decisions. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495, 1531 (2001). These decisions "can be made much more efficiently in litigation" since "only a tiny percentage of patents are ever litigated or even licensed to others." *Ibid.* When a patent is asserted in litigation, accused infringers are entitled to demonstrate that the patent should not have issued.

The role of litigation in uncovering invalid patents is essential given how many patents issued by the Patent Office are later found to be invalid. Empirical studies have consistently shown that at least 40% of granted patents that are litigated to decision are invalid.[3] These

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

figures are even higher in the pharmaceutical industry, with a study by the FTC finding that generics prevailed in 73% of paragraph IV challenges between 1992 and 2000. FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 16 (2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

B. This Court Has Recognized the Importance of Challenging Invalid Patents

This Court explained in *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969), that a patent "simply represents a legal conclusion reached by the Patent Office" that is "predicated on factors as to which reasonable men can differ widely." The Patent Office "is often obliged to reach its decision in an ex parte proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity." *Ibid.* As a result, "it does not seem to us to be unfair to require a patentee to defend the Patent Office's judgment when his licensee places the question in issue." *Ibid.*

Lear's conclusion did not simply rest on the realities of an imperfect PTO. Rather, it reflected an affirmative policy judgment that invalidating weak patents served the public good. The Court emphasized "the important public interest in permitting full and free competition in the use

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and 1996); Kimberly A. Moore, *Judges, Juries, and Patent Cases – An Empirical Peek Inside the Black Box*, 99 Mich. L. Rev. 365, 385 (2000) (alleged infringer prevailed in 42% of patent cases that reached trial between 1983 and 1999); University of Houston Law Center, Decisions for 2000-2004, Issue Codes 01-16, 23, 24, *available at* http://www.patstats.org/2000-04.htm (in patent cases between 2000 and 2004, courts found 43% of patents invalid and 75% not infringed).

of ideas which are in reality a part of the public domain." *Ibid.* Nor was *Lear* alone. This Court has repeatedly emphasized the importance of testing weak patents and protecting the public from monopolies based on invalid patents. *See, e.g., MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2007) (licensees have standing to challenge patent validity or infringement without repudiating their licenses); *United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57 (1973) (emphasizing "public interest in free competition" in concluding that licensee in antitrust suit "may attack the validity of the patent under which he is licensed even though he has agreed not to do so in his license"); *Blonder-Tongue Labs. v. Univ. of Illinois Found.*, 402 U.S. 313, 349-50 (1971) (allowing alleged infringer to claim estoppel where patent previously declared invalid); *Microsoft Corp. v. i4i LLP*, 131 S. Ct. 2238, 2253 (2011) (Breyer, J., concurring) (offering measures designed to "increase the likelihood that discoveries or inventions will not receive legal protection where none is due").

Challenging invalid patents is even more important today than it was at the time this Court decided *Lear*. The burdens on the Patent Office have only increased in the past four decades as the number of patent applications filed has skyrocketed to over 500,000 per year, more than five times the number filed when *Lear* was decided. U.S. PTO, *U.S. Patent Statistics Chart,* http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm.

C. The Patents at the Heart of Exclusion-Payment Settlements Present Concern

While many of the concerns expressed about the validity of patents issued by the PTO have arisen in the context of software and business methods, the problem

of invalid patents is by no means limited to those industries. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1294 (2012), this Court concluded that medical tests that relied on correlations between treatment and drug dosages were not patentable, explaining that the process involved "well-understood, routine, conventional activity" that had been "previously engaged in by researchers in the field." Nor is overbroad patent protection costless. As the Court recognized in *Prometheus*, patent exclusivity "can impede the flow of information that might permit, indeed spur, invention" by "raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements." *Id. at* 1305.

The risk is particularly great in the pharmaceutical industry because the regulatory scheme governing that industry, the Hatch-Waxman Act, gives patentees substantial benefits merely for filing a patent suit, including an automatic 30-month stay of generic entry. 21 U.S.C. § 355(j)(5)(B)(iii). This has led many pharmaceutical companies to file suit on weak patents in order to delay competition and to engage in other forms of regulatory subterfuge. In *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012), this Court allowed generics to challenge brand firms' overly broad "use codes," which describe patents, are not reviewed by the FDA, and block generic competition. This Court found that, in enacting the statute, Congress "sees, raises, and bests" the arguments of brand companies based on "gamesmanship." *Id. at* 1682. And it emphasized the purpose of the Hatch-Waxman Act to encourage generic

entry as soon as possible when a patent was invalid or not infringed. *Id. at* 1688.

Generic challenges to drugs are disproportionately brought against weak patents, not strong ones. New drug compounds provide most of the social value of pharmaceutical inventions. And in fact, patents covering a new active ingredient—the compound itself—tend to be strong and (in satisfying the requirement of bioequivalence) more likely to be infringed by the production of the generic drug. C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Empirical Legal Stud. 613, 621 (2011) [Hemphill & Sampat, *Generic Challenges*].

Drug companies, however, are increasingly patenting and asserting ancillary, non-active ingredients, like a formulation, dissolution profile, or method of use. *Id.* at 615. Those patents are less innovative (and so less likely to be valid) and easier to avoid. Asserting them accordingly bears more potential for anticompetitive mischief. For under the regulatory regime, even a weak patent or one on a minor advance like a method of delivery can prevent market entry by the generic.

Empirical research has shown that generics disproportionately challenge these weaker "follow-on" patents, not those covering the active ingredient. Hemphill & Sampat, *Generic Challenges*, at 643. In particular, non-active-ingredient patents and drugs with "more questionable" patents and "greater patent life generated by late patents" are "much more likely to draw challenges." *Ibid.* While generics challenge 75% of non-active-ingredient patents, they challenge only 29% of

active-ingredient patents. C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 Journal of Health Economics 327, 334 (2012). In short, "generic drug makers use challenges as a route to entry" when brand drugs have "patents of questionable validity or scope" that "would, in the absence of challenges, block competition." Hemphill & Sampat, *Generic Challenges*, at 615.

This case involves just such a narrow, potentially questionable patent. The active ingredient, synthetic testosterone, was artificially synthesized in 1935 and has been available in drug products since the 1950s. Second Amended Complaint for Injunctive and Other Equitable Relief, *FTC v. Watson*, No. 1:09-CV-00955-TWT ¶ 31 (N.D. Ga. May 28, 2009) [Complaint]. Even pharmaceutical gel products have been available for decades. *Ibid.* The patent on AndroGel® at issue in this case, however, only covers the use of a particular gel formulation containing ingredients in certain amounts. *Id.* ¶ 39.

The law need not permit anticompetitive settlements in an effort to protect strong patents. Generics overwhelmingly challenge weak patents used to block competition. When those challenges are allowed to proceed, the generic prevails nearly three times in four. FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 16 (2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. And generics would be even more likely to focus their attention on weak patents if exclusion-payment settlements were deemed presumptively illegal. Some generics today may challenge strong patents in the hopes of being paid to drop the challenge. But if that payment is illegal, generics would focus their attention

precisely where public policy wants them to: on patents they think they can defeat in court.

D. The Presumption of Patent Validity Does Not Justify Exclusion-Payment Settlements

The presumption of validity is an evidentiary device designed to establish the standard of proof; it is not a substantive judgment that the PTO's decision was correct. *See Microsoft Corp.*, 131 S. Ct. at 2245; *id. at* 2253 (Breyer, J., concurring) ("[I]n this area of law as in others the evidentiary standard of proof applies to questions of fact and not to questions of law . . . Where the ultimate question of patent validity turns on the correct answer to legal questions—what these subsidiary legal standards mean or how they apply to the facts as given—today's strict standard of proof has no application."); *Reckendorfer v. Faber*, 92 U.S. 347, 355 (1875) (patent is "a prima facie right only . . . subject to an examination by the courts"). Indeed, the Federal Circuit, the court of appeals with jurisdiction over patent cases, has recognized that the presumption of validity is merely a procedural device with no substantive impact. *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983).

As the evidence discussed above indicates, while issued patents are presumed valid, 35 U.S.C. § 282, that presumption is far from an irrebuttable one. Indeed, it is quite often rebutted in practice. One flaw in the court of appeals' scope-of-the-patent test is that it unwittingly transformed a procedural device for allocating the burden of proof into an irrebuttable presumption, a position this Court has repudiated. *Reckendorfer*, 92 U.S. at 355. By

presuming that Solvay's payment was within the scope of the patent, the court irrebuttably assumed that the patent was valid and infringed. *See In re K-Dur Antitrust Litigation*, 686 F.3d 197, 214 (3d Cir. 2012) (noting that the "scope of the patent" test "assumes away the question being litigated in the underlying patent suit, enforcing a presumption that the patent holder would have prevailed"); Carrier, *Scope Test*, at 5-6.[4] A presumption of validity does not entitle a patentee to evade the test of patent litigation any more than a criminal defendant's presumption of innocence entitles him to avoid trial.

The illogic of treating a burden of proof as having conclusive substantive effect, as the court below did here, can readily be illustrated. While an accused infringer must demonstrate the invalidity of a patent by clear and convincing evidence, *Microsoft Corp.*, 131 S. Ct. at 2245, it is the *patentee* that "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); *see also Lehigh Valley R.R. Co. v. Mellon*, 104 U.S. 112, 119 (1881) (infringement "cannot be presumed"). A natural application of the Eleventh Circuit's scope-of-the-patent logic would lead to a presumption that the patent was valid but also not infringed. As the leading treatise on IP and antitrust law explains:

> By the same reasoning the Eleventh Circuit used, courts should conclusively presume patents

4. As the Third Circuit observed, "the scope of the patent test does not subject reverse payment agreements to *any* antitrust scrutiny." *K-Dur*, 686 F.3d at 214 (emphasis added). In fact, "no court applying the scope of the patent test has ever permitted a reverse payment antitrust case to go to trial." *Ibid.*

> valid whenever a settlement occurs, but must for the same reason conclusively presume that those patents were not infringed. And if they are (presumptively) not infringed, any settlement that excludes the generic necessarily "exceeds the scope" of "the exclusionary potential of the patent." That would be an irrational result, but so is conclusively presuming that a patent is valid. In both cases, the error lies in substituting a conclusive presumption for the actual evidence before the court.

1 *Herbert Hovenkamp et al.*, IP and Antitrust § 15.3a1, at 15-41 (2012 Supp.).[5]

E. Exclusion Payments Themselves Provide Evidence That the Patent Is Invalid

Exclusion payments are not merely anticompetitive because they exclude competition with potentially invalid patents. They also provide strong evidence that a patent could be found invalid if tested in court.

If a patent is invalid, the patentee has no justification whatsoever for paying the generic one cent to delay competition one day. That is market division. In these

5. As it happens, in this case, there was substantial evidence that the generics did not infringe Solvay's patent. The patent (mistakenly) covered gel with 1% sodium hydroxide, which "any skilled chemist" knew would "burn a patient's skin." *In re Androgel Antitrust Litigation*, 687 F. Supp. 2d 1371, 1380 (N.D. Ga. 2010). There was evidence—enough to survive a motion to dismiss—that the generic version did not infringe since it contained a diluted solution that was "50 to 250 times less concentrated." *Ibid.*

cases, it is not the patent that "cripple[s] competition," *Schering-Plough v. Federal Trade Comm'n*, 402 F.3d 1056, 1065-1066 (11th Cir. 2005), but the additional payment that immunizes the patent from challenge.

The court below worried about relitigation of the very patent dispute the parties settled. That is a difficult inquiry to undertake, particularly because the parties with the best evidence bearing on the issue have entered into the exclusion-payment settlement and now have incentives to claim that the patent would have been held valid and infringed.

Fortunately, there is another, more reliable source of evidence on the validity of the patent in question. Large exclusion payments (greater than avoided litigation costs) themselves provide powerful evidence that *at the time of settlement*, the parties themselves believed the patent was likely to be invalid or not infringed. At the extreme, a sufficiently large payment should cause a generic to drop even challenges it would surely win. Even in adopting a very deferential scope-of-the-patent test, the Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 206, 208 (2d Cir. 2006) was "suspicious" when a patentee settles litigation by paying "more than either party anticipates the [generic] would earn by winning the lawsuit and entering the . . . market in competition with the patent holder."[6]

6. It is the relationship to expected generic profits, not patentee profits, that matters here. Patentees will always have an incentive to pay to delay a challenge. If the payment is large enough, generics will no longer have any incentive to litigate, no matter how weak the patent.

The court of appeals' decision to reject the FTC's complaint on a motion to dismiss precluded the development of a full evidentiary record. Even so, the FTC's allegations strongly suggest that the parties thought the patent was on shaky ground. Solvay stood to lose $125 million per year in profits (from its top-selling product) if it lost the case. 677 F.3d at 1305; Complaint ¶ 2. Generics would have priced their drugs at no more than 25% of Solvay's price, *id.* ¶¶ 50-51, meaning that unless they could expand the market dramatically (which was unlikely, Gautier Duflos & Frank R. Lichtenberg, *Does Competition Stimulate Drug Utilization*, 32 Int'l Rev. L. & Econ. 95, 106–07 (2012)), the most they could be expected to make in profits each year would be $31.25 million, and it likely would be far less.[7] Under the settlement, Solvay paid the generics between $29 million and $42 million per year to stay off the market, meaning that the payment at least approached the amount the generics would have made even if they were completely sure they could enter the market. 677 F.3d at 1305. Payments of such large sums offer powerful evidence that the patentee thought the patent was weak indeed.

7. We cannot determine the exact number because the district court did not allow development of the record. If the market for drugs were elastic—that is, if many patients would buy drugs only at a low price—dropping the price might produce more than $31.25 million in profits. But that's unlikely for a prescription drug like AndroGel® that is a controlled substance whose distribution is restricted by the government. Further, the marginal cost to manufacture a particular dose is unlikely to vary much from maker to maker. So it is quite likely that if anything the generic profit estimate in the text is too high; generics would face the same marginal costs as Solvay but would charge a much lower price.

IV. EXCLUSION PAYMENTS ARE NOT NEEDED TO SETTLE CASES IN THE PUBLIC INTEREST

Courts that have deferred to exclusion-payment settlements have done so in part because of a judicial policy in favor of settlement of disputes. The court below emphasized that "[t]he general policy of the law is to favor the settlement of litigation" and that "patent litigation is costly and complex." *Watson*, 677 F.3d at 1310-11 (citing *Schering-Plough*, 402 F.3d at 1072-74). Similarly, the court found that the agreements in its earlier *Schering* case reflected a "high-stakes reality" and "fell well within the protections" of the patent." *Watson*, 677 F.3d at 1311 (citing 402 F.3d at 1076). In fact, however, this particular form of settlement is unnecessary, undesirable, and at odds with the Hatch-Waxman Act.

1. Not all settlements are desirable. The general preference for settlement over litigation must be tempered when settlements have important adverse effects on third parties; in the language of economics, there is no good reason to encourage settlements that impose significant negative externalities. *See* Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 Harv. L. Rev. 1813, 1867-73 (1984). Patent litigation serves the crucial role of testing weak patents and protecting the public from monopolies based on invalid patents. This benefit is particularly important in the context of the Hatch-Waxman Act, which exhibits a congressional desire to encourage generic drug manufacturers to challenge pharmaceutical patents.

Drug patent settlements with exclusion payments are not typical settlements. They are agreements that dispose

of the validity and infringement challenges central to the Hatch-Waxman scheme. Any general preference in the law for settlement was displaced—or at least significantly weakened—by the Act's specific framework.

A 180-day period of exclusivity for the first generic to challenge a patent only makes sense in the context of encouraging patent challenges. The period applies only to generics that seek to enter before the end of the patent term. It does not apply to challenges that target expired patents or delay approval until the end of the patent term. A successful patent challenge provides valuable (and in the case of medicines necessary) benefits to third parties, including consumers and anyone who seeks to practice the patented technology.[8]

In addition, the 180-day bounty itself demonstrates the unique nature of these agreements. That provision makes clear that settlements in this context are far more worrisome than general patent settlements. General patent settlements do not prevent other competitors from entering the market. In cases outside the Hatch-Waxman context, even if the settling defendant agrees not to challenge the patent, others are free to enter.

The Hatch-Waxman context is different. It is most definitely not the case, as the court below believed, that "many potential challengers . . . attack[]" vulnerable

8. *See, e.g.,* Joseph Farrell & Robert Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 Berkeley Tech. L.J. 943 (2004); Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 Berkeley Tech. L.J. 667 (2004).

patents because they "are not bound by the first challenger's" settlement and they "will attempt to enter the market." *Watson*, 677 F.3d at 1315. Nor is it the case that a patentee's profits "will be eaten away" as "more and more" generics file paragraph IV certifications. *Ibid.* To the contrary, and alone among all categories of patent settlements, the Hatch-Waxman Act blocks alleged infringers from entering the market until the first Paragraph-IV filer enjoys 180 days of marketing exclusivity. This period does not even begin until the first filer enters the market, potentially years down the road.[9]

An Act intended to increase generic entry should not be perverted into a tool to bar that entry by the mere invocation of a general policy in favor of settlement.

2. Fortunately, exclusion payments are not needed to settle cases. Pharmaceutical patent owners and generic firms can and do settle patent cases without exclusion payments. Several options are available to brand firms: (1) agree to let generics enter upon payment of a license fee, (2) agree with generics, based on the strength of the

9. The Medicare Modernization Act of 2003 created various forfeiture events that resulted in generics forfeiting their 180-day exclusivity period. But a careful reading of the statute shows that these "use it or lose it" provisions do not trigger forfeiture as quickly as might be assumed. Simplifying greatly, the statute provides that the first filer loses exclusivity if it fails to market the drug by the later of (1) 75 days after FDA approval and (2) 75 days after an appellate court decision finding invalidity or non-infringement. 21 U.S.C. § 355(j)(5)(D)(i). Appellate court decisions typically will not occur until years in the future. While the first filer in this case waived its 180-day exclusivity, the legal rule announced by the court below would also shelter settling parties that do not.

patent alone (not supplemented by exclusion payments), on a time of entry, or (3) take other actions that do not involve paying the generic to forego competition. *See* 1 Herbert Hovenkamp et al., *IP and Antitrust* §15.3a1[C] (2d ed. 2010) ("the *ex ante* effect of a harsh rule will not necessarily impede settlement; it may simply make the settlement take on a different form"). The treatise authors endorse settlements of various forms that do not involve payment for delay.

Indeed, empirical evidence makes it clear that abolishing exclusion payments does not prevent settlement. In 2000, the FTC announced that it would challenge exclusion-payment settlements. Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle, and Thomas B. Leary, 65 Fed. Reg. 17506 (April 3, 2000), http://www.ftc.gov/os/2000/03/hoeschtandrxcommstmt.htm. In the succeeding four years, between 2000 and 2004, *not one* of twenty reported agreements involved a brand firm paying a generic filer to delay entering the market. Bureau of Competition, FTC, *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*, at 4 (2006), http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf.

During this period, parties continued settling their disputes, but in ways less restrictive of competition, such as through licenses allowing early generic entry. Indeed, the FTC Report identified 14 such settlements without exclusion payments in 2003-2004 alone. *See id. at* 4. The fact that drug companies can and do settle litigation

without exclusion payments shows that there is no need to tolerate these anticompetitive payments. As was recently shown, an exclusion payment "that exceeds the patent holder's anticipated litigation costs is never necessary to secure a *desirable* settlement." Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 Tex. L. Rev. 283, 303 (2012) [Elhauge & Krueger, *Solving Settlement Puzzle*] (emphasis in original).

V. THIS COURT SHOULD ADOPT A "QUICK LOOK" ANALYSIS THAT PRESUMES THAT EXCLUSION-PAYMENT SETTLEMENTS ARE ILLEGAL

Given the potentially severe anticompetitive effects of exclusion-payment settlements, the appropriate analysis is not the deferential standard applied by the Eleventh Circuit.

A. The Overwhelming Consensus of Scholars Rejects the Eleventh Circuit's Test

Academic commentators have offered different standards for exclusion-payment settlements. But they uniformly agree that such agreements should not be considered per se legal. Some, including some of the undersigned, have written that settlements involving a payment from the patent holder to the challenger that exceeds avoided litigation costs should be presumptively anticompetitive.[10] Others have argued for applying the rule

10. *See, e.g.,* 1 Herbert Hovenkamp et al., *IP and Antitrust* §15.3a1(C) (2d ed. 2010); Robin Cooper Feldman, *The Role of Science in Law* 167 (2009); Jeremy Bulow, *The Gaming*

of reason.[11] Others have advocated per se illegality.[12] But *none* has taken the position adopted by the court below in this case—that the court can just assume the patent is valid and the brand can prevent validity from being tested by paying the generic millions of dollars.

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of Pharmaceutical Patents, in 4 *Innovation Policy and the Economy* (Adam B. Jaffe et al. eds. 2004); Carrier, *Unsettling Drug Settlements*; Tom Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments*, 71 Antitrust L. J. 1069 (2004); Elhauge & Krueger, *Solving Settlement Puzzle*; Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents?*, 98 Am. Econ. Rev. (2008); Hemphill, *Paying for Delay*; Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (2003); Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. Econ. Persp. 75 (2005); Rudolph J.R. Peritz, *Three Statutory Regimes at Impasse,* in *More Common Ground for International Competition Law?* (Josef Drexl et al. eds. 2010); Catherine J.K. Sandoval, *Pharmaceutical Reverse Payment Settlements*, 26 Santa Clara Comp. & High Tech. L.J. 141 (2009); Shapiro, *Antitrust Limits*.

11. Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747 (2002); Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 Antitrust Bull. 491 (2002); David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 Geo. L.J. 1303 (2010).

12. Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 Minn. L. Rev. 1767 (2003); Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal*, 41 Rutgers L.J. 255 (2009).

B. A Quick-Look Framework is Appropriate in Analyzing Exclusion-Payment Settlements

1. The relevant antitrust framework that courts apply to business activity is based on an assessment of the likelihood and magnitude of anticompetitive effects and procompetitive justifications.

The problem with the framework adopted by the court below is that it sweeps all anticompetitive issues under the "patent scope" rug and essentially concludes that, as a matter of law, exclusion-payment settlements are per se legal. Under this approach, the issuance alone of a patent (often by an overworked patent examiner) demonstrates its validity and infringement. Even worse, brands can pay generics any amount of money they wish from their newly-guaranteed stream of monopoly profits to make sure this assumption is never tested in court.

That cannot be right. For if the patent would not hold up in court or is not infringed (as evidence has shown applies to many patents), the parties are nakedly dividing markets. And if market division were ever justified, it is certainly not the case in this setting, with consumers paying billions of dollars extra a year and forgoing access to prescription medications.

A full-blown application of the rule of reason also is not appropriate. This is not a garden-variety business arrangement bursting with procompetitive justifications. It is a private settlement that eliminates challenges to patents central to the patent regime and Hatch-Waxman Act.

2. The most appropriate framework for analysis would recognize the anticompetitive concerns with exclusion-payment settlements while giving the settling parties an opportunity to show that they have legitimate justifications that outweigh any anticompetitive effects. That approach could take the form of a quick-look analysis that treats exclusion payments as presumptively unlawful.

This Court has recognized that certain agreements threaten significant anticompetitive harm but also might be justified. In *National Society of Professional Engineers v. United States*, 435 U.S. 679, 692 (1978), this Court found that "no elaborate industry analysis" was needed to "demonstrate the anticompetitive character" of a ban on competitive bidding among members of a professional association. In *Federal Trade Commission v. Indiana Federation of Dentists*, 476 U.S. 447, 459 (1986), the Court did not engage in a full-blown market analysis before finding that a dental association's refusal to submit x-rays to insurers was anticompetitive. And in *National Collegiate Athletic Association v. Board of Regents of University of Oklahoma*, 468 U.S. 85, 113 (1984), the Court placed on the defendant a "heavy burden of establishing an affirmative defense" since a plan for televising college football games "on its face constitute[d] a restraint upon the operation of a free market" and "operated to raise prices and reduce output."

Exclusion payments "represent a significant threat to competition," which "mak[es] a full rule of reason inquiry unnecessary." XII Hovenkamp, *Antitrust Law* ¶ 2046c3, at 350-51 (3d ed. 2012). The "size of the payment" is "a strong indicator of power" since "[a] firm pricing at marginal cost cannot afford to pay large sums to others

to stay out of its market." *Ibid.* ¶ 2046c3, at 351. Settling companies are entitled to offer evidence showing that their settlement is procompetitive, but absent such evidence, an exclusion-payment settlement should be presumed illegal.

3. This approach was applied by the Third Circuit in *K-Dur*. That court articulated a "quick look rule of reason analysis based on the economic realities of the reverse payment settlement." 686 F.3d at 218. In particular, "the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade." *Ibid.*

The presumption in *K-Dur* "could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit." *Ibid.* The court supported this analysis by pointing to "a long line of Supreme Court cases recognizing that valid patents are a limited exception to a general rule of the free exploitation of ideas" and that "the public interest supports judicial testing and elimination of weak patents." *Ibid.* Notably, however, the *K-Dur* presumption cannot be rebutted simply by arguing that exclusion payments are procompetitive.

The *K-Dur* approach properly applies this Court's quick-look precedents to exclusion-payment settlements. And it identifies potential circumstances in which a payment might not have its normal anticompetitive effect. Others have suggested that a payment limited to the actual cost of litigation could indicate a settlement motivated by cost-avoidance rather than the elimination of competition. 1 Herbert Hovenkamp et al., *IP and Antitrust* § 15.3a1[C],

at 15-52 (2d ed. 2010); Carrier, *Unsettling Settlements*, at 76-77; Elhauge & Krueger, Solving Settlement Puzzle, at 329; Shapiro, *Antitrust Limits*, at 408. A settlement payment limited to litigation costs need not delay entry; a larger payment necessarily delays the expected date of generic entry.

A quick-look analysis allows courts to consider the potentially severe anticompetitive effects of exclusion-payment settlements while permitting the settling parties to introduce possible procompetitive justifications, if any, for their agreement. The court below erred by ignoring these considerations.

CONCLUSION

For the reasons above, this court should reverse the decision of the court below affirming the district court's grant of defendants' motion to dismiss.

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