No. 12-416

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

ACTAVIS, INC., ET AL.

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

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA) AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

JAMES M. SPEARS
MELISSA B. KIMMEL
PHRMA
950 F Street, NW
Suite 300
Washington, DC 20004

ELIZABETH N. DEWAR
ROPES & GRAY LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199

DOUGLAS HALLWARD-DRIEMEIER
Counsel of Record
MARK S. POPOFSKY
ROPES & GRAY LLP
One Metro Center
700 12th Street, NW; Suite 900
Washington, DC 20005
(202) 508-4600
Douglas.Hallward-Driemeier@ropesgray.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases:

Cases—Continued:

Cases—Continued:

Cases—Continued:

Constitution and Statutes:

Miscellaneous:

Miscellaneous—Continued:

Miscellaneous—Continued:

Miscellaneous—Continued:

INTEREST OF AMICUS[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's mission is to advocate in support of public policies that encourage the discovery of life-saving and life-enhancing new medicines. During 2011 alone, PhRMA members invested an estimated $49.5 billion in discovering and developing new medicines, and they have invested more than $500 billion since 2000.[2] PhRMA closely monitors pertinent legal issues and has frequently participated in cases before this Court.

The question presented in this case—whether innovator companies can lawfully settle Hatch-Waxman patent litigation on terms that do not affect competition beyond the exclusionary scope of the patent and that also include some form of consideration flowing to the alleged infringer—is of critical importance to the

---

[1] The Federal Trade Commission (FTC) has consented to the filing of amicus curiae briefs in support of either party or of neither party, in a letter on file with the Clerk. Counsel for each of the respondents consented to the filing of this brief pursuant to Rule 37.3(a). No counsel for any party authored this brief in whole or in part, and no person or entity, other than amici curiae or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. A list of PhRMA's member companies resides at www.phrma.org/about/member-companies (last visited Feb. 27, 2013). PhRMA's members include AbbVie, Inc., which is the parent company of respondent Solvay. AbbVie neither participated in PhRMA's preparation of the brief, nor made a monetary contribution intended to fund the brief's preparation.

[2] See PhRMA, *Pharmaceutical Industry 2012 Profile* 28 fig. 10 (2012), http://www.phrma.org/sites/default/files/159/phrma_industry_profile.pdf (last visited Feb. 27, 2013).

pharmaceutical industry. In order to continue the extraordinary investments in research and development necessary to offer new life-saving and life-enhancing treatments, innovators must have the option of reasonably settling the proliferation of Hatch-Waxman litigation that almost inevitably follows introduction of a new pharmaceutical.

SUMMARY OF THE ARGUMENT

The stakes at issue for innovator companies in Hatch-Waxman Act patent litigation are immense. The cost of developing and obtaining the FDA's approval of a new medicine can total well over a billion dollars. Patent protection is essential to encouraging and potentially recouping that investment as well as funding future research into new medicines. The cycle of successful medicines funding the next generation of breakthroughs is a quintessential example of the Framers' idea that patents should "promote the Progress of Science and useful Arts." U.S. Const. art. I, § 8. Yet patent litigation is notoriously unpredictable, and the innovator faces a rapid loss of sales within a few months of generic entry into the marketplace. Under these circumstances, an innovator could reasonably prefer to achieve certainty through compromise rather than litigate to final judgment, even if it firmly believes that the patent at issue is valid and infringed by generic applicants.

Flexibility in resolving Hatch-Waxman litigation becomes even more important when one considers that the structure of the Act puts patents at risk while minimizing risk to the generic challengers. The Act creates a framework for the litigation of patent disputes under which litigation begins prior to generic entry. Thus, unlike the typical (non-Hatch-Waxman) patent litiga-

tion, alleged infringers can force innovators to defend their patents without incurring any exposure to actual damages from marketing the potentially infringing product. Those suits create uncertainty, which both the innovator and generic challenger have an interest in managing.

The asymmetric character of the risks naturally affects the parties' negotiations. Because the generic typically has no damages liability to forgive, that common form of consideration to an infringer in non-Hatch-Waxman patent litigation is usually unavailable. Instead, Hatch-Waxman settlements can result in some other form of consideration flowing from the innovator company to the generic, often in addition to the generic being licensed to enter the market and practice the patent commercially before the expiration of its remaining term.

These settlements benefit patients and the public. By protecting the innovator company's investment and funding source for new research, they ensure the continued research and development of new treatments against our most grievous and deadly diseases. In addition, by allowing generic entry prior to the end of the patent terms, these settlements speed the introduction of lower-cost medicines into the market. And they conserve scarce financial and managerial resources that would otherwise be spent on litigation.

Under well-established principles of antitrust and patent law, such settlements are permissible. Indeed, the law strongly favors resolution of litigation through compromise, given the public and private costs of litigation. Until recently, faced with antitrust challenges to such settlements, the courts of appeals united in concluding that the correct expression of the rule of

reason in the case of a Hatch-Waxman settlement is to permit settlements of bona fide, non-sham, non-fraudulent patent litigation if the exclusionary scope of the settlement is no greater than the patent's own reach—*i.e.*, the settlement does not exceed the scope of the patent. This "scope of the patent" test accords with the presumption of validity afforded patents and with the fundamental principle of antitrust law that the challenger must prove, rather than assume, that an alleged restraint eliminates actual or potential competition. The test is readily administrable, reducing the costs of enforcement and potential for erroneously condemning procompetitive settlements.

Blind to the benefits of such settlements, the FTC seeks to impose a rule of presumptive illegality. Such a rule would eviscerate the presumption of patent validity—perversely assuming that a patent must be weak simply because an innovator chose to settle—and relieve the antitrust plaintiff of its burden to demonstrate an impairment of actual or potential competition. It also lacks any foundation in this Court's precedent. The Court applies "quick look" analysis only when the irredeemably anticompetitive nature of a restraint is plain. Such is not the case here, where settlements with consideration flowing to generics foster procompetitive benefits, and the supposed anticompetitive effects rest upon the indefensible assumption that generic challengers in patent infringement litigation will win. The FTC, moreover, proposes an unworkable doctrine: an invitation to post-settlement antitrust litigation as protracted and burdensome as the patent litigation sought to be settled. It would deprive innovator companies of an important tool to manage risk and, instead, force them to fight to judgment. The end

result would not further competition, but instead harm patients by hindering development of new and innovative medicines.

ARGUMENT

I. HATCH-WAXMAN SETTLEMENTS, INCLUDING WHERE CONSIDERATION FLOWS TO THE INFRINGER, PRESERVE THE PATENT LAW'S PROCOMPETITIVE INCENTIVES TO INNOVATE

Hatch-Waxman litigation puts at risk the billion-dollar-plus investment that an innovator company has made in bringing a new medicine to market, as well as the company's ability to fund new technological breakthroughs. As in other contexts, settlements enable the patent holders to manage litigation risk. Such settlements, including where consideration flows to the alleged infringer, foster innovation by producing certainty, conserving resources, and *accelerating* generic entry earlier than the patent's expiration.

Contrary to the FTC's contention that such settlements "depart from usual settlement practices," Pet. Br. 16, and thus are a tell-tale sign of some conspiracy against the public interest, they in fact reflect the ordinary give-and-take inherent in a settlement process. To the extent such settlements differ from settlements in ordinary infringement litigation, those differences reflect the special features of the Hatch-Waxman Act, which establishes a framework in which patent litigation takes place before the alleged infringer has incurred any actual damages. To reach a reasonable settlement, innovators at times must compensate generic challengers for *not* infringing during some or all of the remaining life of the disputed patent. The law favors settlement over litigation, and such Hatch-

Waxman settlements are equally entitled to the benefit of that rule.

A. Hatch-Waxman Settlements Foster Innovation By Allowing Innovators To Maintain The Considerable Investment Needed To Develop Medicines

Hatch-Waxman settlements foster innovation and benefit consumers by mitigating the uncertainty and risk of error associated with patent litigation, vagaries that pose a direct threat to PhRMA member companies' ability to continue making tremendous investments in researching new and better treatments.

Innovator pharmaceutical companies invest, on average, more than a billion dollars for each FDA-approved medicine. Such investment inherently involves a high degree of uncertainty. As even the FTC has acknowledged, for every 5,000 to 10,000 compounds screened in pre-clinical testing, only five reach clinical testing, and only one receives FDA approval. FTC Bureau of Economics, *The Pharmaceutical Industry: A Discussion of Competitive & Antitrust Issues in an Environment of Change* 178 (March 1999) (FTC 1999 Report) http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf (last visited Feb. 27, 2013). The research and development of a new medicine takes an average of 10 to 15 years. PhRMA, *Drug Discovery and Development: Understanding the R&D Process* 1 (2007), http://www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf (last visited Feb. 27, 2013). The estimated cost to develop a pharmaceutical treatment (including the cost of failures) in 2005 was $1.2 billion. J.A. DiMasi & H.G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 Managerial & Decision Econ. 469, 475-476

(2007); J.A. DiMasi *et al.*, *The Price of Innovation, New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 181-182 (2003). Only two of ten marketed medicines return revenues that match or exceed the average costs of research and development. *Id.* at 16 (citing J.A. Vernon *et al.*, *Drug Development Costs When Financial Risk is Measured Using the Fama-French Three-Factor Model*, 19 Health Econ. Letters 1002-1010 (2010)).

Successful patented products accordingly are vital to innovator companies' financial future and their ability to develop the next generation of life-saving medications. Precisely as the Constitution's Framers envisioned, patents allow innovators to reinvest the revenue streams generated by present inventions into further research endeavors. See U.S. Const. art. I, § 8. Innovator companies are able to undertake costly research with uncertain payoff only because patent protection offers the prospect of recovering that investment during the period of patent exclusivity. "[E]mpirical research indicates that new product development in the pharmaceutical industry is more dependent on patent protection than in many other industries." FTC 1999 Report 180. One study found that 60 percent of inventions within the pharmaceutical industry would not have been developed in the absence of patent protection. *Ibid.* (citing Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 Mgmt. Sci. 173 (1986)); see also Richard C. Levin *et al.*, *Appropriating the Returns from Industrial Research & Development*, 3 Brookings Papers on Econ. Activity 783, 796 (1987) (multi-industry survey finding, *inter alia*, the pharmaceutical industry to be the only one in which product patents were viewed as the

most effective means of obtaining a return on research and development).

Not surprisingly, novel innovations that are successful in the marketplace also attract challenges from would-be generic competitors, and PhRMA's members must manage the enormous risks associated with such litigation. It is precisely when an innovative pharmaceutical is successful that generic firms are most incentivized to challenge the patent—regardless of its perceived strength. See H.G. Grabowski *et al.*, *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 Health Affairs 2157, 2161 (2011) (noting higher probability of Paragraph IV challenge for new drugs with sales greater than $100 million, "increasing from 17 percent in 1995 to 75 percent in 2008"). Indeed, the FTC's own calculations suggest that, based on the large potential upside and negligible downside for a would-be generic challenger, "a rational [g]eneric company would challenge patents on drugs accounting for 90 percent of pharmaceutical sales if it had a likelihood of success *in the low to mid-single digits*." 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 Chronicle 6 (2012) (emphasis added), https://www.competitionpolicyinternational.com/file/view/6746 (last visited Feb. 27, 2013).

The Hatch-Waxman Act facilitates such patent challenges by establishing a framework under which the innovator's patent's validity and generic's infringement can be litigated without the generic launching a competing product and incurring any significant damages liability. See Pet. Br. 4-6. Such litigation

poses grave risks to innovator companies. Studies have shown that "pharmaceutical companies experienced sharp drops in market value after key patents were held noninfringed or invalid." James Bessen & Michael J. Meurer, *Lessons for Patent Policy from Empirical Research on Patent Litigation*, 9 Lewis & Clark L. Rev. 1, 10 (2005) (citing example of innovator company that "lost nearly 30% of its stock market value" after losing patent challenge).[3]

PhRMA's members accordingly must manage the considerable litigation risk that such suits pose to the revenue stream that rewards past investment and allows reinvestment in further medical advancements. As the court of appeals recognized, patent litigation is an "infamously costly and notoriously unpredictable process." Pet. App. 3a. Regardless of an innovator's own confidence in the strength of a patent, "[n]o one can be *certain* that he will prevail in a patent suit." *Asahi Glass Co.* v. *Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J.). The risk that the factfinder may not understand the technical complexities of modern patents is inherent in any patent

---

[3] The importance of patent protection in the pharmaceutical industry is also reflected in the fact that innovators' rewards diminish much more quickly upon patent expiration than in other industries. See Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context & Fidelity to First Principles*, 15 Fed. Cir. Bar J. 617, 624-625 (2006). When a generic version of a medicine first becomes available, it can capture more than 90% of the sales within the very first month. See PhRMA, *Chart Pack: Biopharmaceuticals in Perspective* 41 (2010), http://catalyst.phrma.org/wp-content/uploads/fromPhrma/phrma_chart_pack.pdf (last visited Feb. 27, 2013) (citing Medco Health Solutions, *2009 Drug Trend Report* (2009)).

litigation. And even the district court's own rulings are an uncertain guide to the litigation's ultimate outcome. By one account, "nearly 40 percent of claims constructions are changed or overturned by the Federal Circuit." *TM Patents, L.P.* v. *IBM Corp.*, 72 F. Supp. 2d 370, 378 (S.D.N.Y. 1999). Indeed, Hatch-Waxman litigation can raise questions that even members of the Federal Circuit find difficult to resolve. In *Purdue Pharma L.P.* v. *Endo Pharm. Inc.*, for example, a panel of Federal Circuit judges initially affirmed a ruling in favor of the generic challenger, only to reverse itself on reconsideration eight months later. See 438 F.3d 1123, 1125-1126 (2006).

Faced with such litigation uncertainty, many pharmaceutical innovators quite reasonably choose to settle challenges to their patents, just as patent holders do in the vast majority of cases. Indeed, across all patent cases, 95% are resolved by settlement. Marc G. Schildkraut, *Patent-Splitting Settlements & the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1048 (2004). This high rate of settlement reflects in part the recognition that patentees are likely to suffer irreparable harm if, for example, a generic launches after a favorable district court decision, but the patent is ultimately upheld and found infringed on appeal. Under those circumstances, the brand would never recover its previous position, and a damages award against the generic will not make the innovator whole. For innovators, the prospect of being forced to subject all of their most successful patents to the vagaries of litigation would chill the massive investments they make in developing and marketing life-saving medications.

The ability to settle Hatch-Waxman litigation is thus essential to preserving the incentives to innovate.

Consideration flowing to the generic company, in turn, may be necessary at times to make settlement possible. As in other settlement contexts, parties may have different expectations of the outcome of the suit. Both the innovator and generic may predict victory. A payment to the alleged infringer may be needed to help bridge the gap separating the parties' assessment of the case's merits—and, in the long run, may preserve the incentive to invest in innovation crucial to securing consumer welfare. Or the parties may simply have asymmetric risk profiles. See Schildkraut, *supra*, at 1034 (describing some of the "many circumstances where a reverse payment is necessary to resolve a patent litigation and that resolution is better for consumers than continued litigation"); Bernard & Tom, 15 Fed. Cir. B.J. at 629-631 (further describing these scenarios).

The adverse consequences of deterring innovation by effectively banning these settlements would be severe. Benefits from innovation are far more valuable to consumers than static price competition. See Mark A. Lemley, *A New Balance Between IP & Antitrust*, 13 Sw. J. Law & Trade Am. 237, 248 (2007). To take just one very specific example, since 1980, life expectancy for cancer patients has increased by about 3 years, with 83% of the gains attributable to new treatments, including medicines. E. Sun, *et al.*, *The Determinants of Recent Gains in Cancer Survival: An Analysis of the Surveillance, Epidemiology and End Results (SEER) Database*, 26 J. of Clinical Oncology suppl. 15 (2008). More generally, a National Bureau of Economic Research working paper found that 40% of the increase in longevity from 1986-2000 was due to the launch of new medicines. Frank R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence from Longitu-*

dinal, Disease-Level Data from 52 Countries, 1982-2001, NBER Working Paper No. 9754 (2003), http://www.nber.org/papers/w9754 (last visited Feb. 27, 2013).

Furthermore, contrary to the suggestion of petitioner's amici, see Br. of Public Patent Found. 9-13, multiple generic challengers often attack patents covering the core active ingredient in innovators' medicines—not just the so-called "secondary" patents on improvements to existing medicines denigrated by amici. Very recently, among scores of other such examples, the Federal Circuit upheld the patent for the active ingredient in Crestor against challenges by eight generic pharmaceutical companies. See *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511 (Fed. Cir. 2012); see also, *e.g.*, *Sanofi-Aventis* v. *Apotex Inc.*, 659 F.3d 1171 (Fed. Cir. 2011) (upholding patent for active ingredient in Plavix); *AstraZeneca Pharm. LP* v. *Teva Pharm. USA, Inc.*, 583 F.3d 766 (Fed. Cir. 2009) (upholding patent for active ingredient in Seroquel against challenges by two generic companies); *Pfizer, Inc.* v. *Teva Pharm. USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008) (upholding patent for active ingredient in Celebrex); *Pfizer, Inc.* v. *Teva Pharm. USA, Inc.*, 882 F. Supp. 2d 643 (D. Del. 2012) (upholding patent for active ingredient in Lyrica against challenge by eight generic pharmaceutical companies); *Schering Corp.* v. *Mylan Pharm., Inc.*, No. 09-6383, 2012 WL 1473329 (D.N.J. Apr. 27, 2012) (slip copy) (upholding patent for active ingredient in Zetia and Vytorin); *Pfizer Inc.* v. *Teva Pharm. USA, Inc.*, 803 F. Supp. 2d 409 (E.D. Va. 2011) (upholding patent for active ingredient in Viagra).

In any event, amici's denigration of so-called "secondary" patents is wholly unwarranted, since innovations covered by improvement patents—such as new formulations—also yield significant benefits to consumers. See Int'l Fed'n of Pharm. Mfrs. & Ass'ns (IFPMA), *Incremental Innovation: Adapting to Patient Needs* 8-14 (2013), http://www.ifpma.org/resources/publications.html (last visited Feb. 27, 2013). These innovations benefit consumers by, for example, improving the efficacy of a medicine; eliminating the need for administration by a highly skilled medical professional; reducing or eliminating side effects that deprive some patients of a medicine's benefit; and reducing the required frequency of administration. See, *e.g.*, *id.* at 10-14, 19-22 (describing examples). Such improvements can, in turn, increase patient compliance, thereby preventing treatment failure. *Id.* at 12-13 (discussing, *e.g.*, improved anti-malaria formulation that reduced dosing regimen from 8 tablets per day to 2). If a particular "secondary" patent is said to lack value, the market provides a ready cure, since patents on improvements do not prevent the advent of generic versions of the original product. *Id.* at 17. The market will then decide if the improved product is worth a premium over cheaper generic versions of the original.

B. Settlements With Consideration Flowing To Alleged Infringers Can Accelerate Generic Entry

In addition to preserving the incentive to innovate, Hatch-Waxman settlements, including those with consideration flowing to the alleged infringer, also benefit patients and payers by facilitating entry of generic competitors prior to the expiration of innovators'

patents. This very case provides such an example: Respondent Solvay agreed to allow the respondent generic manufacturers to enter in 2015, five years before the disputed patent for Androgel expires. See Pet. App. 10a, 12a. Patients and payers will thus benefit from five years of generic price competition more than if Solvay had prevailed in invoking its patent to exclude such competition until 2020. Similarly, in the agreements at issue in *Merck & Co.* v. *Louisiana Wholesale Drug Co.* (No. 12-245) (petition pending), the innovator settled on terms that resulted in generic entry five years earlier than the patent's expiration.

There is no basis for the FTC's contention that, but for these settlements, generic entry usually (or even often) would occur earlier. Pet. Br. 28-30. As noted, in some circumstances a settlement that includes some form of consideration flowing to the generic company may be needed to make settlement possible. See p. 11, *supra*. Including consideration to the generic "may allow the brand-name and generic manufacturers to bridge the settlement gap" between them. Bret Dickey *et al.*, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 367, 394 (2010). If compromise on such terms is forbidden, more cases will be litigated to conclusion. When the innovator prevails, it will be able to prevent generic entry until the patent's expiration.

The suggestion by the FTC and its amici that, in the absence of settlement, such patent litigations would more likely than not terminate in the generic firms' favor is baseless. The FTC and amici rest their entire argument on a 73% figure that is deeply flawed. See Pet. Br. 6 (citing FTC, *Generic Drug Entry Prior to Patent Expiration* 16 (2002) (FTC 2002 Report),

http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (last visited Feb. 27, 2013) (claiming a generic success rate of 73%)). The 73% figure is more than a decade old and out of date. More recent data regarding cases litigated to decision indicates that generic challengers prevail less than half the time. See Adam Green & D. Dewey Steadman, *Analyzing Litigation Success Rates*, RBC Capital Markets 4 (Jan. 15, 2010), http://amlawdaily.typepad.com/pharmareport.pdf (last visited Feb. 27, 2013) (finding only 48% generic success rate from 2000-2009 in 171 cases litigated to decision).

Moreover, subsequent developments revealed that the cases the FTC surveyed (from 1992-2000) were skewed based on the very high proportion of cases that settled. A study from immediately after that period reported that, "after FTC and private antitrust actions began to discourage settlement," there was a "significant jump in the number of cases won by innovator companies." Bernard & Tom, 15 Fed. Cir. B.J. at 627-628. In other words, by discouraging settlements, the FTC succeeded in pushing more innovators to litigate cases, which they won, enabling them to prevent generic entry until patent expiration.[4]

Tellingly, many Hatch-Waxman settlements, including settlements that involved payments to the alleged infringer and permitted generic entry prior to the

---

[4] Even on its own terms, the FTC's 73% figure is dubious. As of the time of the FTC's report, the generic had prevailed in a final decision with respect to only 22 of 75 products. FTC 2002 Report 10, 14 16. To reach the 73% figure, the FTC disregarded all cases still pending at the time of the survey, all cases that had settled (no matter the settlement's terms), and instances in which the same patent was vindicated multiple times. See *id.* at 16-19.

patent's expiration, have been followed by subsequent patentee victories with respect to the very same patent. In these situations, settlement undoubtedly accelerated generic competition. In the *Ciprofloxacin* case, for example, "despite payments from a patentee to an infringer of more than $400 million, 'the patent was subsequently approved * * * on reexamination and unsuccessfully challenged in court three times.' " Bernard & Tom, 15 Fed. Cir. B.J. at 627 (quoting *Valley Drug Co.* v. *Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003) (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003))). Litigation over Plavix illustrates the same point: the innovator offered to settle the case, including allowing the generic to enter early and offering consideration in the form of an agreement not to issue an authorized generic; the FTC refused to approve the settlement (pursuant to a court order entered in a different case); and the innovator ultimately prevailed on its infringement claim, obtaining damages for the period during which the generic had launched at risk. See *Sanofi-Aventis*, 659 F.3d at 1174-1177; see also, *e.g.*, *Pozen, Inc.* v. *Par Pharmaceutical, Inc.*, 696 F.3d 1151 (Fed. Cir. 2012) (upholding multiple patents covering Treximet against challenge by three generic companies, after Pozen had settled with fourth); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193, 195, 204 (2d Cir. 2006) (as amended) (rejecting antitrust challenge to settlement, where patent had subsequently been upheld against three generic challenges), cert. denied, 551 U.S. 1144 (2007). The alternative to settlement on terms involving consideration to the alleged infringer will often be litigation to a judgment favorable to the patentee, thus preventing early generic entry before the patent expires. It is perverse to deter set-

tlements that enable a generic competitor to bring its product to market years before it could if the patent were fully enforced.

C. The Flow of Consideration To Alleged Infringers Is A Natural And Appropriate Result Of The Statutory Scheme

Contrary to the FTC's contention, see Pet. Br. 16, consideration flowing to the alleged infringer is not a sign of an anticompetitive scheme. Such terms are "a natural by-product of the Hatch-Waxman process" designed by Congress. *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006).

In a run-of-the-mill settlement, consideration flows from the plaintiff-innovator to the alleged infringer when, as part of the parties' bargain, the plaintiff-innovator forgoes collecting a portion of the alleged damages. See *Ciprofloxacin*, 261 F. Supp. 2d at 252 (recognizing that "even in the traditional context," "[i]n reality, what has occurred is the alleged infringer is permitted to keep a portion of the profits from its sales"). Because Hatch-Waxman litigation, by Congress's design, commences at the time the Paragraph IV certification is filed (and deemed an act of infringement) but before any damages would be incurred, the usual form of consideration from the patentee to the infringer—declining to collect a portion of the damages—does not yet exist. See Pet. Br. 4-6 (discussing statutory scheme). This structure creates an asymmetry: while the "statutory scheme could then cost [the innovator] its patent," *Schering-Plough*, 402 F.3d at 1074, the would-be generic competitor, faces only "exposure to liability amount[ing] to litigation

costs," *ibid.*, and a delay in the ability to recoup its relatively modest investment in submitting an ANDA.

In this context, a payment (or other compensation) to an alleged generic infringer may at times provide the only reasonable terms on which a settlement can be achieved. See p. 11, *supra*. "Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement." *Valley Drug Co.* v. *Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003), cert. denied, 543 U.S. 939 (2004); see p. 8, *supra*. It is not surprising, then, that Hatch-Waxman settlements often contain such terms. See FTC Bureau of Compet., *Agreements Filed with the FTC Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003* 2 (2012), http://www.ftc.gov/os/2013/01/130117mmareport.pdf (last visited Feb. 27, 2013) (among all Hatch-Waxman settlements from 2004-2012, according to the FTC, 165 settlements—approximately one quarter—involved compensation flowing to the generic manufacturer).

From the innovator's perspective, providing consideration to the generic company serves the same purpose as agreeing to forgo a portion of the alleged damages in other settlement contexts: to reach a compromise, including conceding some ground to the alleged infringer (including, at times, providing terms that could not be obtained as relief in the litigation), rather than bearing the many burdens and risks entailed in litigating the dispute to its end. See *Asahi Glass*, 289 F. Supp. 2d at 993. For similar reasons, patent settlements outside of the Hatch-Waxman context also often contain consideration flowing to the alleged infringer in the form of a license pertaining to an unasserted pa-

tent, such as one related to the patent-in-suit. Such consideration, though beyond what the infringer could win at trial, may be necessary in the process of getting a deal done. Indeed, "a*ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." *Id.* at 994. And, just as with other settlements, a settlement in this context that involves consideration flowing to the alleged infringer benefits not only the parties, but also consumers and society.

D. Hatch-Waxman Settlements Conserve Resources

Finally, as do all settlements, Hatch-Waxman settlements in which consideration flows to the generic company reduce the many direct and indirect costs of litigation that innovators, generic manufacturers, and consumers bear. Such costs include the non-negligible time spent by firm employees "preparing the case, producing documents, working with lawyers on litigation strategy, being deposed, traveling for lawsuit-related events, testifying at trial, and observing legal proceedings." Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 Minn. L. Rev. 698, 703-704 (2004). Discovery also imposes risks, including loss of control of sensitive competitive information and harm to business relationships. *Id.* at 704.

And on-going litigation may sap an innovator's resources in more subtle ways. For example, "[t]he length of patent litigation may * * * mak[e] marketing, research and development, and other business planning difficult while the outcome of the case remains uncer-

tain." Crane, 88 Minn. L. Rev. 704; see also *Schering-Plough*, 402 F.3d at 1075-1076 (recognizing that "[p]atent litigation breeds a litany of direct and indirect costs"). And, of course, litigation entails social costs in the expenditure of judicial resources overseeing litigation that can take up to a decade, through trial and eventual appeal. See *ibid.* (noting the "public problems associated with overcrowded court dockets").

Because of the considerable savings gained by settlement, the law strongly favors resolution of litigation through compromise. See, *e.g.*, *McDermott, Inc.* v. *AmClyde*, 511 U.S. 202, 215 (1994). These considerations apply with equal force to, and provide yet an additional procompetitive rationale for, Hatch-Waxman settlements.

II. CORRECT APPLICATION OF THE RULE OF REASON THROUGH THE "SCOPE OF THE PATENT" TEST SECURES THESE BENEFITS

A. The "Scope Of The Patent" Test Is The Correct Expression Of The Rule Of Reason In Evaluating Patent Settlements

The "scope of the patent" test employed by the majority of circuits, see *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) (describing consensus of Second, Eleventh, and Federal Circuits), cert. denied, 557 U.S. 920 (2009), appropriately secures the above-described benefits to consumers. "[T]his Court presumptively applies rule of reason analysis, under which antitrust plaintiffs must demonstrate that a particular contract or combination is in fact unreasonable and anticompetitive before it will be found unlawful." *Texaco Inc.* v. *Dagher*, 547 U.S. 1, 5 (2006); see also *Leegin Creative Leather Prods.* v. *PSKS, Inc.*, 551 U.S. 877, 885-886 (2007),

cert. denied, 131 S. Ct. 1476 (2011). The inquiry under the rule of reason must be appropriate for the type of restraint at issue. *Cal. Dental Ass'n* v. *FTC*, 526 U.S. 756, 781 (1999) (inquiry must be "meet for the case, looking to the circumstances, details, and logic of a restraint"). Accordingly, antitrust courts have long recognized that the correct expression of the rule of reason can consist of a conduct-specific rule applicable to a particular type of conduct. See, *e.g.*, *Brooke Grp. Ltd.* v. *Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 222-224 (1993) (setting rules for low pricing under Section 2).

Here, as explained below, the correct expression of the rule of reason in the context of Hatch-Waxman settlements is the "scope of the patent" test—a test the FTC incorrectly characterizes as a rule that such settlements are "per se lawful." See Pet. Br. I (question presented).

1. The FTC mischaracterizes the "scope of the patent" test

As an initial matter, the "scope of the patent" test does not, as the FTC claims, see Pet. Br. I, render all settlements *per se* lawful. As the FTC itself acknowledges, the scope of the patent test does not protect settlements where the patent was itself obtained by fraud, or where the patent litigation was a sham. *Ibid*; Pet. App. 28a. As developed and applied by the courts of appeals, the scope of the patent test permits consideration to the alleged infringer *only* in settlements of bona fide, non-sham, non-fraudulent Hatch-Waxman litigation. See, *e.g.*, *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 208 (2d Cir. 2006) (as amended) (recognizing that settlements of sham litigation would be "devices—masks—for fixing prices, in violation of

antitrust law") (quoting *Asahi Glass Co.* v. *Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003) (Posner, J.)), cert. denied, 551 U.S. 1144 (2007).

Moreover, under the court of appeals' test, the FTC can still establish liability if it can prove that the settlement in question restricts competition beyond the force of the patent itself. See *Valley Drug Co.* v. *Geneva Pharm., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003) (If the settlement strays beyond the patent's scope, those excesses "may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether [they] violate § 1 of the Sherman Act."), cert. denied, 543 U.S. 939 (2004); see, *e.g.*, *Andrx Pharm., Inc.* v. *Elan Corp.*, 421 F.3d 1227, 1235 (11th Cir. 2005) (plaintiff stated claim where settlement terms allegedly precluded post-expiration generic entry). In other words, the court of appeals' test does not categorically bless all Hatch-Waxman settlements. Rather, it puts the burden where it belongs, on the party challenging the settlement as violating the antitrust laws.

2. The "scope of the patent" test is the correct expression of the rule of reason

The "scope of the patent" test is the correct expression of the rule of reason because it accords with basic principles of antitrust law in the patent context: (i) the law does not protect supposed "competition" via infringement of patents that are presumptively valid; (ii) antitrust rules must take into account long-run effects on competition and consumers; and (iii) readily administrable rules, like the scope of the patent test, best secure procompetitive benefits for consumers. By

contrast, the FTC's unwarranted rule violates each of these precepts.

(i) To begin with, the scope of the patent test—by permitting innovators to restrict competition within, but only within, the scope of the patent—recognizes that the law does not protect "competition" in the form of patent infringement, and that it is improper to circumvent this fundamental principle by assuming the patentee will lose its suit.

A settlement of litigation implicates the antitrust laws only if the two firms are indeed actual or potential competitors; otherwise, no competition is restrained. See *United States* v. *MMR Corp.*, 907 F.2d 489, 498 (5th Cir. 1990) ("[A]n agreement not to compete between two parties who are not actual or potential competitors is not per se or otherwise illegal.") (collecting cases), cert. denied, 499 U.S. 936 (1991); accord *United States* v. *Sargent Elec. Co.*, 785 F.2d 1123, 1127 (3d Cir. 1986) (noting that antitrust courts have recognized in numerous contexts that "[a]n agreement among persons who are not actual or potential competitors in a relevant market is for Sherman Act purposes *brutum fulmen*"), cert. denied, 479 U.S. 819 (1986).

For the same underlying reason, the antitrust laws protect only *lawful* competition—not competition in markets for illegal goods or services, such as infringing products. See *Bement* v. *National Harrow Co.*, 186 U.S. 70, 92 (1902); see also, *e.g.*, *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 789-792 (8th Cir. 2006) (non-FDA-approved prescription medications); *Access Telecom, Inc.* v. *MCI Telecomms. Corp.*, 197 F.3d 694, 712-713 (5th Cir. 1999) (export from the United States of telecommunications services illegal in the country of import), cert. denied, 531 U.S. 917

(2000). Indeed, the federal government's own compliance guidelines recognize that licensors and licensees are potential competitors only if they would compete in the absence of a license. The government finds licensing agreements anticompetitive when the "arrangement harms competition among entities that *would have been actual or likely potential competitors* in a relevant market in the absence of the license." DOJ & FTC, Antitrust Guidelines for the Licensing of Intellectual Property § 3.1 (1995) (emphasis added), www.justice.gov/atr/public/guidelines/0558.htm (last visited Feb. 27, 2013).

Of course, whether a patent license *is* necessary for lawful competition is the very issue being settled by the parties in Hatch-Waxman litigation. But under elemental principles of antitrust and patent law, there is no basis for assuming—as the FTC's rule of presumptively illegality does—that a license is unnecessary. To the contrary, patents must be presumed valid. See 35 U.S.C. 282; *Roper Corp.* v. *Litton Sys., Inc.*, 757 F.2d 1266, 1270 (Fed. Cir. 1985) ("A patent is born valid," and so remains "until a challenger proves" otherwise.). Indeed, this Court recently reaffirmed that Congress intended the presumption of validity to be overcome only by "clear and convincing evidence." *Microsoft Corp.* v. *i4i Limited Partnership*, 131 S. Ct. 2238 (2011). A pharmaceutical patent, which confers "a monopoly over the manufacture and distribution of the patented invention," is therefore presumed valid, and "[a] settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled." *Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d at 1337.

Moreover, a party—such as the FTC here—seeking to invalidate a restraint bears the burden of establishing the predicate for its condemnation, including the existence of a restraint of trade. See *Continental T.V., Inc.* v. *GTE Sylvania, Inc.*, 433 U.S. 36, 49 (1977); *FTC* v. *Indiana Fed'n of Dentists*, 476 U.S, 447, 461 (1986) ("finding[s]" supported conclusion "that the challenged restraint was unreasonable"). Here, there is no "restraint" on competition at all unless the FTC can demonstrate that the alleged infringer is indeed a potential (*i.e.*, lawful) competitor. See *Sargent Elec.*, 785 F.2d at 1127. Yet the FTC's contrary rule of presumptive illegality turns this elemental principle on its head by, in effect, resolving against the patentee the question whether the would-be generic could lawfully enter the market absent a license.

The "scope of the patent" test, in short, takes account of the fact that no restraint of competition exists unless the parties are *shown* to be lawful potential competitors. The FTC's reliance on the principle that " '[t]he anti-trust laws are as much violated by the prevention of competition as by its destruction,' " Pet. Br. 20-21 (quoting *United States* v. *Griffith*, 334 U.S. 100, 107 (1948)), is accordingly misplaced. The FTC cites cases, where, for example, two asserted competitors "agreed not to compete in the other's territories." *Palmer* v. *BRG of Ga., Inc.*, 498 U.S. 46, 49 (1990) (per curiam); see Pet. Br. 20. But that principle has no application here. The question whether the parties *are* lawful potential competitors is the very issue the parties agreed to settle in the Hatch-Waxman litigation. And the FTC itself recognizes that the antitrust litigation should not require the court to determine how the patent suit would have been resolved. Pet. Br. 53-55. That is why this Court has recognized that "[w]here

there are legitimately conflicting [patent] claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [antitrust laws]." *Standard Oil Co.* v. *United States*, 283 U.S. 163, 171 (1931).

(ii) The scope of the patent test also secures for consumers the long-term benefits of preserving investments in life-saving and life-improving innovation and, in some cases, accelerating generic entry, thereby reducing costs for consumers. See Part I, *supra*. This Court recognizes that antitrust rules must take into account the long-run benefits (or detriments) to consumers. See *Verizon Commc'ns, Inc.* v. *Law Offices of Curtis* v. *Trinko*, 540 U.S. 398, 412-415 (2004) (rejecting proposed new Section 2 rule that was not in consumers' long-run best interests under a cost and risk-of-error analysis); see also, *e.g.*, *Brooke Grp.*, 509 U.S. at 226-227 (emphasizing that the high standard for predatory pricing safeguards against the possibility of "standards * * * so low that antitrust suits themselves bec[o]me a tool for keeping prices high").

The FTC's proposed test fails to consider the full range of procompetitive effects. Hatch-Waxman settlements bring both short- and long-term procompetitive benefits. In the short term, such settlements frequently carry the immediate procompetitive benefit of permitting generic entry, prior to the expiration of the patent. See Part I.B, *supra*. In the long run, they foster procompetitive innovation. See Part I.A, *supra*. The FTC would have this Court ignore such settlements' short- and long-run benefits to consumer welfare and instead maximize certain purported short-term consumer benefits by forcing the parties to settle on different terms (or not settle at all). But that rule

would preclude the benefits of many procompetitive settlements, such as where the innovator would have prevailed, and the generic's entry would have been further delayed, had the suit been litigated to judgment. Moreover, in the long run, the FTC's rule would hinder innovation and consumer welfare.

More fundamentally, the antitrust laws impose no duty upon the parties to maximize competition. "The Sherman Act * * * does not give judges carte blanche to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition." *Trinko, LLP*, 540 U.S. at 415-416 (internal quotation marks and citation omitted). "There is simply no precedent for [the] argument that the parties to a settlement are required to preserve the public's interest in lower prices." *In re Ciprofloxacin Antitrust Litig.*, 363 F. Supp. 2d 514, 540-541 (E.D.N.Y. 2005), aff'd, 544 F.3d 1323 (Fed. Cir. 2008), cert. denied, 557 U.S. 920 (2009). Heeding this basic principle is all the more important where, as here, improperly forcing parties to maximize competition in the short-run will ultimately harm consumers in the long run. See *Trinko*, 540 U.S. at 412-415; *Brooke Grp.*, 509 U.S. at 226-227

(iii) Not only does the "scope of the patent" test accord with elemental antitrust and patent principles, but it is also administrable and reduces enforcement costs and the risk of enforcement error. As this Court has recognized, the risk of error is especially important in devising appropriate antitrust doctrines, because "[m]istaken inferences and the resulting false condemnations * * * chill the very conduct the antitrust laws are designed to protect." *Trinko*, 540 U.S. at 414 (quoting *Matsushita Elec. Indus. Co.* v. *Zenith Radio*

Corp., 475 U.S. 574, 594 (1986)); see, *e.g.*, *id.* (finding that "[t]he cost of false positives counsel[ed] against an undue expansion of § 2 liability"). In *Credit Suisse Sec. (USA) LLC* v. *Billing*, for example, this Court rejected application of the antitrust laws in the context of alleged violations of the securities laws, largely because "antitrust courts [we]re likely to make unusually serious mistakes" and chill desirable conduct. 551 U.S. 264, 282-283 (2007).

Here, consideration of enforcement costs and the likelihood of error counsel strongly in favor of the "scope of the patent" test. In the absence of special circumstances suggesting that the underlying litigation was a sham or fraudulent, see pp. 21-22, *supra*, administering the test requires only that a court determine whether the restraint imposed by a settlement extends beyond the scope of a patent. See, *e.g.*, *Ciprofloxacin*, 544 F.3d at 1333 (upholding settlement because its terms were "well within [plaintiff's] rights as the patentee"). If, on the other hand, a settlement restricts competition outside the patent's scope, or is the result of sham or fraudulent litigation, it may be subject to further challenge.

3. The FTC's proposed "quick look" approach lacks foundation

Finally, there is no basis for the FTC's proposal to subject settlements with consideration flowing to an alleged infringer to a presumption of illegality under a "quick look" approach. Any departure from the rule of reason requires a significant justification. See, *e.g.*, *Bus. Elecs. Corp.* v. *Sharp Elecs. Corp.*, 485 U.S. 717, 724 (1988). Thus, this Court has rejected the quick-look mode of analysis where conduct "might plausibly be thought to have a net procompetitive effect." *Cal.*

Dental, 526 U.S. at 771. A quick look is appropriate only where "the great likelihood of anticompetitive effects can be easily ascertained," and the court can make "a confident conclusion about the principal tendency of a restriction." *Id.* at 770, 781. Here, no such "conclusion" can be reached with "confiden[ce]."

For one thing, contrary to the FTC's notably qualified assertions that Hatch-Waxman settlements with consideration flowing to alleged infringers have "manifest anticompetitive *potential*" and are "*generally* devoid of any countervailing virtue," Pet. Br. 17, 34 (emphasis added), such settlements, as demonstrated, secure numerous procompetitive benefits. See Part I, *supra*.

For another, the FTC's proposed rule erroneously assumes that such settlements extinguish competition the Sherman Act protects, whereas that is the very issue being settled. See pp. 23-26, *supra*. The FTC's entire argument hinges on the possibility that, with respect to *some* settlements, if the parties had not settled the litigation, the patentee would ultimately have lost. See, *e.g.*, Pet. Br. 16 (referring to the settling patentee's "*artificially prolonged* period of market exclusivity") (emphasis added). As explained, elemental antitrust and patent principles preclude presuming the patentee would have lost, and preclude disregarding the long-term adverse consequences for consumers of undermining patent rights in order to maximize certain short-term benefits.

The FTC's retort—that the fact of consideration to the alleged infringer shows that the patentee likely would have lost, Pet. Br. 44-45—lacks foundation. As demonstrated above, such settlements are driven not by the likelihood that the innovator's patent is invalid,

but by the massive investment that is at stake for the innovator, the risk of litigation error, and the parties' asymmetric risks under the Hatch-Waxman framework. Indeed, as discussed above, see pp. 15-16, *supra*, in numerous cases, innovators have entered into settlements with infringers that might have run afoul of the FTC's proposed rule, yet the innovators' patents were upheld in subsequent litigation. See, *e.g.*, *Sanofi-Aventis* v. *Apotex, Inc.*, 659 F.3d 1171, 1175-1176 (Fed. Cir. 2011). In such cases, without the settlements the FTC condemns, the innovator would have been able to exclude the generic during the *entire* patent term. In fact, data reflecting the outcomes of Hatch-Waxman litigation to decision over the last decade suggests that patentees prevail more often than not. See p. 15, *supra*. The mere possibility that competition will be restrained in some unknown proportion of cases in which, in the absence of such a settlement, the generic challenger might have won, cannot support "a confident conclusion" that such settlements have a "principal tendency" to restrict competition. *Cal. Dental*, 526 U.S. at 781.

There is, in short, no basis for concluding that settlements with consideration flowing to alleged infringers have "manifestly anticompetitive effects," let alone that they "lack * * * any redeeming virtue." *Leegin Creative Leather Prods.*, 551 U.S. at 886. There is thus no justification for "quick look" condemnation.

B. The FTC's Unworkable Rule Would Disserve Innovation And Consumers

The FTC's proposed "quick look" approach not only lacks foundation, but is also fundamentally unworkable. It would severely diminish if not destroy innovators' ability to obtain repose from the onslaught

of patent litigation that inevitably plagues their successful new products—and would ultimately thereby harm consumers.

The FTC's own account of how a party might rebut its rule of presumptive illegality shows that the rule is unworkable. See Pet. Br. 37-38. The FTC concedes that there is "no fixed formula" for rebuttal and suggests that the "court would need to consider the totality of the circumstances surrounding the agreement," including a lengthy list of highly fact-intensive factors touching on, *inter alia*, "industry standards," "previous dealings between the parties," a "demonstrated interest in or need for the property or services on the part of the brand-name manufacturer," and the entire "course and content of the * * * negotiations." *Ibid.* Under such an amorphous test, no party to a settlement involving consideration flowing to the would-be generic could feel confident of victory in defending the settlement, no matter whether the consideration was indeed "bona fide." *Id.* at 37.

Worse, in many cases, the FTC's rule would require the parties to litigate the merits of the very patent dispute the parties sought to settle. The FTC purportedly concedes that "[a]dministrative concerns * * * strongly disfavor" forcing the settling parties to litigate the merits of the underlying dispute, and, indeed, concedes that such a requirement would be a "powerful disincentive to settlement." Pet. Br. 54. Yet the FTC's test would require just such a relitigation whenever an innovator attempted to defend its presumptively unlawful settlement on the ground that its patent was, in fact, valid and infringed, so that any delay prior to generic entry imposed no anticompetitive effect. Moreover, as even the FTC concedes in

a euphemistic fashion, "[q]uantification of damages in a private antitrust action might require an assessment of *what sequence of events would likely have ensued* in the absence of a reverse payment." *Id.* at 55 n.11 (emphasis added).

Such an undertaking would be extremely onerous, increasing enforcement costs and taxing judicial economy—including in this very case. See Pet. App. 33a ("In this case, assaying the infringement claim 'as of the time of settlement' would have required mining through mountains of evidence—when the lawsuit settled, more than 40 depositions had been taken and one side alone had produced more than 350,000 documents."). As the court of appeals below recognized, "[t]he settlement made that [undertaking] unnecessary, but the FTC's approach would put that burden back on the parties and the court, undo much of the benefit of settling patent litigation, and discourage settlements." *Ibid.* And the burden is not just one of marshaling potentially large amounts of evidence, but also of proving the almost-unprovable: "It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case," *Whitmore* v. *Arkansas*, 495 U.S. 149, 159-160 (1990), and "retroactively predicting from a past perspective a future that never occurred is even more perilous," Pet. App. 32a.

Furthermore, under such a regime, forced to litigate the hypothetical outcome of a hypothetical patent trial, an innovator faces the same if not greater risk of litigation error that led it to settle the Hatch-Waxman litigation in the first place. As the court below noted, this post-hoc, retrospective inquiry would be "unlikely to be reliable," in part because the determinations

would be left to the "non-specialized circuit courts [that] have no expertise or experience in the area" and are admittedly "ill-equipped to make a judgment about the merits of a patent infringement claim." Pet. App. at 33a-35a. By contrast, the "scope of the patent" test avoids the burdens and risks of "a patent case within an antitrust case about the settlement of the patent case." *Id.* at 36a.

The uncertain—and potentially extremely wide-ranging—breadth of the FTC's proposed rule would further chill procompetitive settlements. The FTC's suggestion, Pet. Br. 40, that other forms of consideration may be acceptable under its rule rings hollow. The FTC has taken the position that nearly any form of settlement can be characterized as a verboten "payment" constituting "*prima facie* evidence of an unreasonable restraint of trade" under the Third Circuit's decision in *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (2012). See FTC Brief as Amicus Curiae, *In re Effexor XR Antitrust Litig.*, No. 3:11-cv-05479, 1-2 (D.N.J. Aug. 10, 2012) (quoting *K-Dur*, 686 F.3d at 218). In the *Effexor* case, for example, the FTC contends that an innovator's exclusive licensing of an alleged generic infringer for the generic version of Effexor XR during the alleged infringer's 180-day exclusivity period—which means that the innovator itself would not issue its own "authorized generic" version during that period—alone constitutes an anticompetitive "payment." The FTC has thus asserted that it regards *any* consideration to the alleged infringer as a potentially illicit "reverse payment."

Confronted with the likely prospect of a post-settlement enforcement action by the FTC or private treble damages suits, parties may instead choose to lit-

igate their Hatch-Waxman suits to final judgment, depriving the public of all the potential benefits of settlement identified above, see Part I, *supra*. Innovators will incur burdensome costs and face the prospect of unknown and potentially incorrect litigation outcomes that may decrease incentives to innovate. See *Ciprofloxacin*, 261 F. Supp. 2d at 256; Crane, 88 Minn. L. Rev. at 706 ("[R]estricting patent settlements will have the effect of increasing the anticipated costs of litigation for any firm considering entering a patent-intensive market."). "[T]he results will be fewer new drugs that have led in the past to healthier and more productive lives for U.S. customers and large gains to the U.S. economy." *Ciprofloxacin*, 261 F. Supp. 2d at 256; see also *Valley Drug*, 344 F.3d at 1309 (similar).

* * *

The FTC's proposed rule would hinder innovation and disserve the interests of consumers. This Court should instead apply traditional principles of antitrust and patent law to conclude, as have the majority of courts of appeals, that parties to bona fide patent disputes may settle such litigation on the terms of their choosing, as long as those terms do not exceed the scope of the patent.

CONCLUSION

The judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

JAMES M. SPEARS
MELISSA B. KIMMEL
PHRMA

DOUGLAS HALLWARD-DRIEMEIER
MARK S. POPOFSKY
ELIZABETH N. DEWAR
ROPES & GRAY LLP

FEBRUARY 2013