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 OF LOUISIANA WHOLESALE DRUG COMPANY, INC., CVS PHARMACY, INC., RITE AID CORPORATION, WALGREEN CO., ECKERD CORPORATION, THE KROGER CO., SAFEWAY INC., ALBERTSON'S, INC., HY-VEE, INC., AND MAXI DRUG, INC. D/B/A BROOKS PHARMACY IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI*[1]

Amici curiae are Louisiana Wholesale Drug Company, Inc., CVS Pharmacy, Inc., Rite Aid Corporation, Walgreen Co., Eckerd Corporation, The Kroger Co., Safeway Inc., Albertson's, Inc., Hy-Vee, Inc., and Maxi Drug, Inc. d/b/a Brooks Pharmacy. As direct purchasers and sellers of pharmaceutical products (or their assignees), *amici* have a strong interest in acquiring and distributing low-cost generic drugs. Because a generic drops to thirty percent or less of the price of the equivalent brand within a year of introduction, agreements by brand manufacturers to delay generic entry cost consumers – *amici*'s customers – billions of dollars each and every year. *See* FTC Staff Study, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 2 (Jan. 2010) ("FTC, *Pay-for-Delay*") (annual cost of $3.5 billion).

In recent years, *amici* have seen reverse payment agreements to settle Hatch-Waxman patent litigation proliferate. The previously accepted wisdom of pharmaceutical executives that such agreements are illegal and immoral has evaporated, encouraged by court opinions giving brand companies virtual carte blanche to pay competitors to delay competition. *See* FTC Bureau of Competition, *Overview of Agreements Filed in FY 2012*, at 2 (Jan. 17, 2013), available at http://www.ftc.gov/os/2013/01/130117mmareport.pdf

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* affirm that no counsel for any party authored this brief in whole or in part and that no one other than *amici* or their counsel made a monetary contribution intended to fund the preparation or submission of this brief. The parties have consented in writing to the filing of this brief.

("FTC FY 2012 Overview") (reporting record number of potential pay-for-delay deals in 2012). Seeking to encourage competition in pharmaceutical sales, *amici* have participated as plaintiffs in nearly every private suit challenging the use of such reverse payments, including litigation concerning the agreements at issue in this case and *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012), *pets. for cert. pending* (Nos. 12-245, 12-265). Through that litigation, *amici* and their counsel have developed particular expertise concerning the lawfulness and anti-competitive effects of reverse payment agreements.

BACKGROUND

This case arises from petitioner FTC's complaint challenging reverse payment agreements between respondent Solvay (the manufacturer of AndroGel, a branded testosterone gel) and two would-be generic competitors, respondents Watson and Paddock (the latter partnering with respondent Par). Solvay sued the generic respondents for patent infringement pursuant to the Hatch-Waxman Act. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355). The generics countered that Solvay's patent was invalid and that their products did not infringe. The parties settled in 2006, with Solvay paying the generics millions of dollars to stay out of the market until 2015.

Because the district court granted respondents' motion to dismiss, this Court must decide the case based on the complaint's well-pleaded facts, construed in the light most favorable to petitioner FTC. But the Court should know that the facts of this case are representative of many other similar reverse

payment agreements. This brief brings to the Court's attention the extensive records compiled by *amici* in three similar cases plus a fourth in which a brand refused to make a reverse payment. The cases illustrate the severe threat to pharmaceutical competition posed by reverse payments.

I. K-Dur

K-Dur 20 ("K-Dur") was the subject of reverse payment agreements that gave rise to separate suits by the FTC and private plaintiffs. *See K-Dur*, 686 F.3d 197 (private suit); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (FTC action), *cert. denied*, 548 U.S. 919 (2006).

K-Dur is Schering's brand-name sustained release potassium chloride product. It treats potassium deficiencies, such as those that arise from the use of diuretics prescribed for high blood pressure. In 1997, Schering's annual U.S. sales of K-Dur were approximately $190 million. But Schering expected generic entry to reduce annual sales to $70 million or less by 2001. *K-Dur* 3d Cir. App. A-2026.

The potassium chloride compound in K-Dur was unpatentable. *K-Dur*, 686 F.3d at 203. However, Schering owned a formulation patent (the "'743 patent") claiming the controlled-release coating on the potassium chloride crystals. Particularly important, the '743 patent specifically claimed the use of ethylcellulose, a standard pharmaceutical ingredient, with a viscosity (resistance to flow) of greater than 40 centipoise (cp) (a measure of viscosity). Schering listed the patent in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

In November 1995, generic manufacturer Upsher filed the first Abbreviated New Drug Application ("ANDA") for generic K-Dur. Upsher's generic product used Ethocel 20, an ethylcellulose product with a viscosity of only 18-22 cp, significantly lower than the minimum 40 cp viscosity claimed by Schering's patent. Upsher provided a Paragraph IV certification that its product would not infringe the '743 patent. Schering responded by suing Upsher for infringement.

Upsher represented to the court that Schering's infringement claims were "baseless and could not have been made in good faith." *K-Dur*, 686 F.3d at 205; *K-Dur* 3d Cir. App. A-6972-73; A-6772. Schering had secured its patent only by surrendering the use of ethylcellulose with a viscosity of less than 40 cp. *K-Dur*, 686 F.3d at 205. Because Upsher intentionally designed its product to use subject matter that Schering had surrendered, the doctrine of prosecution history estoppel precluded any finding that Upsher's product infringed Schering's patent. *K-Dur* 3d Cir. App. A-6972-73; A-6772.

In settlement negotiations, Upsher repeatedly asked Schering to pay it to delay introducing generic K-Dur, but Schering repeatedly responded that such a payment would violate the antitrust laws. *K-Dur*, 686 F.3d at 205.

On June 17, 1997, the parties argued summary judgment motions. In that argument, the district judge repeatedly challenged Schering's allegation that Upsher's product using low-viscosity ethylcellulose infringed the '746 patent, which expressly claimed a viscosity of greater than 40 cp. *See, e.g.*, *K-Dur* 3d Cir. App. A-7110 ("You're saying 20 is 40?");

id. at A-7111 ("That's what you're saying 20 is 40?"); *id*. at A-7123 ("Don't words mean anything?").

Schering and Upsher settled just hours before the district court was to rule on the summary judgment motions. *K-Dur*, 686 F.2d at 205. Schering agreed to pay Upsher $60 million. In exchange, Upsher agreed to delay generic K-Dur for over four years. *Id.* The agreement also granted Schering licenses for several other Upsher products. After entering the reverse payment settlement, Schering predicted that its sales of K-Dur would grow rather than decrease as was expected had a generic been introduced. *K-Dur* 3d Cir. App. A-2026.

About a year after settling with Upsher, Schering made another reverse payment – this time to generic manufacturer ESI, which had filed a subsequent ANDA to sell generic K-Dur. ESI agreed not to market any generic version of K-Dur before January 2004, and Schering agreed to make a payment of up to $10 million contingent on the timing of FDA approval of ESI's generic. *K-Dur*, 686 F.3d at 206. The maximum payment corresponded to the earliest anticipated FDA approval date and decreased if delays in FDA approval rather than the parties' agreement prevented generic entry. *Id*.

In subsequent private antitrust litigation, *amici* presented a detailed economic expert report demonstrating that Schering's predicted losses from generic entry and Upsher's predicted gains would have allowed them to settle their patent dispute without a reverse payment. *K-Dur* 3d Cir. App. A-3158-64, A-3818. But a settlement without a cash payment would necessarily have had to grant Upsher a much earlier generic entry date, thereby benefitting consumers. *Id.* at A-3158-64. *Amici*'s expert also dem-

onstrated that Hatch-Waxman litigation can almost always be settled without a reverse payment. *See* Christopher Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements: Payments By the Patent Holder Should Be Per Se Illegal*, 21 RESEARCH IN LAW & ECON. 477, 483-84 (2004) ("Leffler & Leffler, *Settling the Controversy*").

II. Cipro

Cipro is a branded antibiotic sold by Bayer. Prior to generic entry, it had sales of over a billion dollars. *In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 363 F. Supp. 2d 514, 538 n.22 (E.D.N.Y. 2005)**.** Bayer estimated that it would lose between $510 million and $826 million in Cipro sales in the first two years of generic competition. *Id*. at 522.

Generic manufacturer Barr filed the first ANDA to sell generic Cipro. Because Bayer's patent claimed the active compound (ciprofloxacin) in Cipro, Barr's generic necessarily infringed, but Barr maintained that the patent was invalid. *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 102 n.5, 106 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1606 (2011). Barr entered into an agreement with Rugby (then a subsidiary of HMR) to share the costs of any patent litigation and any revenues arising from it. *Arkansas* 2d Cir. App. A-476.

After Bayer sued Barr for patent infringement, the parties settled on the eve of trial. Bayer acknowledged that Barr had raised a "substantial question" as to the patent's validity. *Arkansas* 2d Cir. App. A-996.

Bayer paid Barr $49.1 million and agreed to either supply ciprofloxacin to Barr to sell under license (for a royalty to Bayer of 70% of Cipro's average sell-

ing price) or to make quarterly payments beginning January 1998. *Arkansas Carpenters*, 604 F.3d at 102 & n.8. To avoid licensed generic competition, Bayer ultimately paid Barr an additional $349 million to stay out of the market. *Id.*

The payments gave Barr and its partner between 97% and 200% of the profits that they would have earned had they won the patent litigation and entered the market. *Arkansas* 2d Cir. App. A-5835; A-3427-28. Under the optional license, Barr would have entered the market at a substantial discount to branded Cipro, generating at least $125 million to $200 million in consumer savings. *Id.* at A-5931; A-5842. Bayer's reverse payments purchased relief from these consumer savings.

The agreement prohibited Barr and HMR/Rugby from supporting any other generic challenge to the '444 patent and disabled Barr's outside counsel from representing other generic manufacturers by requiring that they switch sides and represent Bayer. *Arkansas Carpenters*, 604 F.3d at 106; *Arkansas* 2d Cir. App. A-2796-97; A-2825.

The agreement eliminated generic competition for at least three years. *Id.* at A-5827. A second challenger could not have entered any earlier because it would have had to prepare and file a Paragraph IV ANDA and then wait out the automatic 30-month Hatch-Waxman stay. 21 U.S.C. § 355(j)(5)(B)(iii).

By the time another generic was in a position to enter the market, Bayer's patent was already near expiration, leaving that generic insufficient time to litigate its best challenge to the patent – that Bayer had secured the patent through inequitable conduct. *Arkansas* 2d Cir. App. A-4901-02; A-8356.11. Bayer

prevailed on the remaining, weaker defenses. *Arkansas Carpenters*, 604 F.2d at 102 n.9.

III. Provigil

The drug Provigil is used to treat sleep disorders. Its active ingredient, modafinil, is not patentable. However, brand manufacturer Cephalon owned a narrow patent claiming a particular formulation in which 95% of the modafinil particles had a diameter below 200 microns. *See King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 521 (E.D. Pa. 2010). From 2004 to 2008, Cephalon's annual U.S. Provigil sales rose from $420 million to $920 million.

Four generic manufacturers – Teva, Ranbaxy, Barr, and Mylan – each submitted separate ANDAs on the same day containing Paragraph IV certifications that Cephalon's patent was invalid or not infringed. Cephalon sued all four generics.

Between December 2005 and February 2006, Cephalon entered into reverse payment agreements, under which each generic agreed to delay marketing generic Provigil for six years. *King*, 702 F. Supp. 2d at 521-23. Cephalon expected to pay up to $136 million to Teva, Ranbaxy, and Barr, and a further $45 million to Mylan. *Id.* at 522. As Cephalon's CEO candidly admitted: "We were able to get six more years of patent protection [from the settlement]. *That's $4 billion in sales that no one expected*." John George, *Hurdles Ahead for Cephalon*, PHILA. BUS. J. (Mar. 20, 2006) (emphasis added).

Cephalon used this period of purchased exclusivity to encourage buyers to switch to Nuvigil, its patented successor brand product containing a closely related active ingredient. As Cephalon's Vice Presi-

dent of Investor Relations explained: "You should expect that we will likely raise Provigil prices to try to create an incentive for the reimbursers to preferentially move to Nuvigil." Jonathan D. Rockoff, *How a Drug Maker Tries to Outwit Generics*, WALL ST. J., Nov. 18, 2008, at B1.

A subsequently filed case involving a fifth generic competitor that was not paid off took years to litigate and is currently on appeal. In that suit, Cephalon's patent was invalidated on numerous grounds. *Apotex Inc. v. Cephalon, Inc.*, No. 2:06-cv-2768, 2011 WL 6090696, at *1 (E.D. Pa. Nov. 07, 2011) (holding that patent was unenforceable due to inequitable conduct and also was invalid because (1) the invention was on sale more than one year before the patent application was filed; (2) the invention was made by a French company not named in the patent application; (3) the subject matter was obvious; and (4) the written description was inadequate). Even had it been valid and enforceable, the patent was exceedingly narrow and was not infringed by Apotex's product that used larger modafinil particles than it specified. *See Apotex, Inc. v. Cephalon, Inc.*, No. 2:06-CV-2768, 2012 WL 1080148 at *1 (E.D. Pa. Mar. 28, 2012); *Apotex, Inc. v. Cephalon, Inc.*, No. 2:06-CV-2768, 2010 WL 3933274, at *6-8 (E.D. Pa. Oct. 7, 2010).

IV. Prozac

In 2001, Prozac, Eli Lilly's blockbuster antidepressant, had roughly $2.4 billion in annual sales. *See* Bethany McLean, *A Bitter Pill*, FORTUNE, Aug. 13, 2001, at 1. At that time, Lilly's patent on Prozac's active ingredient (fluoxetine) had expired. Generic manufacturer Barr asserted that Lilly's follow-on pa-

tent – which claimed the way that fluoxetine worked – was invalid for double patenting. *Id.* at 5.

Lilly sued Barr for patent infringement. Barr (which previously convinced Bayer to pay it $398 million to delay generic Cipro) demanded a reverse payment of at least $200 million to settle the case. But Lilly refused. At that time – before the Second, Eleventh, and Federal Circuits suggested that pharmaceutical patents included the right to pay off a potential competitor – Lilly's CEO believed that "such a settlement violated antitrust laws, and it isn't morally right." *Id.*

Barr continued litigating and won the patent case thereby invalidating the Lilly patent. The resulting entry of generic Prozac saved consumers an estimated $2.5 billion. *See Comment of the Generic Pharmaceutical Ass'n in Support of Citizen Pet.,* FDA Docket No. 2004P-0075/CP1, at 3 (filed May 21, 2004), available at http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00003-vol1.pdf.

SUMMARY OF ARGUMENT

Reverse payments follow a common, recurring pattern. Brand and generic manufacturers often enter reverse payment agreements when generic competition is imminent. The payment delays entry by the competitor, generally for years. Indeed, that is precisely the point. The payments are otherwise unnecessary: Hatch-Waxman patent cases can be settled without reverse payments, and, without such payments, the brand and generic would agree to earlier generic entry. To avoid scrutiny, drug companies frequently seek to camouflage the payments as something other than a naked payoff to delay competition.

The brand typically makes a reverse payment to the generic that files the first ANDA, which is the biggest competitive threat. That generic is closest to entering the market. It also has 180 days of marketing exclusivity – the bounty granted by Hatch-Waxman to encourage pharmaceutical patent challenges. Following that pay-off, it may take years for another generic to emerge as a competitor because the subsequent generic must file its own ANDA and resolve any ensuing litigation over the brand's patent. Subsequent generics may have to surmount the bottleneck often created by the first filer's 180-day exclusivity. If subsequent generics represent real competitive threats, the huge monopoly profits of the brand permit it to make multiple reverse payments.

The cases illustrate the inadequacies of the Eleventh Circuit's broad approval of reverse payment agreements. The ruling below virtually impels horizontal competitors to join together to split monopoly profits that would otherwise be competed away to the benefit of consumers. In contrast, a rule regarding reverse payments as *prima facie* anticompetitive would substantially encourage competition. Under such a rule, the parties would be free to reach an alternative no-payment settlement with an earlier entry date or litigate to a conclusion that would lead to earlier generic entry or establish the brand's right to exclude.

Nothing in antitrust law, Hatch-Waxman, or patent law supports the Eleventh Circuit's approach. Antitrust law prohibits horizontal competitors such as the respondents here from agreeing not to compete. By contrast, the Eleventh Circuit relies on standards developed to evaluate *unilateral* conduct that may implicate constitutional First Amendment

concerns – *i.e.*, standards for evaluating fraudulent patent procurement and sham litigation.

Congress enacted Hatch-Waxman to benefit the public by encouraging the fastest possible entry of low-priced generic products. Yet the Eleventh Circuit's ruling turns that statute on its head by permitting it to be used to purchase delays that impose higher prices on consumers.

And, as a matter of patent law, the Eleventh Circuit's ruling impairs innovation by encouraging brand manufacturers to buy protection for their weak patents, which would otherwise be compromised in settlement or eliminated by litigation. That result cannot be reconciled with this Court's precedent, which rejects attempts to broaden patent monopolies, encourages the authoritative testing of such exclusive rights, and safeguards incentives to challenge patents.

The Third Circuit has adopted the correct approach. That court applies a "quick look" rule of reason analysis, treating reverse payments as *prima facie* anticompetitive. That rule is consistent with the purposes of the antitrust and patent laws, yet flexible enough to take account of the circumstances of an individual case. The *prima facie* case may be rebutted by *evidence* that the payment either was made for something other than delay or provided a competitive benefit that could not otherwise have been achieved.

ARGUMENT

I. The Eleventh Circuit's "Scope of the Patent" Test Violates the Policies of Antitrust Law, Hatch-Waxman, and the Patent Act.

a. Competition in the pharmaceutical industry often depends on patent litigation. As the Eleventh Circuit acknowledged, the "huge profits that new drugs can bring frequently attract competitors in the form of generic drug manufacturers that challenge or try to circumvent the pioneer's monopoly in the market." Pet. App. 2a-3a. If permitted by law, a brand name company has every incentive to avoid the risks of patent litigation and pay "the allegedly infringing generic company to delay entering the market until a specified date, thereby protecting the patent monopoly against a judgment that the patent is invalid or would not be infringed by the generic competitor." *Id.* at 3a.

In any other context, such a payment not to compete would be obviously illegal. *See, e.g.*, *Palmer v. BRG of Ga., Inc.,* 498 U.S. 46 (1990); *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986) (under the rule of reason applicable to most antitrust questions, plaintiffs meet their initial burden by proving either that: (a) the practice has harmed consumers; or (b) the defendant has market power and its conduct is of a type likely to harm consumers).[2] Respon-

[2] The anticompetitive effects of delaying generic competition are clear. For example, in *Cipro*, before generic entry, Bayer was able to sell Cipro at a price more than twenty times the competitive price. *Ciprofloxacin*, 363 F. Supp. 2d at 523.

dents nonetheless argued, and the court of appeals agreed, that the "patent made all the difference because it meant that the patent holder had a 'lawful right to exclude others' from the market." Pet. App. 17a (quoting *Valley Drug Co. v. Geneva Pharms, Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004)).

That was error. The Patent and Trademark Office issues patents in *ex parte* administrative proceedings. Such issuance does not conclusively establish the patent's validity. And, it manifestly does not establish that any generic product infringes the patent. As the Provigil and Prozac cases illustrate, *see supra* pp. 9-10, brand name manufacturers' patents are often found invalid and/or not infringed by would-be generic competitors. *See also* FTC, *Pay-for-Delay*, *supra*, at 3 (estimating that roughly 75% of litigated pharmaceutical patents are found to be invalid or not infringed).

The Eleventh Circuit rested its decision on the abstract notion that a patent represents an unassailable right to exclude competition. But that reasoning ignores the very purpose of Hatch-Waxman to encourage litigation to weed out weak patents that impair competition in the pharmaceutical industry. Hatch-Waxman was intended "to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990)). It did so by creating a streamlined application process for generics and granting 180 days of marketing exclusivity to the first generic whose application contains a "Paragraph IV Certification" asserting that the brand's patent "is invalid or will not be infringed by the manufacture,

use, or sale of the [generic] drug." *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This bounty for entering the market via a patent challenge is a huge incentive to generics to challenge weak or narrow patents. It can be worth hundreds of millions of dollars in profits because the generic can substantially underprice the brand yet still earn a high profit margin given the low cost of the active chemical ingredients in most drugs. If federal law is construed to permit brand companies to buy off the generic companies that Congress deputized to challenge weak patents, the very purpose of the Act to promote generic competition will be subverted.

Nor are reverse payments justified by patent law. Patents are "affected with a public interest." *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). They are limited exceptions to the general policy of the Sherman Act favoring free competition. *United States v. Masonite Corp.*, 316 U.S. 265, 280 (1942) ("Since patents are privileges restrictive of a free economy, the rights which Congress has attached to them must be strictly construed so as not to derogate from the general law beyond the necessary requirements of the patent statute."). And, it "is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *Lear, Inc. v. Adkins*, 395 U.S. 653, 663-64 (1969) (quoting *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892)).

Accordingly, this Court has repeatedly condemned attempts to broaden the physical or temporal scope of the patent monopoly *and* encouraged the authoritative testing of patent validity. *Blonder-Tongue Labs, Inc. v. University of Illinois Found.*, 402 U.S.

313, 343 (1971). *See also Lear*, 395 U.S. at 670 (patentee cannot "muzzle[ ]" those who otherwise have an "economic incentive to challenge the patentability of an inventor's discovery"). Consistent with these principles, this Court has held that patent law does not confer a right to expand the exclusionary power of a patent through private contract.[3]

Particularly relevant here, the Court has also held that ownership of a patent does not preclude antitrust liability.[4] Thus, competitors are properly held liable for violating the antitrust laws, notwithstanding that their agreement seeks to settle patent litigation. *Masonite*, 316 U.S. at 279 (denouncing patent holder's attempt "under the guise of his patent monopoly not merely to secure a reward for his invention but to secure protection from competition which the

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[3] *See*, *e.g.*, *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 136-37 (1969) (a patentee "may not use the power of his patent to levy a charge for making, using, or selling products not within the reach of the monopoly granted by the Government"); *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 668 (1944) ("If such an expansion of the patent monopoly could be effected by contract, the integrity of the patent system would be seriously compromised."); *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 492 (1942) ("the public policy which includes inventions . . . forbids the use of the patent to secure an exclusive right or limited monopoly not granted by the Patent Office and which it is contrary to public policy to grant").

[4] *See*, *e.g.*, *Masonite*, 316 U.S. at 277 ("The owner of a patent cannot extend [its] statutory grant by contract or agreement. A patent affords no immunity for a monopoly not fairly or plainly within the grant."); *Standard Sanitary Mfg. Co. v. United States*, 226 U.S. 20, 49 (1912) ("Rights conferred by patents are indeed very definite and extensive, but they do not give any more than other rights a universal license against positive prohibitions.").

patent law unaided by restrictive agreements does not afford"). *See also United States v. Singer Mfg. Co.*, 374 U.S. 174, 200 (1963) (White, J., concurring) (collusion to prevent prior art from being presented to patent office should be "presumptively bad" because "patent laws do not authorize, and the Sherman Act does not permit, such agreement between business rivals to encroach upon the public domain and usurp it to themselves").

b. The Eleventh Circuit's "scope of the patent" test cannot be reconciled with this Court's precedents. Despite this Court's efforts to keep patents within their prescribed temporal *and* physical boundaries, the only "scope" that the test considers is whether the settlement bars entry after expiration of the patent.[5] It otherwise assumes the generic to be within the substantive scope of the patent based solely on the brand's allegations. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213-14 (2d Cir. 2006). *See also* Michael Carrier, *Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem*, 16 STAN. TECH. L. REV. 1, 5-6 (2012) (criticizing "scope of the patent" test as it has developed for assuming the validity issues "central to the determination of antitrust analysis").

As a result, the "scope of the patent" test permits brands to purchase from the generics a further period of exclusivity by avoiding authoritative judicial determinations of validity and infringement. As the Second Circuit recognized, the approach creates the

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[5] The name of the test is highly misleading in that it relies entirely on the brand's allegation and makes no assessment of the patent's substantive scope.

"troubling dynamic" in which brand name manufacturers with the weakest patents – even if "fatally weak" – are most likely to secure the greatest immunity from competition by paying off their competitors. *Tamoxifen*, 466 F.3d at 211-12. It protects "intellectual property, not on the strength of a patent holder's legal rights, but on the strength of its wallet." *K-Dur*, 686 F.3d at 217 (citing C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1614 (2006)).

Affirmance of the Eleventh Circuit would cause reverse payment agreements to further proliferate.[6] The "scope of the patent" test has no meaningful limits. It permits brands to pay as much as they wish to as many generics as they wish to block generic competition right up to the date of patent expiration. Because such payments preserve the brand's monopoly, the brand and generic profit more from them than they would from competition. As a result, if generally permitted, reverse payments will displace more competitive settlements as well as litigated judgments.

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[6] In fact, the number of reverse payments would likely explode. Reverse payments have already dramatically increased as a result of just three permissive appellate opinions even though this Court never ruled on them, pharmaceutical executives publicly expressed concerns about their legality, and three other appellate decisions called their legality into doubt. *See In re Cardizem CD Antitrust Litig.,* 332 F.3d 896, 907 (6th Cir. 2003) (*per se* illegality of reverse payments), *cert. denied*, 543 U.S. 939 (2004); *Andrx Pharm. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 813 (D.C. Cir. 2001) (reverse payment undoubtedly "harms consumers"), *cert. denied*, 535 U.S. 931 (2002); *K-Dur*, 686 F.3d at 218 (reverse payments *prima facie* anticompetitive).

There will be little rational economic or legal reason for generics to ever settle without a reverse payment or to litigate Hatch-Waxman cases to a final judgment. Companies like Lilly facing generic competition will be unwilling to subject their multi-billion dollar drug franchises to the litigation risk of losing exclusivity if they may avoid that risk by sharing monopoly profits with their competitors. *See supra* p. 10 (Prozac). Nor will they need to reach early-entry settlements taking that risk into account because they can simply pay to delay generic entry until the end of the patent term. Weak and otherwise "fatally weak" patents will continue to block competition, and consumers will pay much higher prices.

The public will suffer from lessened innovation caused by preserving weak patents and private agreements extending patents beyond their substantive terms.[7] *See generally United States v. Aluminum*

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[7] The Eleventh Circuit suggested that the high cost to develop new brand products somehow justifies collusive payments to delay competition. Pet. App. 2a. But patent holders are not exempt from the antitrust laws. *See supra* note 4. Moreover, the development costs cited by the Eleventh Circuit (and brand companies) have been severely criticized as applicable only to a few of the most expensive drugs. *See* MARCIA ANGELL, THE TRUTH ABOUT DRUG COMPANIES 42 (2004). The methodology behind the estimates has been criticized for *inter alia*: (1) calculating "opportunity costs" based on hypothetical returns on alternate investments for R&D expenditures; (2) failing to recognize that much of the initial research for new chemical entities is performed by the National Institutes of Health or universities; and (3) ignoring R&D-related tax credits received by pharmaceutical firms. *See id.* at 44-65. *See generally* MERRILL GOOZNER, THE $800 MILLION PILL: THE TRUTH BEHIND THE COST OF NEW DRUGS (2004); Donald W. Light & Rebecca Warburton,

Co. of Am., 148 F.2d 416, 427 (2d Cir. 1945) (L. Hand, J.) (observing that "immunity from competition is a narcotic, and rivalry is a stimulant, to industrial progress; [ ] the spur of constant stress is necessary to counteract an inevitable disposition to let well enough alone").

Pharmaceutical patents often cover minor formulations that are not critical to a drug's biological activity. As a result, like Upsher in *K-Dur*, generic competitors can often design around those patents by developing new formulations. *See supra* p. 4. Under the patent laws, such innovations can be excluded only if the brand proves infringement, but reverse payments allow brands to pay to convert a mere allegation of infringement into guaranteed exclusivity.

Without reverse payments, earlier generic entry could occur in several ways. A generic manufacturer might launch upon expiration of the thirty-month stay ("at risk" because the litigation is unresolved) or after final judgment establishing the patent to be invalid or not infringed. *See supra* pp. 9-10 (judgments in *Provigil* and *Prozac*). Alternatively, the parties may settle by negotiating an earlier no-payment entry date or agreeing to licensed generic entry. An arm's length license negotiated in accordance with the value that the parties put on their respective claims does not ordinarily violate the antitrust laws. *See Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931).

Demythologizing the High Costs of Pharmaceutical Research, BIOSOCIETIES, Mar. 2011, at 34-50.

A reverse payment settlement is unlike a license agreement or a compromise of patent damages. In both of those cases, the accused infringer benefits by selling its product in competition with the patent holder. In the absence of a reverse payment, a generic will negotiate to enter the market as early as possible or remain on the market for as long as possible consistent with its view of the strength of the patent (and the brand will seek to minimize that time consistent with its own views of patent strength). In contrast, a brand makes a reverse payment to a generic to compensate it for staying off the market and *not* making sales.[8] *See K-Dur*, 686 F.3d at 218 (agreeing that "[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise" (quoting

[8] Pharmaceutical manufacturers argue that reverse payment settlements are procompetitive if they permit generic entry before patent expiration. Such arguments necessarily assume that the brand is entitled to exclude the generic for the full term of the patent even though it paid to avoid just such a determination. No such assumption is warranted. Compared to alternate outcomes (*e.g.*, a no-payment settlement or the risk adjusted expected outcome of the litigation), reverse payments reduce competition. Moreover, the "scope of the patent" test, if adopted, would allow brand companies to pay generics to stay off the market right up to the date of patent expiration. The test as it has developed contains no limiting principle. While the legal standard has been in flux, manufacturers have exercised some restraint in agreeing to permit generic entry before patent expiration. However, were the Court to adopt the "scope of the patent" test as the law of the land, nothing in the test would prevent brands from buying exclusion for the entire term of the patent.

In re Schering-Plough Corp., 136 F.T.C. 956, 988 (2003)). *Cipro* proves this logic. There, the settlement agreement included an optional license that would have allowed generic entry with a royalty, but Bayer chose to make additional reverse payments to delay entry beyond the agreed-upon licensed entry date. *See supra* pp. 6-7.

In the absence of a reverse payment, the interests of the generic and consumers are aligned because both benefit by early sales of a low-priced generic. In contrast, when a generic accepts compensation to delay competition, it profits by agreeing not to make such sales. As a result, consumers are robbed of the benefits that they would have otherwise received. *K-Dur* 3d Cir. App. A-3158. This severance of interests between the potential entrant and consumers is the hallmark of anticompetitive conduct. *Premier Elec. Constr. Co. v. Nat'l Elec. Contractors Ass'n, Inc.*, 814 F.2d 358, 369-70 (7th Cir. 1987). *See also* XII HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2046c, at 343 (3d ed. 2012) (explaining difference between reverse payment and licensed entry).

c. The fraudulent procurement and sham litigation exceptions to the "scope of the patent" rule do not address the anticompetitive effect of reverse payments. These standards distinguish unprotected unilateral conduct actionable under the antitrust laws from protected conduct (which may be within the First Amendment). *See Professional Real Estate Investors, Inc., v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) (sham litigation as Section 2 violation); *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965) (fraudulent patent procurement as Section 2 violation). They do not address the anticompetitive effects of collusive agree-

ments in which entrenched monopolists pay potential competitors not to compete. Such joint conduct has always been "judged more sternly" than unilateral conduct under antitrust law. *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984). *See also Alvord-Polk, Inc. v. F. Schumacher & Co.*, 37 F.3d 996, 1000 (3d Cir. 1994), *cert. denied*, 514 U.S. 1063 (1995).

II. There Is No Merit to the Justifications Offered in Support of the Eleventh Circuit's Rule Broadly Approving Reverse Payment Agreements.

The litigated challenges to reverse payment agreements demonstrate that the justifications offered in support of the Eleventh Circuit's "scope of the patent" test have no merit. To the extent that the circumstances of a particular case provide special justification for a reverse payment, the courts are well equipped to address such a case under the "quick look" rule of reason, which is not a rule of *per se* illegality. The *prima facie* case established by evidence of a reverse payment may be rebutted by showing that the payment was made for a reason other than delay or offered a pro-competitive benefit that could not be achieved in the absence of the reverse payment. *K-Dur*, 686 F.3d at 218. Unlike the "scope of the patent" test, the "quick look" rule of reason does not make counterfactual assumptions. It acknowledges the unmistakable anticompetitive effects of reverse payments, but allows them to be rebutted with specific evidence.

A. A Patent's Presumptive Validity Does Not Confer a Right to Conspire to Delay Competition.

The principal justification for the Eleventh Circuit's ruling is that the law presumes issued patents to be valid. *See* 35 U.S.C. § 282; *Schering*, 402 F.3d at 1066; *Tamoxifen*, 466 F.3d at 208-09 & n.22; *In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 544 F.3d 1323, 1337 (Fed. Cir. 2008).

But the presumption of validity is not an ironclad "right to exclude." It is a *rebuttable* presumption that may be challenged by accused infringers. Indeed, it is only a "procedural device and is not a substantive right of the patent holder." *K-Dur*, 686 F.3d at 214 (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983)). *See also Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 625 F.3d 779, 781 (2d Cir. 2010) (Pooler, J., dissenting) (finding "no basis for treating [the presumption of validity] as virtually conclusive and allowing it to serve as a substantive basis to limit the application of the Sherman Act").

The presumption of validity has never before entitled a patentee to exclude a competitor. In preliminary injunction proceedings, the patentee must establish the likelihood of a patent's validity; it may not rest on the presumption. *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991). *See also Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994). Courts frequently deny preliminary injunctions on the ground that, until there is a judicial finding of validity and infringement, the alleged infringer has a "right to compete." *See, e.g.*, *Illinois*

Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679, 684 (Fed. Cir. 1990).

Even after entry of a final judgment of infringement, a patentee is not automatically entitled to the kind of exclusivity purchased with reverse payments. In *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393 (2006), this Court held that a prevailing patentee must satisfy the traditional requirements for equitable relief before such exclusion is ordered.

There is no basis in law or logic to give greater force to the rebuttable presumption of validity in this context. Many pharmaceutical patents subject to reverse payments are of low quality or cover minor features not critical to the biological properties of the drug. *See* XII HERBERT HOVENKAMP, ANTITRUST LAW, *supra,* at 345. In *Provigil*, a generic that was not paid off established that the patent was invalid and not infringed. *See supra* p. 9. In *Prozac*, after Lilly refused to make a reverse payment, the district court found the patent invalid. *See supra* p. 10. *See also Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm.*, 107th Cong. (Apr. 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12 (warning of questionable brand patents).

Reliance on the presumption of validity is "particularly misguided" to justify reverse payments made to generic competitors that seek to introduce non-infringing alternatives. *K-Dur*, 686 F.3d at 214. A patent's "validity" says nothing at all about a right to exclude a competitor that has sought to avoid the patent by designing around it, as in *K-Dur* (lower viscosity ethylcellulose) and *Provigil* (larger particle size). *See supra* pp. 4, 9. In such circumstances, the

patentee (the brand) must prove infringement by the competitor (the generic).[9] In broadly approving reverse payments on the basis of the presumption of validity, the Eleventh Circuit has repeatedly failed to understand the critical difference between proof of invalidity and infringement. *See Schering*, 402 F.3d at 1066-67 (incorrectly asserting that Schering's patent gave it the right to exclude until the generic manufacturers "proved either that the '743 patent was invalid or that their products . . . did not infringe Schering's patent"); Pet. App. 24a (repeating error from *Schering*).

B. The Anticompetitive Effects of Reverse Payments Are Not Ameliorated by the Prospect of Subsequent Generic Entry.

Some courts have asserted that the market will quickly correct the anticompetitive effects of reverse payments. According to the Eleventh Circuit, a patent holder may be able to "escape the jaws of competition by sharing monopoly profits with the first one or two generic challengers [but] those profits will be eaten away as more and more generic companies en-

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[9] *See, e.g., Lehigh Valley R.R. Co. v. Mellon*, 104 U.S. 112, 119 (1881) (infringement "cannot be presumed"); *Imhaeuser v. Buerk*, 101 U.S. 647, 662 (1879) ("burden to prove infringement never shifts"); *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 678 (Fed. Cir. 2008) ("the burden of proof as to infringement remains on the patentee"), *cert. denied*, 129 S. Ct. 1917 (2009). In the infringement analysis, the patent holder's construction of its patent is "entitled to no deference" and may be rejected entirely. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 983 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996).

ter the waters by filing their own paragraph IV certifications attacking the patent." Pet. App. 36a. *See also Tamoxifen*, 466 F.3d at 195.

On that logic, brand manufacturers are making a terrible miscalculation, handing over tens of millions of dollars to generic competitors, when others will promptly take their place in the market. In fact, the brands are smarter than that. The court's simplistic analysis ignores the reality of pharmaceutical markets.

The complex regulatory scheme for pharmaceutical patents means that, by paying off one ANDA filer, a patent owner may be able to delay entry by subsequent generic challengers for years. *See* HERBERT HOVENKAMP ET AL., IP AND ANTITRUST § 15.3a1(C), at 15-50 (Supp. 2012). *See also* C. Scott Hemphill, *Paying for Delay*, *supra*, 81 N.Y.U. L. REV. at 1586. The entry barriers for subsequent generics include the substantial cost and time to develop the generic and to prepare and file an ANDA; the cost and time to gain FDA approval; the Hatch-Waxman automatic thirty-month stay, 21 U.S.C. § 355(j)(5)(B)(iii); and the first filer's 180 days of exclusivity, *id.* § 355(j)(2)(A)(vii)(IV). *K-Dur* 3d Cir. App. A-3309-10. In *Tamoxifen*, the brand paid off the generic manufacturer in March 1993, while awaiting a Federal Circuit ruling. *See Tamoxifen*, 466 F.3d at 193. Subsequent challengers did not obtain a Federal Circuit ruling until April 1997 – more than four years later. *See Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144 (Fed. Cir. 1997). And, every day that a generic for a multi-billion-dollar-a-year brand is delayed equals millions of dollars of harm to consumers.

In addition, subsequent generic filers do not have the same motivations to litigate as the first filer. The

first generic is substantially more likely to incur the costs of litigating against the brand because if successful it receives the 180 days of marketing exclusivity that Hatch-Waxman provides as a bounty to spur such challenges. Later challengers do not get the benefit of that exclusivity. *See K-Dur*, 686 F.3d at 215; *Arkansas Carpenters*, 604 F.3d at 109-10. *Contra Tamoxifen*, 466 F.3d at 214 (incorrectly suggesting that exclusivity would roll over to subsequent challengers).

As a result, subsequent generics may not have the time or the motivation to press expensive and time-consuming legal theories. Indeed, in *Cipro*, Bayer prevailed against subsequent generic manufacturers pursuing different theories after paying the first generic manufacturer almost $400 million and disabling its counsel from representing any subsequent generic. *See supra* pp. 7-8.

Even when another generic can effectively enter the market, however, the Eleventh Circuit's decision leaves the brand free to use its huge monopoly profits to pay off subsequent competitors. Indeed, the cases show that the brand can pay off multiple generic entrants. Here and in *K-Dur*, the brand paid off two generics. *See supra* p. 5. And, in *Provigil*, the brand paid off *four* generics. *See supra* p. 8.

C. Reverse Payments Are Not Necessary to Settle Hatch-Waxman Cases.

Courts have sought to justify the "scope of the patent" test on the ground that reverse payments are necessary to settle Hatch-Waxman cases. *See* Pet. App. 33a; *Tamoxifen*, 466 F.3d at 212; *Ciprofloxacin*, 544 F.3d at 1333. That assertion is somewhat ironic given that drug manufacturers often deny making

reverse payments, claiming the payments to be compensation for benefits other than delayed generic entry such as backup supply arrangements or co-promotion services (*Watson*) or license fees for other drugs (*K-Dur*).

In any event, the parties can almost always settle Hatch-Waxman cases without reverse payments. When the FTC announced in 2000 that it would aggressively prosecute reverse payments, pharmaceutical manufacturers stopped using them. But they continued to settle Hatch-Waxman patent cases, using instead the tools litigants employed in patent litigation for decades – principally, early-entry licenses. Statement of FTC Commissioner J. Leibowitz to the Special Committee on Aging of the U.S. Senate on Barriers to Generic Entry 13-14 (July 20, 2006), available at http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf. The use of reverse payments dramatically increased after lower court rulings broadly immunizing them from antitrust liability. FTC FY 2012 Overview, *supra*, at 2 (reporting record number of potential pay-for-delay deals in 2012).

In Europe, after the European Commission seriously questioned their legality, reverse payments declined significantly. *See* European Commission, 3d Report on the Monitoring of Patent Settlements (period: January - December 2011) ¶ 45 (July 25, 2012), available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report3_en.pdf. Notably, the increased scrutiny of reverse payments did not impair the ability of parties to settle patent litigation: the number of pharmaceutical patent settlements has actually increased in Europe. *Id.* ¶ 50.

Brand and generic manufacturers can almost always reach a settlement in which the generic receives an earlier entry date rather than a payment. Generic entry has a predictable financial impact on brand and generic manufacturers. As a result, it is a relatively simple matter for a brand and generic to reach an arm's length agreement setting an entry date that reflects their independent evaluations of the risks of litigation. Such an agreement is not anticompetitive because the generic profits by entering the market rather than dividing the brand's monopoly profits.

In *K-Dur*, *amici*'s expert demonstrated that reverse payments are necessary to achieve an efficient settlement in only one-half of one percent of all Hatch-Waxman cases, and that *K-Dur* itself could have been settled without such a payment. *K-Dur* 3d Cir. App. A-3164; Leffler & Leffler, *Settling the Controversy*, *supra*, 21 RESEARCH IN LAW & ECON. at 486. Indeed in *Cipro*, the parties actually agreed upon a royalty-bearing license as an alternative to continued reverse payments. Bayer elected to make $349 million in additional payments rather than allowing earlier licensed generic entry. *See supra* pp. 6-7.

D. Reverse Payments Are Not Warranted As a "Natural By-Product" of the Hatch-Waxman Regime.

Drug companies argue that reverse payments must be tolerated as a "natural by-product" of Hatch-Waxman, which purportedly increased the generic's leverage to negotiate a favorable settlement from the brand. *Tamoxifen*, 466 F.3d at 206; *Schering*, 402 F.3d at 1074. The argument has no merit.

Hatch-Waxman does not increase the generic's settlement leverage. Hatch-Waxman grants the

brand the option to confer such leverage on the generic. It allows the brand to sue the generic based on its ANDA without waiting for the generic to introduce its generic product. 21 U.S.C. § 355(j)(5)(B)(iii). The brand benefits from such a suit because it triggers an automatic thirty-month stay of generic entry, but, as a consequence, the generic gets to challenge the brand's patent without entering the market and subjecting itself to the threat of damages.

The brand need not confer this leverage on the generic. Instead, it may wait until the generic enters the market and file a traditional infringement suit. In that case, the generic is subject to ordinary infringement damages and enjoys no increased settlement leverage. *See* 35 U.S.C. § 271(a). As brand manufacturer Merck acknowledged in its pending petition for certiorari, the patentee has no reason to offer a reverse payment in such a traditional infringement suit. Petition of Merck & Co. at 5-6 (Aug. 2012), in *Merck & Co., Inc. v. Louisiana Wholesale Drug Co.*, No. 12-245. Accordingly, any increased generic "leverage" under Hatch-Waxman results entirely from the brand's decision to institute an anticipatory suit.

In any event, any increased leverage conferred by Hatch-Waxman should be a reason to safeguard that leverage against collusion, not to exempt it from antitrust scrutiny. For example, Congress might adopt a statutory scheme to incentivize construction of plants in a new industry in an effort to spur competition and lower prices. If suppliers responded to the resulting competition by colluding to keep prices high, their price-fixing agreement would be unlawful, not excused as a "natural by-product" of Congress' effort to increase price competition. *See* Herbert Hovenkamp,

Anticompetitive Settlement of Intellectual Property Disputes, 87 MINN. L. REV. 1719, 1758-59 (2003); C. Scott Hemphill, *Paying for Delay*, *supra*, 81 N.Y.U. L. REV. at 1577 (that exclusion payments are "not unexpected" under the Act "in no way justifies" them).

Congress could adopt a special antitrust regime that approved reverse payments eliminating pharmaceutical competition, but it has done no such thing. To the contrary, the very point of Hatch-Waxman was to encourage generic competition, in order to benefit consumers. *See* H.R. Rep. No. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48 (Act's purpose is "to make available more low cost generic drugs"). And, the statute confers benefits only on manufacturers that actually enter the market. *See* 21 U.S.C. § 355(j)(5)(B)(iv). "Although it is true that the first to file an ANDA is permitted to delay marketing as long as it likes, the statutory scheme does not envision the first applicant's agreeing with the patent holder of the pioneer drug to delay the start of the 180-day exclusivity period." *Andrx*, 256 F.3d at 809. *See also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1072 (D.C. Cir. 1998) (collusion between brand and generic manufacturers is "at odds with Congress's apparent purposes, in enacting [the Act], of rewarding innovation and bringing generic drugs to market quickly"). It is therefore not surprising that the co-authors of Hatch-Waxman have denounced reverse payments as "appalling," 148 Cong. Rec. S7565-01 (daily ed. July 30, 2002) (remarks of Sen. Hatch), and as "a grossly anticompetitive abuse . . . of the generic drug approval process," 146 Cong. Rec. E1538-02 (daily ed. Sept. 20, 2000) (remarks of Rep. Waxman).

III. The Court Should Not Address Damage Issues in This Case.

As the Solicitor General explains, this case in which the FTC seeks injunctive relief does not raise any issue regarding the methodology for proving damages in a private antitrust suit. Pet. Br. 55 n.11. To the extent reverse payment cases raise questions related to antitrust damages, the Court should leave those issues to be addressed in a case in which they actually arise.

Causation in private damage actions is an intensely factual issue that should not be resolved in the abstract. *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 566 (1931). The issue is whether the antitrust violation is a "material cause" of plaintiffs' injury. *Zenith*, 395 U.S. at 114 n.9. No defendant is entitled to defend on the ground that its own conduct has made it difficult to prove what would have happened but for its wrongful conduct. III HERBERT HOVENKAMP ET AL., ANTITRUST LAW, *supra*, at ¶ 651c (3d ed. 2012).

The precise evidence required to prove damages caused by a reverse payment – *i.e.,* that a generic manufacturer would have entered the market earlier in the absence of a reverse payment – is likely to vary from case to case. Plaintiffs may use basic principles of economics and the expected impact of generic entry (including the companies' own forecasts) to estimate the generic entry date in an alternative no-payment settlement. *See, e.g.*, K-Dur 3d Cir. App. A-3158-64. Alternatively, nothing would prohibit plaintiffs in an appropriate case from offering evidence of the outcome of the patent litigation but for the reverse payment. *Id.* at A-3179. Courts and juries in legal mal-

practice cases regularly consider such evidence when they decide who would have won the underlying litigation absent attorney error. *See, e.g.*, *First Union Nat'l Bank v. Benham*, 423 F.3d 855, 860 (8th Cir. 2005). *See also Tamoxifen*, 466 F.3d at 229 (Pooler, J., dissenting). Or plaintiffs may elect to prove that in the absence of the reverse payment the generic would have entered "at risk" upon the expiration of the thirty-month stay. *See, e.g.*, *Cardizem*, 332 F.3d at 911 (finding antitrust injury because "a trier of fact may well find that the [brand's] $89 million payment *renders incredible* the defendants' claim that [the generic] would have refrained from marketing [during the patent litigation] simply because of its fear of infringement damages") (emphasis added).

There may be other ways to establish causation on the facts of particular cases. These issues are not presented by the FTC's complaint and should be left for further development by the lower federal courts in appropriate cases.

CONCLUSION

The Court should reverse the judgment of the Court of Appeals for the Eleventh Circuit in this case and hold that reverse payments are *prima facie* anti-competitive.

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