No. 12-416

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

—v.—

ACTAVIS, INC., ET AL.,

Respondents.

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

BRIEF OF ANTITRUST ECONOMISTS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF THE *AMICI CURIAE*

Amici curiae are economists who teach at leading colleges and universities throughout the United States and consultants who specialize in the economics of the pharmaceutical industry. (A list of the *amici curiae* is attached as Appendix A.) *Amici* have written extensively in the field of economics, including industrial organization, competition, and antitrust economics and policy. They write to bring to the Court's attention economic analysis relevant to determining the appropriate antitrust standard for evaluating patent dispute settlement agreements in which a pharmaceutical patent owner makes a payment to a potential generic competitor.

Amici believe that the available economic evidence does not adequately support Petitioner's contention that "reverse payment" settlement agreements must be presumptively illegal, and that Petitioner's approach threatens to disrupt a competitive market that serves both consumers' short and long term interests. For these reasons, *amici* believe that this Court should reject Petitioner's request to treat "reverse payment" settlements as presumptively illegal.[1]

SUMMARY OF ARGUMENT

Citing harm to consumer welfare, Petitioner contends that this Court should adopt a standard by which "reverse payment" patent settlements will be

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[1] The parties have consented to the filing of this brief. *Amici* and their counsel have authored the entirety of this brief, and no person or entity has made a monetary contribution to its preparation or submission.

presumptively unlawful, notwithstanding whether the patent holder had a good faith basis to petition a court to protect its presumptively lawful patent exclusivity rights and subsequently entered into an arm's length settlement with the challenger. Economic evidence does not support this Court's adoption of the approach Petitioner proposes.

Ample economic evidence documents that pharmaceutical innovation produces significant consumer benefits. Pharmaceutical innovation provides major improvements in the standard of living, and acts as an important driver of economic growth. The patent system provides economic incentives that reward the high-risk, capital-intensive investments necessary to produce innovations in this market. Through existing regulations, policymakers have addressed the need to encourage and protect innovation and the dynamic efficiencies it produces while simultaneously promoting utilization of generic drugs and the static efficiencies they produce.

For example, the Hatch-Waxman Act reflects Congress's effort to balance incentives for researching and developing new pharmaceutical products with consumers' interest in accessing the existing stock of drugs. It provides additional protections for drug patents, while providing incentives for generic companies to challenge brand patents. Contrary to Petitioner's contention, reverse payments have not altered the balance policymakers sought to achieve. Generic drug utilization—driven in part by challenges to pharmaceutical patents and settlements resolving those challenges—is at a historically high level. Moreover, reverse payment settlements account for only a fraction of all

pharmaceutical patent settlements and typically allow for generic entry many years prior to patent expiration. Reverse payments have not led to an increase in the length of market exclusivity for brand-name drugs, as would be expected if such settlements altered the balance between dynamic and static efficiencies. Thus, Petitioner's suggestion that the Hatch-Waxman Act and current market dynamics are not sufficiently promoting generic utilization does not withstand scrutiny.

Reverse payments in patent settlements can occur for a variety of reasons having nothing to do with payment for delaying entry. For example, reverse payments may be necessary for the parties to reach a settlement in cases where a generic company's high discount rate makes it unwilling to settle with a long wait until entry. They may also be necessary for brand companies to overcome bargaining disadvantages caused by risk aversion. Brand companies are likely to be more risk averse than their generic challengers because they usually have significantly more to lose from a negative trial outcome. In contrast, generic companies are generally not at risk for damages and risk only litigation costs. A settlement with a reverse payment therefore cannot necessarily be replaced with a different settlement enabling earlier generic entry as opposed to continuing litigation.

The data and analysis on which Petitioner relies to show that reverse payment settlements harm consumers do not provide support for a standard of presumptive illegality. Petitioner's failure to identify a defensible definition of "reverse payment" settlements undermines its analysis. For the purposes of its economic analysis, Petitioner defines

a "reverse payment" settlement as any settlement that involves a component other than a negotiated entry date. This definition sweeps in many agreements that do not have any net payment from a patent holder to a generic challenger. Moreover, because settlements that actually involve net payments from the brand to the generic are not economically different from many patent settlements seen outside the pharmaceutical industry, applying a presumptive illegality standard to even this narrower universe of settlements could have far reaching effects well beyond pharmaceutical industry patent cases.

Petitioner's analyses of (1) the percentage of patent cases that generics won, and (2) the exclusion period associated with "reverse payment" patent settlements are inaccurate and misleading. For example, contrary to Petitioner's assumption, the outcome of litigation is not sufficiently predictable that the presence of a reverse payment presumptively demonstrates harm. Neither economists nor litigants possess such predictive powers, and certainly not to a degree that would justify imposing added costs on litigants and shifting the current balance between dynamic and static efficiencies.

Petitioner's economic evidence does not support its contention that this Court's adoption of a standard by which "reverse payment" patent settlements will be presumptively unlawful would benefit consumer welfare. In fact, the economic evidence weighs against the adoption of such a standard.

ARGUMENT

A. Pharmaceutical Innovation Drives Consumer Well-Being

Consumers benefit both from efforts to develop new products—dynamic efficiency—and from improved access to lower priced versions of existing products—static efficiency.[2] Dynamic efficiencies attributable to innovation in health and pharmaceuticals are a major cause of improved standards of living over the last century. *See* Mark A. Lemley, *Industry-Specific Antitrust Policy for Innovation*, 2011 Colum. Bus. L. Rev. 637, 638–39 (2011) [Lemley, *Antitrust Policy for Innovation*] ("Think for a moment about whether static or dynamic efficiency is a more important driver of our economy, and the answer will be obvious. We benefit from market competition between existing products, but we benefit far more from the development of new products.") Economic analysis shows that innovative pharmaceuticals have been responsible for much of the increase in U.S. life expectancy[3] and the reduction in infant mortality over the past decades.[4]

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[2] Static efficiency concerns the optimal use of current resources (*e.g.*, drugs already developed) to maximize short-run welfare, while dynamic efficiency balances static efficiency with incentives to develop new resources (*e.g.*, new drug development) over the long run.

[3] *See* Frank R. Lichtenberg, *Sources of the U.S. Longevity Increase, 1960-2001*, 44 Q. Rev. Econ. & Fin. 369, 369 (2004); Frank R. Lichtenberg, *The Impact of New Drugs on US Longevity and Medical Expenditure, 1990-2003: Evidence from Longitudinal, Disease-Level Data*, 97 Am. Econ. Rev. 438, 442 (May 2007).

[4] Pierre-Yves Crémieux, et al., *Pharmaceutical Spending and Health Outcomes in the United States, in Investing in*

Economic studies of particular drug classes indicate that societal returns to pharmaceutical development are large. For example, a study of HIV/AIDS drugs showed that every dollar spent paying for such drugs benefited society by approximately $19 dollars. Tomas Philipson & Anupam B. Jena, *Who Benefits from New Medical Technologies? Estimates of Consumer and Producer Surpluses for HIV/AIDS Drugs* (Nat'l Bureau Econ. Research, Working Paper No. 11810 at 3–4, 2005) (published in *Forum for Health Economics and Policy: Biomedical Research and the Economy* (2005)). Another study of statins found that the benefits of statin use in terms of reduced hospitalizations and increased life expectancy were four times the costs. *See* David C. Grabowski, et al., *The Large Social Value Resulting From Use Of Statins Warrants Steps To Improve Adherence And Broaden Treatment*, 31 Health Aff. 2276, 2280 (2012).

Pharmaceutical research has also been found to be more effective in delivering benefits to consumers than other medical expenditures. For example, one study's results indicate that, while approximately $9,640 in medical expenditures is required to gain one life-year, only $926 in pharmaceutical research and development is needed to yield the same benefit. Frank Lichtenberg, *Sources of the U.S. Longevity Increase, 1960–2001*, 44 Q. Rev. Econ. & Fin. 369, 369 (2004). Results from another study also show that substituting new drugs for older drugs leads to significant improvements in patient health. Frank

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Health: The Social and Economic Benefits of Health Care Innovation 59, 68 (I. Farquar, K. Summers & A. Sorkin eds., 2001)

R. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS*, 20 Health Aff. 241, 241–245 (Sept./Oct. 2001).

Economic research has found that increased life expectancy and health have produced gains in Americans' well-being as important as those from increases in material abundance. *See* Kevin M. Murphy & Robert H. Topel, *The Value of Health and Longevity*, 114 J. Pol. Econ. 871, 872, 902 (2006); William D. Nordhaus, *Irving Fisher and the Contribution of Improved Longevity to Living Standards*, 64 Am. J. Econ. & Soc. 367, 367–68, 382-90 (Jan. 2005). An economic study found that the increase in life expectancy over the past century has provided a representative American the equivalent of over $1.2 million in value. Murphy & Topel, *The Value of Health and Longevity*, 114 J. Pol. Econ. at 871-72.

The average cost to develop and bring to market a single FDA-approved prescription drug (including the cost of development failures) was estimated at over $1.3 billion in 2007. *See* Joseph A. DiMasi & Henry G. Grabowski, *The Costs of Biopharmaceutical R&D: Is Biotech Different?*, 28 Managerial & Decision Econ. 469, 469 (2007). By contrast, FDA estimates that it costs a generic firm between $300,000 and one million dollars to prepare and submit an abbreviated new drug application ("ANDA"). Requirements for Submission of In Vivo Bioequivalence Data; Proposed Rule, 68 Fed. Reg. 61,640, 61,645 (Oct. 29, 2003). Even *amici* writing in support of Petitioner have recognized these disparities. *See* Lemley, *Antitrust Policy for Innovation*, 2011 Colum. Bus. L. Rev. at 641–43 ("Pharmaceutical innovation is notoriously expensive

and time-consuming. . . . Although imitation of a drug is reasonably costly in absolute terms, a generic manufacturer that can prove bioequivalency can avoid almost all of the R&D cost and can get FDA approval much more quickly than the original manufacturer.").

The economic risks associated with pharmaceutical research and development are widely recognized. FDA ultimately approves for sale as few as one in ten thousand compounds that enter preclinical testing.[5] Patent protection allows brand companies to recoup these high-risk investments and thereby provides incentives to make such large investments. *See* Lemley, *Antitrust Policy for Innovation*, 2011 Colum. Bus. L. Rev. at 643 ("[I]t is likely that innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection. Indeed, a wealth of empirical evidence finds that patents are extremely important to innovation in pharmaceuticals.").

If patent protection were removed or lessened, or if settlement restrictions reduced patent value, decreases in dynamic efficiency (innovation) would likely more than offset the supposed short-term gains from access to generic drugs on which Petitioner focuses. Indeed, one economic study analyzed the effects of eliminating drug patents and found that the reduced flow of new therapies would cause consumer losses three times the short-term gains

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[5] Martin S. Lipsky, & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. Am. Board Fam. Pract. 362, 364 (2001) ("For approximately every 5,000 to 10,000 compounds that enter preclinical testing, only one is approved for marketing.").

from immediate generic competition on all drugs. James W. Hughes, Michael J. Moore & Edward A. Snyder, *Napsterizing Pharmaceuticals: Access, Innovation, and Welfare* (Working Paper at 3, 15–16, Jan. 2011).

Petitioner's analysis of consumer welfare largely ignores the value of innovation and the potential adverse impact Petitioner's presumptive illegality standard would have on the dynamic efficiencies innovation provides to consumers.

B. The Hatch-Waxman Act Carefully Balances Access to Generic Drugs and Innovation

Policymakers recognize that promoting innovation with the potential for a period of exclusivity is inherently at odds with the competing benefits of allowing the largest number of entities to compete in a given market. Congress has addressed this trade-off in the pharmaceutical sector, most notably through the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act").

The Hatch-Waxman Act balances incentives for innovative efforts that result in new pharmaceutical products against enhanced access to existing products through generic drugs.

In economic terms, the Hatch-Waxman Act addresses the tradeoff between dynamic efficiency and static efficiency. As Congressman Henry Waxman stated: "The law that became known as Hatch-Waxman represented a careful balance between access and innovation. Because both are vitally necessary to our nation's health." Henry A. Waxman, Speech: Rep. Waxman Delivered a Speech

to the Generic Pharmaceutical Association (Jan. 28, 2003), *available at* http://waxman.house.gov/speech-rep-waxman-delivered-speech-generic-pharmaceutical-association. The Hatch-Waxman Act (i) reduced the cost of generic entry by relieving generic manufacturers of the burden of proving that their drugs are safe and effective as opposed to biologically equivalent to the related brand pharmaceutical, *see* 21 U.S.C. § 355(j); (ii) effectively granted generic manufacturers royalty-free licenses to use patented drugs to perform bioequivalency testing, *see* 35 U.S.C. § 271(e)(1); and (iii) provided a framework to encourage and facilitate challenges to patents covering brand pharmaceuticals, *see* 21 U.S.C. § 355(b), (j). In addition, as discussed below, the Hatch-Waxman Act allows generic manufacturers to challenge a patent without entering the market and risking damage exposure.

To achieve a socially desirable balance, the Hatch-Waxman Act included measures to lengthen the effective patent life of innovative pharmaceuticals and thereby increase the development of new drugs. For example, the Act extends the life of one patent for each drug by up to five years to take into account some of the patent life lost during the lengthy drug testing and approval process. *See* 35 U.S.C. § 156. The Act also provides an automatic 30-month stay of generic approval when a brand company sues a generic challenger, permitting the patent holder time to enforce its intellectual property rights. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(II). If the patent holder prevails in the patent litigation, the Act provides for an automatic injunction barring approval of the generic challenger. *See* 35 U.S.C. § 271(e)(4)(A) (2000).

Thus, while encouraging generic access, the Act also protects innovation and the companies engaged in high-stakes investments in pharmaceutical research and development.

1. Quantifying the Impact of Hatch-Waxman on Access to Generics

Petitioner's suggestion that the Hatch-Waxman Act and current market dynamics are not sufficiently promoting generic utilization does not withstand scrutiny. Under the Hatch-Waxman regime, use of generic drugs is at an all-time high. The Hatch-Waxman Act has been extremely successful at facilitating generic entry, thereby achieving lower drug prices for consumers. *See* Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation*, 18 Int'l J. Econ. Bus. 177, 177–78, 181–198 (2011).[6] Over time, the share of generics in the marketplace has increased dramatically. *See* Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993, 1993–6 (2007). When Hatch-Waxman was enacted in 1984, generic drugs accounted for 19 percent of all U.S. prescriptions; by 2001 generic usage rose to 47 percent. FTC, *Generic Drug Entry Prior to Patent Expiration* at 3

[6] *See also* Ernst R. Berndt, *Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price*, 16 J. Econ. Persp. No. 4, 45, 62–63 (2002).

(July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. The increase has been more rapid in recent years. As of 2011, generic usage stood at 80 percent, a fourfold increase since Hatch-Waxman was enacted. IMS Institute for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2011* at 26 (Apr. 2012) http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf.

Legislative efforts to increase the incentives for generic companies to challenge brand-name drug patents have contributed to this increase. Unlike other industries, generic manufacturers can develop a generic pharmaceutical and pursue FDA approval without the patent holder having the ability to challenge that conduct as violating its intellectual property rights. *See* 35 U.S.C. § 271(e)(1). The generic company can then challenge the validity of the patent just by applying for FDA approval. Thus, generic challengers do not have to enter the market and expose themselves to damages.[7] *See* 21 U.S.C. § 355(j); Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. Corp. L. 309, 316–17 (2005) [Greene, *A Prescription for Change*]. Generic companies rarely risk exposure to patent damages by attempting to launch products prior to resolving the underlying patent litigation. Further, the first generic challenger (or in some cases

[7] In other industries, many potential patent infringers may never choose to challenge a patent because of the risk of damages.

challengers) may obtain a 180-day period of generic market exclusivity. FDA, *Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day*, http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072851.pdf.

Consistent with Congress's policy objective, in recent years there has been an overall increase in pharmaceutical patent challenges, as well as a sharper increase in challenges soon after initial approval of the brand-name drug. *See, e.g.,* C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. 327, 327–28 (2012); Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 Managerial & Decision Econ. 491, 492, 495-96, 501 (2007) [Grabowski & Kyle, *Generic Competition and Market Exclusivity Periods*]. The low costs and large incentives to challenge patents, combined with the unpredictable and imperfect nature of litigation and the lack of damage exposure, encourage generic firms to challenge patents without regard to the likelihood of prevailing. *See generally* Grabowski & Kyle, *Generic Competition and Market Exclusivity Periods*.[8]

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[8] *See also* Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, CPI Antitrust Chron. (Sept. 2012 (2)); C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents*, 8 J. Empirical Legal Stud. 613, 624, 626 (2011) (showing a rise in the rate of challenges to "new chemical entity," drugs with novel active ingredients); Martin A. Voet, *The Generic Challenge:*

While generic competition lowers drug prices, the prevalence of prescription benefit plans whereby consumers pay a "co-payment" for their prescription drugs diminishes any concerns about underutilization of drugs that do not have generic equivalents. *See* Kaiser Family Foundation, *Prescription Drug Trends* at 5 (May 2010), http://www.kff.org/rxdrugs/upload/3057-08.pdf. The vast majority of consumers can access brand-name drugs for amounts substantially below list prices (generally below $50 per prescription). With the passage of the Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (2010), the percentage of U.S. citizens with prescription drug benefits will increase yet further. *Id.* at 5–6.

2. The Use of Reverse Payments in the Context of the Hatch-Waxman Act

Petitioner contends that "reverse payment" settlements must be treated as presumptively illegal to protect consumers. However, the available economic evidence does not support Petitioner's theory that use of "reverse payments" has altered the balance between dynamic and static efficiencies that policymakers sought to achieve. A large portion of the increase in the availability and use of generic drugs, as demonstrated above, has occurred alongside the use of "reverse payments."

Indeed, the use of reverse payments has not displaced the incentive for multiple generics to submit Paragraph IV challenges, as some *amici* suggest. *See, e.g.,* Br. of Apotex, Inc. as *Amicus Curiae* Supporting Pet'r at p. 7. The amendments to

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Understanding Patents, FDA and Pharmaceutical Life-Cycle Management (2005).

the Hatch-Waxman Act in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 ("MMA"), contain incentives for multiple Paragraph IV challenges by allowing the first-filer exclusivity period to be shared, and providing methods by which subsequent generic challengers may enter the market despite the terms of any settlement between the patent holder and the first-filer. *See e.g., Dey Pharma, LP v. Sunovion Pharms., Inc.*, 677 F.3d 1158, 1160 (Fed. Cir. 2012) (describing use of declaratory judgment by a subsequent filer to accelerate its ability to market a generic pharmaceutical); Greene, *A Prescription for Change*, 30 J. Corp. L. at 349-50. These amendments incentivize multiple and subsequent generics to pursue Paragraph IV patent challenges.

In addition, the profits available to generic challengers who gain the ability to enter the market can be substantial even without the benefit of the 180-day exclusivity period. Contrary to what some *amici* suggest, evidence shows that it is common to have multiple Paragraph IV challenges after the first challenge has been filed. An economic study found that the average number of generic manufacturers filing a Paragraph IV certification within six months of the first filing increased from approximately 1.5 to nearly two in recent years. Ernst R. Berndt, et al., *Do Authorized Generic Drugs Deter Paragraph IV Certifications? Recent Evidence*, (Working Paper at 12–13, Apr. 2007), http://www.analysisgroup.com/uploadedFiles/Publishing/Articles/PhRMA_Authorized_Generic_Entry.pdf. The same study shows that, not surprisingly, high revenue brand drugs are the most likely targets for Paragraph IV certifications from multiple generic manufacturers. *Id.* at 15.

Indeed, it is not uncommon to find six or more generic challengers in Hatch-Waxman patent cases, with new challengers surfacing throughout the litigation.[9] There is no evidence that the use of reverse payments has diminished the average number of generic manufacturers filing Paragraph IV challenges per drug.

Underlying the argument that reverse payment settlements should be presumptively illegal is the

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[9] *See, e.g., Eli Lilly & Co. v. Wockhardt Ltd.*, No. 08-cv-1547 (S.D. Ind.) (docket sheet for Hatch-Waxman litigation involving nine ANDAs for Cymbalta); *Pfizer, Inc. v. Teva Pharms. U.S.A., Inc.*, 882 F. Supp. 2d 643 (D. Del. 2012) (describing eight lawsuits arising from ANDAs for Lyrica); *Avanir Pharm. Inc. v. Actavis South Atl. LLC*, No. 11-cv-704 (D. Del.) (docket sheet for Hatch-Waxman litigation involving five ANDAs for Nuedexta); Bristol-Myers Squibb Co., Annual Report (Form 10-K), at 101 (Feb. 17, 2012) (describing Hatch-Waxman litigation against seven generic companies regarding Abilify); *SmithKline Beecham Corp. v. Geneva Pharm., Inc.*, 2001 WL 1249694, at *2-4 (E.D. Pa. Sept. 26, 2001) (describing Hatch-Waxman litigation against six groups of generic companies regarding Paxil); *In re Gabapentin Patent Litig.*, 214 F.R.D. 178, 180 (D.N.J. 2003) (noting that Warner Lambert "sued seven generic companies" for filing ANDAs for gapabentin (Neurontin)); *In re Rosuvastatin Calcium Patent Litig.*, 2008 WL 5046424, at *1–3, *7 (D. Del. Nov. 24, 2008) (describing eight ANDAs for Crestor); Sanofi, Annual Report (Form 20-F), at 188 (Mar. 6, 2012) (reporting that generic companies filed "over a dozen ANDA certifications" regarding Eloxatin and that "[e]ach of the generic manufacturers was sued for infringement"); *AbbVie Inc. v. Watson Labs. Inc.*, No. 12-cv-324 (D. Del.) (docket sheet for Hatch-Waxman litigation involving five ANDAs for Niaspan); *Pfizer Inc. v. Apotex Inc.*, No. 12-cv-808 (D. Del.) (docket sheet for Hatch-Waxman litigation involving more than ten ANDAs for Pristiq); Shire plc, Annual Report (Form 10-K), at F-40 (Feb. 23, 2012) (describing six ANDAs for Vyvanse); Abbott Labs., Annual Report (Form 10-K), at 16 (Feb. 23, 2007) (describing six lawsuits arising from ANDAs for Depakote).

mistaken premise that they systematically extend the market exclusivity of brand-name drugs. To the contrary, the average effective length of market exclusivity of brand-name pharmaceuticals has remained constant, if not decreased. *See* Grabowski & Kyle, *Generic Competition and Market Exclusivity Periods*, 28 Managerial & Decision Econ. at 491, 495-96, 501; C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents*, 8 J. Empirical Legal Stud. 613, 640–44. The average length of market exclusivity for drugs experiencing first generic entry in 1995 to 1996 was 13.5 years. During this time period, reverse payment settlements were much less common.[10] For drugs experiencing first generic entry in 2007–2008, the period was reduced by just over one year. *See* Henry G. Grabowski, et al., *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act,* 30 Health Affairs 2157, 2157–2166 (2011). Thus, the prevailing equilibrium established by Congress has not been disturbed in recent years. *See* Hemphill & Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. at 327–339.

Similarly, if use of reverse payment settlements guaranteed extended exclusivity, one would expect widespread adoption of such settlements. Yet, reverse payments are still only modestly used as a component of patent settlements. With the increase

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[10] According to an FTC study of branded drugs receiving a Paragraph IV challenge between January 1, 1992 and January 1, 2001, only 9 final settlements contained agreements for the brand-name company to pay the generic applicant. *See* FTC, *Generic Drug Entry Prior to Patent Expiration* (July 2002) at 10, 25.

in patent challenges there has been an accompanying increase in the number of settlements. According to Petitioner, settlements have increased tenfold, from 14 in federal fiscal year ("FY") 2004 to 140 in FY 2012. Yet, according to Petitioner only 26 percent of final settlements have included a potential reverse payment since 2004, and this percentage has not increased over time. 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 A Report by the Bureau of Competition*, [*Agreements Filed with the FTC* (2012)], http://www.ftc.gov/os/2013/01/130117mmareport.pdf. Moreover, as explained in more detail below, even this figure markedly overstates the number of settlements that include a net payment from a brand to a generic. *See infra* at § D.1.

Nor have settlements with a reverse payment component typically sought to extract all possible profits associated with market exclusivity by delaying entry for the full remaining length of the patent. Instead, settlements—including those Petitioner characterizes as containing reverse payments—typically result in a negotiated patent split that often shortens the effective life of the patent by multiple years, as observed in the current case.

In sum, the available economic evidence does not show that the use of reverse payment settlements has undermined the balance between incentivizing innovation and accelerating the entry of lower-priced generics. The adoption of a standard that threatens to degrade the value of patents in the pharmaceutical industry, thereby diluting the incentive for

investment in innovation, should occur only in the face of strong economic evidence of a clear need to protect consumers. Here, instead, there is clearly dangerous potential for such a standard to, itself, significantly harm consumers. Put differently,

> An antitrust policy that reduced prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovation lowers the costs of production would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses.

Frank H. Easterbrook, *Ignorance and Antitrust, in Antitrust, Innovation and Competitiveness* 119, 122-23 (Thomas M. Jorde & David J. Teece eds., 1992).

C. Settlements with Reverse Payments Occur for Reasons Other than Delay and Are Not Presumptively Anticompetitive

Reverse payments in patent settlements can occur for a variety of reasons having nothing to do with payment for delaying entry and therefore should not be treated as presumptively anticompetitive. Real-world complexities such as asymmetric information, differing beliefs regarding the likelihood of prevailing in litigation, differing discount rates, and risk aversion could all lead the parties to negotiate patent settlements that involve reverse payments.

Many of the above complexities result in situations where the parties would be unable to reach a settlement agreement without a reverse payment.[11] For example, efforts to arrive at an

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[11] Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements That Settle Patent Litigation*, Antitrust Bull., 655–698 (Fall 2004); Dickey, et al., *An Economic*

agreement on splitting the remaining patent term may require a generic company to consider entry in the distant future. Indeed, with patent challenges coming earlier in the life of branded drugs, the patent terms at issue can often run more than a decade. Hemphill & Sampat, *When Do Generics Challenge Drug Patents*, 8 J. Empirical Legal. Stud. at 626. A generic company with a high discount rate or uncertainty regarding the future size of the market may be unable to accept a split of the patent term that involves a lengthy wait for the generic to enter as compared to "rolling the dice" on the outcome of litigation. In other words, the generic company may only be willing to accept an entry date that is unacceptable to the brand company, given the brand company's expectations of the likelihood of prevailing in litigation. The parties can use a reverse payment in this situation to bridge the gap and arrive at a settlement where otherwise no settlement would be reached.

Reverse payments can also be used to offset bargaining disadvantages that arise from differences in risk aversion. To avoid a potential loss, a risk averse party is willing to accept unfavorable settlement terms. Brand companies are likely to be more risk averse than their generic challengers because they usually have significantly more to lose from a negative trial outcome. In particular, only a limited number of drugs (sometimes only one)

Assessment of Patent Settlements in the Pharmaceutical Industry, 19 Annals Health L. at 368–400; Gregory K. Leonard & Rika Onishi Mortimer, *Antitrust Implications of Pharmaceutical Patent Litigation Settlements*, *in Economic Approaches to Intellectual Property Policy, Litigation and Management* 251, 261–264 (NERA Econ. Consulting 2005).

account for the bulk of a brand company's revenue. In contrast, generic companies face virtually no risk other than legal costs. They do not risk damages and tend to be highly diversified such that losing any single patent dispute is unlikely to have significant financial consequences.

Petitioner's efforts to rely on the size of a reverse payment to suggest that the payment has an anticompetitive effect are also misplaced because its approach ignores the role of asymmetric risk aversion. Risk aversion is difficult to measure and to convert into a dollar equivalent. Yet, the relevant costs of litigation are not just the pecuniary outlays and the costs of business disruption, but also include the significant costs of the resulting uncertainty to risk averse parties. For this reason, it is difficult, if not impossible, to determine whether the size of the reverse payment is consistent with the presence of risk aversion amidst the other costs of litigation, and consequently whether the negotiated entry date is consistent with the brand company's assessment of the probability of success, even assuming such assessment were possible. As a result, the size of a reverse payment generally does not provide a reliable benchmark to determine whether the payment is anticompetitive.

Because there are many reasons why reverse payment settlements maintain the balance between static and dynamic efficiencies, and enable pro-competitive settlements, such settlements should not be considered presumptively illegal.

D. Petitioner's Data Are Insufficient to Justify Adopting a Presumptive Illegality Standard.

Petitioner acknowledges that there are two possible outcomes if reverse payments are not allowed: (1) Parties reach settlement without reverse payments; or (2) Parties are unable to settle and litigate instead. Petitioner bases its argument for the presumptive illegality standard and its critique of the scope of the patent test on the claim that consumers, on average, would be better off under either outcome. However, Petitioner uses flawed reasoning and unreliable evidence to support its claim.

1. Petitioner's Overly Broad Definition of Reverse Payment Settlements Taints Its Economic Analysis.

Any analysis of the economic consequences of reverse payment settlements requires a reasonable definition of "reverse payments" as a starting point. Yet all of Petitioner's economic analysis turns on an overly broad definition of what constitutes a "reverse payment" settlement.

Essentially, Petitioner treats any form of consideration from the patent holder to a generic challenger as a "reverse payment." For example, a brand company's agreement in a patent settlement not to introduce a generic version of its brand drug to compete against its licensee's generic (while continuing to sell its branded drug) would, in Petitioner's view, qualify as a "reverse payment." Last year, agreements of this kind accounted for almost half of the supposed "reverse payment"

settlements. *Agreements Filed with the FTC* (2012) at 1, http://www.ftc.gov/os/2013/01/130117mmareport.pdf. Yet, this is just a watered-down version of an exclusive licensing arrangement frequently found in license agreements. Petitioner's statistics provide no information about whether the generic paid a royalty to obtain such an exclusive license. If settlements where an agreement not to introduce an authorized generic is the only form of "reverse payment" are excluded, then between 2010 and 2012 only about 13 percent of settlements included a potential reverse payment. *Id.* at 2.

In addition, even settlements that include a financial transfer from a brand to a generic may not truly be "reverse payment" settlements. For example, a settlement of a patent dispute between a brand and a generic that involves some form of a patent split and a contemporaneous business transaction is characterized by Petitioner as a "reverse payment" settlement. [12] The magnitude of the brand company's payment to the generic company in such transactions would have to be evaluated against the value the generic conferred on the brand to determine whether there has been a true "reverse payment."

There is typically significant ambiguity around the value of such agreements because they often include the purchase of intellectual property, real options (through joint ventures), supply agreements,

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[12] *Agreements Filed with the FTC* (2009) at p. 2, http://www.ftc.gov/reports/mmact/MMAreport2009.pdf (noting that almost half of potential reverse payment settlements filed in 2009 involved side deals in which the compensation did not relate directly to the elements of the patent dispute).

risk sharing, and the settlement of other litigation. Determining the value of such one-of-a-kind business agreements can be very difficult. *See Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before House Subcomm. on Commerce, Trade and Consumer Prot.*, 111th Cong. 25 (Mar. 31, 2009) (prepared statement of C. Scott Hemphill, Assoc. Prof. of Law, Columbia Univ., at 47) ("In some cases, the generic firm has plausible expertise in the subject of the side deal. It can be difficult to be certain that a deal is collusive without a deep and complex inquiry into the business judgment of the two drug makers."). This underscores the weakness of Petitioner's argument that the parties to such a transaction will be able to deconstruct a complicated business arrangement to rebut a presumption of illegality.

Further, even Petitioner concedes that payments that are commensurate with the patent holder's expected litigation costs do not indicate an unreasonable delay in generic entry and should not be treated as illegal. Pet'r Br. at 38. However, Petitioner's calculation of the number of reverse payment settlements apparently includes settlements with net payments lower than the brand firm's expected litigation costs. *See*, *e.g.*, *Agreements Filed with the FTC* (2006) at p. 3, http://www.ftc.gov/reports/mmact/MMAreport2006.pdf. Moreover, as explained above, the true costs of litigation include the hard-to-measure costs of the resulting business uncertainty to the risk averse parties, in addition to the outlays for legal fees.

In total, between fiscal years 2004 and 2009, 88 percent of the settlements Petitioner characterized as "reverse payment" settlements were categorized as

such because of contemporaneous business transactions (44 percent), agreements not to launch brand-authorized generics (38 percent), or both (three percent), or a payment that was less than tangible saved litigation expenses (three percent). *See Agreements Filed with the FTC* (2004–2009). If these settlements had not been categorized as reverse payment settlements, only four percent of all settlements over this six year period, eight settlements in total, would have been categorized as reverse payment settlements.

Petitioner's difficulty in establishing a rational definition of reverse payment settlements may stem from the fact that there is no economically sound basis to distinguish these settlements from other patent settlements. Through the Hatch-Waxman Act, Congress has created a form of theoretical infringement on the part of the generic firm without actual entry into the market, and thus without any potential damage exposure on the part of the alleged infringer. This feature of the Hatch-Waxman Act encourages generic challenges but also implies that compensation flowing from the patent holder to the infringer cannot take the form of forgiveness of damages. In contrast, in patent cases where entry has occurred, a settlement by the patent holder often includes reducing all or a portion of its damages claims against the alleged infringer. That is a form of compensation flowing from the patent holder to the alleged infringer and is no different in an economic sense from reverse payments seen in pharmaceutical patent settlements. *See* Marc G. Schildkraut, *Patent-Splitting Settlements and Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1048, 1055-56, 1067 (2003-04). For example, suppose

an incumbent company alleges that its patent was infringed when another company entered the market and claims lost profits of one million dollars. Because the incumbent may not be fully confident that its patent will be found valid and infringed, it may settle by agreeing that if the infringer exits the market for some or all of the remaining life of the patent, it will forgo some or all compensation for its lost profits. In such scenarios, the incumbent is forgoing payment from the infringer, which is economically no different from actually paying the infringer. Indeed, a ruling that reverse payment settlements are presumptively unlawful could result in patent settlements outside of the pharmaceutical industry being subjected to antitrust scrutiny. Such a ruling would thus have far-reaching effects on the ability of litigants to settle patent litigation.

Petitioner's overly broad definition renders its economic analysis of the prevalence and impact of "reverse payment" settlements meaningless. The difficulty in identifying "reverse payment" settlements also highlights an additional problem with Petitioner's approach. Because identifying "reverse payment" settlements requires a complex analysis of contemporaneous business transactions, litigation costs, and risk aversion, the presumptive illegality standard would be difficult to apply and would create substantial uncertainty for parties attempting to settle patent disputes.

2. Petitioner's Calculation of Generic Litigation Victories Is Not a Meaningful Figure

Petitioner also relies on the calculation that, as of June 2002, generic companies had won 73 percent of patent cases that were fully litigated. *See* Pet'r Br.

at 6 (citing FTC, *Generic Drug Entry Prior to Patent Expiration* (July 2002) at 19–20). However, this statistic provides no information about the expected outcome of any specific patent dispute or the proportion of patents in dispute today that would be found invalid or infringed were they to be fully litigated.

The percentage Petitioner relies on cannot serve that purpose for two primary reasons. First, the statistic is based on early patent challenges (fully litigated by June 2002). Early patent challenges focused on products with narrower patents, which likely contributed to the high success rate for generic companies when patents were fully litigated during that period. *See* Hemphill & Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. at 327–28 (describing trends in patent challenges). But that success rate applies only to the pre-2002 period and not to the more recent period when almost every patent is challenged, particularly for drugs with large sales. A more recent study of pharmaceutical patent litigation by RBC Capital Markets analyzed 370 final court decisions during the period from 2000 to 2009 and found that brand firms prevailed in 52 percent of the cases that went to trial. Adam Greene & D. Dewey Steadman, *Pharmaceuticals: Analyzing Litigation Success Rates*, RBC Capital Markets, at 1 (Jan. 15, 2010), http://www.aipla.org/committees/committee_pages/FDA/Committee%20Documents/Meeting%20Materials/2010%20Spring%20Meeting/AnalyzingLitigationSuccessRates.pdf.[13] Any

[13] See also Laura E. Panattoni, *The Effect of Paragraph IV Decisions and Generic Entry before Patent Expiration on Brand Pharmaceutical Firms*, 30 J. Health Econ. 126, 127, 137 (2011)

reliance on studies of outcomes of patent litigation must also account for the high rates of reversal in patent litigation, which Petitioner does not do. *See* Stephen P. Swinton & Adam A. Welland, *Patent Injunction Reform and the Overlooked Problem of 'False Positives'*, 70 Pat., Trademark & Copyright J. 337 (July 2005) (noting the "disturbing" rate of reversals after patent trials).

Second, this statistic provides no information about any net benefit to consumers since an unsuccessful challenge to patents providing ten years of market exclusivity and billions of dollars in sales has a far greater impact on short-term consumer welfare than successful challenges to patents with five years of exclusivity for drugs with relatively modest sales.

3. Petitioner's Calculation of the Costs Associated with Reverse Payment Settlements Is Not a Reliable Measure of Harm to Consumers

Petitioner and other *amici* rely heavily on Petitioner's calculation that, on average, patent settlements with potential reverse payments have an exclusion period 17 months longer than patent settlements without reverse payments, and that reverse payment settlements therefore cost consumers $3.5 billion annually.[14] FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers*

(showing that brand companies won 34 out of 72 challenges between 1988 and 2007, and 24 out of 41 challenges between 2003 and 2007, the last five years of the sample).

[14] *See, e.g.,* Br. for the State of New York *et al.* as *Amici Curiae* at p. 3; Pet'r Br. at 31; Br. for AARP, *et al.*, as *Amici Curiae* at 4–5, 10.

Billions at p. 4 (2010), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. The data Petitioner cites are of questionable validity and the conclusions Petitioner draws from them are unsupported by solid economic evidence.

Petitioner defines the exclusion period as the time between settlement execution and the agreed-upon generic entry date. Petitioner calculates that the sales-weighted exclusion period for settlements with reverse payments is 17 months longer, on average, than for settlements without reverse payments, and claims that this implies that reverse payments cause generic entry to be later than it otherwise would be. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010). In turn, Petitioner's cost estimate is based on multiplying (1) the supposed period of delay by (2) Petitioner's estimate of the reduction in price that exists in a mature generic market by (3) the volume of sales it estimates reverse payment settlements impact each year. Petitioner's inference that patent litigation would result in earlier generic entry but for reverse payment settlements, and that these settlements therefore impose high costs on consumers, is incorrect for a number of reasons.

As an initial matter, the data underlying Petitioner's calculation are not available to anyone other than Petitioner. As a result, it is impossible to audit Petitioner's calculations or to correct the flaws in Petitioner's methodology. In addition, as we explained above, *see* § D.1, an important flaw in Petitioner's estimate of the supposed period of delay is its use of an overly broad definition of potential reverse payments to categorize settlements. We are not aware of any analysis concerning differences in

the exclusion periods that employs a more reasonable definition of settlements with net payments from a brand to a generic challenger. Petitioner's overly broad definition of reverse payments also greatly inflates Petitioner's estimate of the volume of sales affected by reverse payment settlements.

Moreover, even if Petitioner's categorization of settlements were correct, correlation does not prove causation. There may be other reasons why settlements with reverse payments have longer exclusion periods that have nothing to do with payment for delay. For example, reverse payment settlements may differ from other settlements in terms of average patent life remaining, or the point in the drug's life cycle when settlement is reached. *See* Bret Dickey, Jonathan Orszag & Robert Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse Payment" Settlements* at p. 3 (Aug. 10, 2010), http://www.compasslexecon.com/highlights/Documents/Dickey%20Orszag%20Willig%20CBO.pdf. To our knowledge, Petitioner has reported no analysis to rule out alternative explanations. In particular, Petitioner apparently has done no analysis to show that the patent lengths at issue in settlements with and without a reverse payment are comparable.

Other concerns with the study have been raised as well. For instance, the 17-month figure is likely to be overstated because it assumes that the generic company was capable of entering the market by the entry date the parties supposedly would have negotiated absent a reverse payment, which is not necessarily the case. *See* Kyle Musgrove & Richard Ripley, *Reverse Payment Settlements: Presumptively*

Bad or Usually Acceptable, CPI Antitrust Chron. (June 2012 (2)). The appropriate measure would take into account when the generic company could have gone to market, an analysis that requires a determination both of when FDA would have given final approval and the entry date that the parties would have negotiated absent a reverse payment.

The reduction in price is also likely to be overstated because Petitioner does not take into account price discounts such as rebates and free samples that brand companies provide and generic companies generally do not.[15]

Lastly, Petitioner's study provides no reason to believe that a reverse payment settlement would otherwise be a settlement without a reverse payment. Absent use of a reverse payment the parties may not reach settlement at all, and the litigation may continue to trial.[16] *See supra* C. However, Petitioner's study does not consider how generic entry dates under reverse payment

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[15] *See* Henry Grabowski, Tracy Lewis, Rahul Guha, Zoya Ivanova, Maria Salgado & Sally Woodhouse, *Does Generic Entry Always Increase Consumer Welfare?*, 36th Ann. Proc. Fordham Competition L. Inst., Ch. 12 (2010); Dep't Health & Human Servs., Office of the Inspector General, *Concerns with Rebates in the Medicare Part D Program* (March 2011).

[16] Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, Antitrust Bull., 655–698 (Fall 2004); Dickey, et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L., at 368–400; Gregory K. Leonard & Rika Onishi Mortimer, *Antitrust Implications of Pharmaceutical Patent Litigation Settlements*, *in Economic Approaches to Intellectual Property Policy, Litigation and Management* 251, 261–264 (NERA Econ. Consulting 2005).

settlements would compare to generic entry dates under litigation. Petitioner's study also fails to account for the costs associated with increased litigation.

Petitioner assumes that the entry dates agreed to in settlements without reverse payments reflect the likely outcome of litigation and therefore provide a "benchmark for the consumer impact of either alternative."[17] This assumption is unfounded. For a variety of reasons, including risk aversion and the parties having only a vague sense of their likelihood of prevailing in litigation, settlement agreements without reverse payments may not reflect what would occur, on average, were the patent cases to be fully litigated.

Indeed, determining whether a settlement reflects the likely outcome of litigation is, in general, a challenging task. Doing so would require a means of assessing the merits of the underlying patent case from which one could calculate the expected generic entry date based on the probability that the patent would be found valid and infringed if it were fully litigated. For example, if the patent holder has a probability of prevailing in litigation of 75 percent and a probability of failing of 25 percent, then any agreement that leaves the patent holder with more than 75 percent of its remaining patent life would be considered anticompetitive under this standard, whether or not it includes a reverse payment.

The problems with this approach in the real world are both substantial and obvious. Not all the

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[17] FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions at p. 9 (2010).

information relevant to the litigation and trial is available at the time of settlement, thus there is inherent uncertainty regarding the outcome of the trial. Even if all the information were available, it would still not be straightforward to assign probabilities to the possible litigation outcomes. Patent litigation is notoriously unpredictable, with high rates of reversal. These reversals include both false positives (*i.e.*, incorrectly finding patents valid and infringed) and false negatives (*i.e.*, incorrectly finding patents invalid or not infringed) at rates so high that some commentators have referred to it as "disturbing." Stephen P. Swinton & Adam A. Welland, *Patent Injunction Reform and the Overlooked Problem of 'False Positives'*, 70 Pat., Trademark & Copyright J. 337 (July 2005).

Moreover, brand companies must assess more than just the ultimate resolution of a case. Prevailing in the Federal Circuit on appeal does little for a brand company that loses in the district court and is unable to stave off generic entry. In the interim, the brand loses its market exclusivity, and experiences a rapid erosion of market share and a decline in price.

Determining the probability that the brand company will win a patent case is, of course, different from, and much harder than, actually trying the patent case to verdict. Trying the patent case once yields a discrete outcome, which itself could be influenced by specific factors such as the particular fact finder and the effectiveness of counsel, the experts, and other witnesses. The discrete outcome from this litigation would not provide a reliable estimate of the *ex-ante* probability that the patent

would be found valid and infringed.[18] To obtain such an estimate would require the impracticable, trying the case a large number of times. Of course, litigating the patent case is precisely what the parties seek to avoid by settling in the first place.

Thus neither past settlements nor past litigation outcomes can be used to assess reliably when entry is likely to occur under litigation. All that is known is that, through litigation, the generic would win some fraction of cases, with entry generally occurring at the end of a potentially lengthy litigation process, and the brand would win the remainder, with entry delayed until patent expiration. Without knowing which cases would fall into each category, it is problematic to determine whether litigation, on average, benefits consumers. Reaching such an understanding would require assessing the patent holder's likelihood of success in the infringement suit, a task Petitioner states is "inappropriate and cumbersome." Pet'r Br. at 54–55.

Further, to the extent that reverse payments are necessary to achieve settlement, Petitioner's estimate of the costs associated with reverse payment settlements must be offset by the impact of increased litigation. Less litigation through settlements eases the burden on the court system, and can provide economic efficiencies by reducing

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[18] Courts that have rejected Petitioner's presumptive illegality rule have recognized this concern. *See, e.g., Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003) ("Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.").

costs associated with court delay and hasty considerations when cases reach trial.[19] Settlement is also generally less expensive since litigants avoid fees for lawyers and experts, costs associated with the time and effort of firm employees and managers, both of which may be passed on to consumers in the form of higher prices, and the costs to risk averse parties of bearing substantial business uncertainties. *See, e.g.*, Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 368, 375–76 (2010).

Petitioner has thus done nothing to show that eliminating reverse payments would result in lower average costs to consumers. It is just as plausible that increased litigation would lead to average outcomes that increase costs to consumers.[20] Petitioner has thus come forward with inadequate economic evidence to justify adopting a new standard that would presumptively bar reverse payment settlements.

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[19] *See, e.g.*, William M. Landes, *An Economic Analysis of the Courts*, 14 J.L. & Econ. 61, 74 (Apr. 1971) ("It is widely recognized that the courts are burdened with a larger volume of cases than they can efficiently handle. The results are often long delays prior to trial, and hasty consideration when cases reach trial." citing U.S. Pres. Comm'n on Law Enforcement and Admin. of Justice, Task Force on the Admin. of Justice, Task Force Report: The Courts, at 38–40 (1967)).

[20] Petitioner's calculation also fails to consider any corresponding impact on innovation, if the Court were to adopt a standard that undermined the value of patents in encouraging pharmaceutical research and development.

CONCLUSION

The available economic evidence does not support Petitioner's effort to impose a standard of presumptive illegality on certain forms of patent settlements. At present:

- Most patented drugs are challenged.
- Most settlements assure generic entry before patent expiration.
- Generics account for a huge and increasing percentage of prescription drug volumes.
- Market exclusivity periods have not increased.

For these reasons, the standard Petitioner advances should not be adopted by this Court.

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APPENDIX A
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