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 GENERIC MANUFACTURERS UPSHER-SMITH LABORATORIES, INC.; TEVA PHARMACEUTICALS USA, INC.; RANBAXY PHARMACEUTICALS, INC.; MYLAN PHARMACEUTICALS INC.; AND IMPAX LABORATORIES, INC. AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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February 28, 2013

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Pursuant to this Court's Rule 37.2, *Amici Curiae* respectfully file this brief in support of Respondents.[1]

INTEREST OF AMICI CURIAE

Amici Upsher-Smith Laboratories, Inc. ("Upsher-Smith"), Teva Pharmaceuticals USA, Inc. ("Teva"), Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy"), Mylan Pharmaceuticals Inc. ("Mylan"), and Impax Laboratories, Inc. ("Impax") (collectively "Generic Manufacturers") are among the largest generic pharmaceutical companies in the world, with customers throughout the United States and over one hundred countries. Over the past two decades, *Amici* have engaged in hundreds of patent challenges under the Hatch-Waxman Act. Through those challenges, *Amici* and other generic manufacturers have brought numerous affordable generic drugs to market years prior to the expiry of branded companies' patents and saved consumers over $1 trillion, including through litigation settlements. *Amici* therefore have a strong interest in preserving the conditions that enable them to bring such patent challenges, including the flexibility to settle litigation when warranted.

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[1] The parties have consented to the filing of this brief, and their letters of consent are either already on file with the Court or are enclosed for filing with this brief. In accordance with Rule 37.6, *Amici* state that no counsel for any party has authored this brief in whole or in part, and no person or entity, other than the *Amici*, has contributed monetarily to the preparation or submission of this brief.

INTRODUCTION

Amici Generic Manufacturers file this brief to address an issue ignored by the Federal Trade Commission and their *amici*—that the number of patent challenges brought by generic pharmaceutical companies under the Hatch-Waxman Act is directly tied to the generic companies' ability to effectively and efficiently litigate and settle patent litigation arising from such challenges when necessary. Patent challenges are the lifeblood of generic competition, and the only avenue through which generic pharmaceutical products may be brought to market prior to expiration of patents on branded pharmaceuticals. However, FTC's proposed rule would essentially render *per se* anticompetitive any settlement involving consideration from the patent holder to the patent challenger, even though *every* patent settlement involves such consideration. As a result, FTC's proposed rule would all but eliminate monetary consideration—as well as most non-monetary forms of consideration—as an element of settlement for Hatch-Waxman patent cases and thereby make many such settlements difficult, if not impossible, to achieve.

Such a rule would decrease the overall number of patent challenges and thus would itself be anticompetitive. As leading commentators and courts that have addressed this issue have consistently recognized, monetary consideration is often necessary to achieve any settlement for a host of reasons, not least of which is the simple economic reality that patent holders and patent challengers place different values on early entry. Because the value of each day of early entry will cost the patent

holder more (at branded prices) than the patent challenger will benefit (at generic prices), there often is not an entry date that will satisfy both parties. The value of a dollar, on the other hand, is the same to both parties, meaning monetary consideration can bridge the gap and make settlement possible (as happens in ordinary patent litigation and ordinary settlement agreements every day). Removing this critical tool for reaching settlement will mean many cases will not settle that otherwise would.

The resulting impact on competition will be twofold. First, the patent challenger will inevitably *lose* some of the cases, resulting in no entry until patent expiry, whereas a settlement would have resulted in early generic competition to the benefit of consumers. Second, and perhaps most important, the cost of bringing patent challenges in the first place will increase, as generic manufacturers will have to assume that settlement will not be possible (or will be more expensive to achieve). Because resources are finite, generic manufacturers will inevitably bring fewer patent challenges, meaning there will be fewer total opportunities for cheaper generic drugs to enter the marketplace. This is no mere speculation: It is well-documented that at a time when certain courts appeared to view Hatch-Waxman settlements with monetary consideration as unlawful there were fewer overall patent challenges.

FTC's proposed rule would thus *harm* competition. And it would do so simply to eliminate a practice—the exchange of consideration—that is present not only in every patent settlement, but in every settlement of litigation (and every contract). FTC provides no basis to radically rewrite the

antitrust laws in such a manner, and there is none. The Court should reject FTC's approach, which would stifle the development and commercialization of generic pharmaceuticals.

BACKGROUND

The Hatch-Waxman Act sought to lower the cost of prescription medication by fostering the development of generic drugs, and it has been wildly successful. *See*, *e.g.*, *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997); *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). Before the Act's passage in 1984, virtually no modern drugs had generic equivalents, and generics filled less than 19 percent of all prescriptions. *See, e.g.*, Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993, 1993 (2007). Today, some 200 companies market generic drugs in the United States, generic drugs make up nearly 80 percent of all prescriptions, and the widespread availability of generic drugs has saved consumers approximately $1.07 trillion over the last decade alone. *See* Generic Pharm. Ass'n, *Generic Drug Savings in the U.S.* 1-2 (2012), *available at* http://www.gphaonline.org/media//cms/IMSStudyAug2012WEB.pdf (last visited Feb. 27, 2013). Indeed, in 2011, the last year for which data is available, "savings from generics increased 22 percent over the prior year, marking the largest year-over-year increase since 1998, and 10 percentage points higher than the 10-year average." *Id.* at 2.

The Hatch-Waxman Act achieved its goals by reducing the costs to generic pharmaceutical manufacturers of developing generic drugs and bringing those drugs to market. *See generally*

PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2574 (2011). In particular, a generic manufacturer may rely on studies previously conducted by the branded manufacturer and file an Abbreviated New Drug Application ("ANDA") showing that its generic drug is "bioequivalent" to its branded counterpart. *See* 21 U.S.C. § 355(j). A generic manufacturer can also challenge a patent covering a branded drug without making any infringing sales (and thus risking incurring significant monetary damages if its challenge is unsuccessful). To do so, a generic manufacturer simply files an ANDA with a "Paragraph IV" certification—a certification challenging the patent as invalid, unenforceable, or not infringed by the generic drug. *See id.* § 355(j)(2)(A)(vii)(IV). Unless a generic manufacturer files a Paragraph IV patent challenge, the generic product cannot be marketed until all patents claiming the branded drug expire. The filing of a Paragraph IV certification is a technical act of patent infringement, *see* 35 U.S.C. § 271(e)(2), which allows the branded manufacturer to sue immediately for patent infringement rather than waiting until the generic company introduces its generic drug into the market.

In the ensuing litigation, a generic company can obtain a judicial determination regarding patent validity and infringement *before* undertaking the risk of producing and selling a potentially infringing competing drug. As long as the generic company waits for a ruling, including on appeal, before coming to market, it will be liable for few (if any) damages if it loses the patent case, because it will not have made any infringing sales. *See* 35 U.S.C. § 271(e)(4)(C). On the other hand, the branded

manufacturer stands to lose a great deal in the litigation: if the generic company's challenge to the patent is successful, the generic company can enter the market immediately and the branded manufacturer will lose its patent protection forever. The Hatch-Waxman Act thus "alter[ed] the litigation risks of patent lawsuits," putting the Hatch-Waxman patent defendant in the shoes traditionally worn by a plaintiff, and the Hatch-Waxman plaintiff in the shoes traditionally worn by a defendant. *In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro I*"), 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003); *see also In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206-07 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005).

This case illustrates the Hatch-Waxman Act operating effectively. Respondent Solvay Pharmaceuticals, Inc. ("Solvay") held a patent covering AndroGel. Pet. Cert. App. 10a. Respondents Watson Pharmaceuticals, Inc. ("Watson") and Paddock Laboratories, Inc. ("Paddock") wanted to sell a generic version of Solvay's AndroGel, so they filed ANDAs with Paragraph IV certifications as to Solvay's patent covering the drug, and Solvay sued both for infringement. *Id.* at 10a-11a. While summary judgment motions were pending in the infringement case, the parties settled their dispute, as parties in all types of litigation routinely do. *Id.* at 12a. Under the terms of the settlement agreement, which included consideration flowing to all parties involved, Watson and Paddock received a license to launch their generic drugs in 2015, fully *five years* before the expiration of Solvay's patent in 2020. *Id.*

SUMMARY OF ARGUMENT

This case presents a straightforward question: can a patent challenger enter into an agreement settling litigation against a patent holder (as litigants do every day), or must it—on threat of treble antitrust damages—litigate the case to the bitter end? Under the rule FTC proposes here, if a patent challenger receives anything of value in that settlement—what FTC pejoratively calls a "reverse" or "exclusion" payment—the settlement would be presumptively unlawful under the antitrust laws, even if the patent challenger received a license to market the patented technology before the expiration of the patent. This is so, according to FTC, because such consideration would be a *quid pro quo* for delayed market entry. But FTC offers a false premise.

As an initial matter, there is simply nothing unusual or untoward about a putative plaintiff providing consideration to a putative defendant as part of a litigation settlement. "*[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." *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation) (emphasis in original). That point applies with special force in the Hatch-Waxman context, in which the traditional stakes and incentives of litigation are altered and a branded manufacturer (although nominally the plaintiff), seeks to defend a challenge to its patent by a generic manufacturer (nominally the defendant), and may be unwilling to "roll the dice" in litigation. *See, e.g.*,

Tamoxifen, 466 F.3d at 210. There is, thus, nothing "reverse" about a so-called "reverse payment."

Nor is there anything "exclusionary" about such a payment. In arguing to the contrary, FTC simply—and simplistically—assumes that consideration provided to a generic patent challenger must be a *quid pro quo* for delayed market entry and that, absent such consideration, the patent litigants would reach a "better" settlement. FTC's argument, however, is not only legally irrelevant, *see Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004), but ignores the real-world complexities that even its own *amici* acknowledge make settlements—which greatly benefit consumers—impossible without monetary or similar consideration passing to the patent challenger.

Moreover, the rule FTC proposes would in fact severely harm consumers by reducing the total number of patent challenges in the first place. Every patent challenge—and *Amici* Generic Manufacturers have brought over 100 patent challenges in recent years—brings with it the imminent threat of patent litigation, which is expensive, time-consuming, and inherently uncertain. Indeed, collectively, *Amici* Generic Manufacturers have invested approximately half a billion dollars in patent litigation over the past few years. Settlement, thus, is a key tool for managing the expense and risk of patent litigation. FTC's proposed rule, by effectively banning Hatch-Waxman settlements that involve monetary consideration—and most forms of non-monetary consideration—would render settlement in many Hatch-Waxman patent cases impossible, and in

others inordinately expensive and risky. Yet, such settlements bring lower-cost generic drugs to market *prior to the expiration of the patents* covering such drugs, engendering competition that would not otherwise be possible. Under FTC's desired regime, generic companies would face the dilemma of being locked into protracted patent litigation or trading that litigation for antitrust litigation (and the specter of treble damages). For generic drug companies, which have finite resources with which to develop drugs and mount patent challenges, the upshot would be fewer challenges and decreased drug competition—all to the detriment of consumers.

ARGUMENT

I. There Is Nothing "Reverse" Or "Exclusionary" About So-Called "Reverse," "Exclusion" Payments.

FTC asserts that the settlements in this case violate the antitrust laws for one reason and one reason alone: the settlements (allegedly) contain monetary payments from the patent holder to the patent challengers. But FTC ignores the basic fact that in *every* settlement agreement, as in every contract, each side provides consideration to the other.

In the typical patent case, outside the context of Hatch-Waxman, litigation is not commenced until the alleged infringer (the patent challenger) enters the market and uses, makes, or sells an infringing product. It is only *after* infringing activity has occurred that the infringer can challenge the patent. The patent holder sues the alleged infringer and seeks damages—its lost profits, which may far exceed the alleged infringer's infringing sales—while

the alleged infringer challenges the validity, enforceability, or applicability of the patent. In such a case, the patent holder runs the risk of losing its patent, but the alleged infringer risks incurring significant, and potentially crippling, monetary damages. The companies often will settle to eliminate their respective litigation risks. To avoid its risk, the alleged infringer will typically pay some amount to the patent holder in exchange for ending the litigation. The compensation paid, however, will necessarily be less—and potentially significantly less—than the full quantum of damages sought by the patent holder. The patent holder accepts this smaller amount—and thus grants consideration to the alleged infringer—in exchange for eliminating its risk of losing its valuable patent.

As one report summarized this dynamic: "In this case, the patent holder pays the infringer to settle the lawsuit by accepting lower damages—[although] this payment is obscured by the fact that some cash flows from the infringer to the patent holder." Bret Dickey, Jonathan Orszag, & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals of Health L. 367, 389 (2010). And where, as is often the case, the alleged infringer does not pay all of its profits on its allegedly infringing sales to the patent holder as damages, the "payment" to the infringer is magnified. *See Cipro I*, 261 F. Supp. 2d at 252 (noting this "implicit consideration" flows to a patent challenger that retains some profit from its infringing sales). Thus, "even in the traditional context, implicit consideration flows from the patent holder to the alleged infringer." *Id.*; *see also Schering-Plough*, 402 F.3d at 1074; Mark G.

Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1046-48 (2004).

Hatch-Waxman patent litigation differs from traditional patent litigation in an important respect (which is completely ignored by FTC). The Hatch-Waxman Act permits a generic manufacturer challenging a patent to commit an act of infringement by simply filing an ANDA with a Paragraph IV certification, before it makes any infringing sales or engages in any other activity that would give rise to compensatory damages. *See* 35 U.S.C. §§ 271(e)(2), 271(e)(4)(C). As a result, Hatch-Waxman patent litigation commences "*before* the filer has spent substantial sums on the manufacturing, marketing, or distribution of the potentially infringing drug," and *before* it has made potentially infringing sales that could subject it to substantial damages. *See Tamoxifen*, 466 F.3d at 206 (emphasis in original); *Cipro I*, 261 F. Supp. 2d at 252. The patent challenger still faces risk—notably, the expense of a drawn-out litigation—but it does not face the threat of substantial money damages. By contrast, the patent holder has the exact same risk it would have in traditional patent litigation—the threat of losing its valuable patent. *See Tamoxifen*, 466 F.3d at 206-07; *Schering-Plough*, 402 F.3d at 1074; *Cipro I*, 261 F. Supp. 2d at 252.

As compared to the traditional patent case, then, the patent challenger in the Hatch-Waxman context faces comparatively less risk and the patent holder faces the same risk. Indeed, the redistributed risks in Hatch-Waxman patent litigation make the patent holder (the branded company) more like the

defendant in a traditional case and the patent challenger (the generic company) more like the plaintiff. For this reason, FTC's attempt to discount Judge Posner's reasoning in *Asahi Glass*, *see* Pet. Br. 30, falls flat, as it fails to understand, or even acknowledge, the economics driving these cases. The patent challenger, although nominally the defendant, has "the whip hand":

> "Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, the generic challengers gain considerable leverage in patent litigation: the exposure to liability amounts to litigation costs, but pales in comparison to the immense volume of generic sales and profits."

Tamoxifen, 466 F.3d at 210 (quoting *Schering-Plough*, 402 F.3d at 1074 (brackets omitted)); *see also In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro Fed. Cir.*"), 544 F.3d 1323, 1333 & n.11 (Fed. Cir. 2008) (similar). In light of this reality, "[g]iven 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).[2]

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[2] Only if the generic challenger were to launch its product at-risk—that is, before definitive resolution of the infringement case at the trial and appellate levels—would the litigation risks revert to those of the traditional patent litigation. In that situation (and only in that situation), the generic patent challenger subjects itself to the possibility of infringement

There is thus nothing "extraordinary" or "distinguishing" about consideration flowing to the patent challenger in Hatch-Waxman patent settlements, as FTC claims. *See* Pet. Br. 30. As many courts have observed, net monetary consideration flowing from the patent holder to the patent challenger is "'a natural by-product of the Hatch-Waxman process.'" *Schering-Plough*, 402 F.3d at 1074 (quoting *Cipro I*, 261 F. Supp. 2d at 251). And, contrary to FTC's argument, *see* Pet. Br. 50, such settlements are not unique to the Hatch-Waxman context, but can be seen in other contexts where the relative risks of litigation are redistributed. *See, e.g.*, *Metro-Goldwyn Mayer, Inc. v. 007 Safety Prods., Inc.*, 183 F.3d 10, 13, 17 (1st

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damages. *Cipro I*, 261 F. Supp. 2d at 204. Such damages can be substantial, and even crippling, for the generic company. Indeed, *Amicus* Teva is facing up to $2.1 billion in damages resulting from its at-risk launch of a generic form of the heartburn drug Protonix. *See* Peter Loftus, *Teva Faces Possible Damages From Selling Generic Protonix*, Wall St. J. Online, Feb. 13, 2013, http://online.wsj.com/article/SB10001424127887324162304578302550657347058.html. And Apotex, following an at-risk launch of its generic form of Plavix that lasted only *23 days* was found liable to the branded company for over $442 million in damages. *See id.*; *see also Sanofi-Synthelabo v. Apotex Inc.*, 492 F. Supp. 2d 353, 357-58 (S.D.N.Y. 2007), *aff'd*, 550 F.3d 1075 (Fed. Cir. 2008). Moreover, generic companies, even if ultimately successful in their infringement litigation, must nonetheless book significant up-front litigation reserves to protect against a potential loss. It is thus unsurprising that at-risk launches are uncommon. *See* RBC Capital Markets, *Pharmaceuticals: Analyzing Litigation Success Rates* 7 (Jan. 15, 2010), *available at* http://amlawdaily.typepad.com/pharmareport.pdf.

Cir. 1999) (enforcing trademark settlement with payment to alleged infringer); *In Time Prods., Ltd. v. Toy Biz, Inc.*, 38 F.3d 660, 662, 666-67 (2d Cir. 1994) (enforcing copyright and trade dress settlement with payment to alleged infringer).

Moreover, FTC's proposed rule is especially misguided—and dangerous—because it would apply not only to monetary consideration received by the patent challenger, but to *any* settlement in which a patent challenger receives *anything of value*. *See* Pet. Br. 36 n.7 (stating that "[i]f the economic realities of a settlement coupling an alternative form of consideration with delayed entry paralleled those of the direct payments here ... then a similar [ ] analysis would be justified"). Although FTC does not further explain its position in its brief, its own recent litigation positions in other cases demonstrate the breathtaking reach of its proposed rule. In these cases, FTC has argued that non-monetary consideration should be deemed a "reverse payment" that triggers its proposed rule of presumptive illegality. Specifically, in *In re Effexor Antitrust Litigation*, No. 11-cv-5479 (D.N.J. filed Sept. 22, 2011), and again in *In re Lamictal Direct Purchaser Antitrust Litigation*, No. 12-cv-995 (D.N.J. filed Feb. 17, 2012), FTC argued that Hatch-Waxman patent settlements were presumptively anticompetitive even though no monetary consideration was exchanged, simply because the branded company granted an *exclusive* license to the generic (thus foregoing introduction of agreed not to introduce an "authorized generic" version of the drug at issue in the litigation during the exclusive license period). *See* FTC Br. as *Amicus Curiae* 5-11, *In re Effexor Antitrust Litig.*, No. 11-cv-5479 (D.N.J. filed Aug. 10,

2012), *available at* http://www.ftc.gov/os/2012/08/120810effexoramicusbrief.pdf; FTC Br. as *Amicus Curiae* 6-12, *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-cv-995 (D.N.J. filed Oct. 5, 2012), *available at* http://www.ftc.gov/os/2012/10/121005lamictalamicusbrief.pdf.

FTC's proposed rule thus calls into question (and subjects to the threat of antitrust treble damages that may be pursued by government agencies and private litigants alike) *all* forms of consideration, and thus all forms of settlement. And it does so even though, as Judge Posner has observed, "*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement." *Asahi Glass*, 289 F. Supp. 2d at 994 (emphasis in original). When one appreciates the fact that the stakes and incentives in Hatch-Waxman patent litigation are redistributed from those of "normal" litigation, it becomes clear that the flow of consideration in a Hatch-Waxman patent settlement is anything but "extraordinary"; rather, it is no different than the flow of consideration in patent settlements that occur every day.

II. By Restricting Settlements, FTC's Proposed Rule Would Reduce Patent Challenges, Decrease Competition, And Harm Consumers.

In the face of this reality, FTC proposes a rule that would re-write antitrust jurisprudence and make Hatch-Waxman settlements involving monetary consideration "presumptively unlawful." In advocating this standard, however, FTC fails to

address what should be a key consideration—that such a rule would render settlements impossible or inordinately expensive and risky and would thus *decrease the number of patent challenges* brought by generic drug manufacturers in the first place, thereby reducing competition in the aggregate to the detriment of consumers.

A. FTC's Rule Would Effectively Prevent Settlements, Thereby Making Patent Litigation More Expensive And Uncertain.

It is of course well-known that litigation in general, and patent litigation in particular, is expensive and time-consuming. *See, e.g.*, *Bell Atl. Corp. v. Twomby*, 550 U.S. 544, 558-60 (2007); *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 336 (1971). Indeed, *Amici* Generic Manufacturers have collectively expended a half billion dollars in patent litigation over the past few years. It is equally well-known that litigation is inherently uncertain. *See, e.g.*, *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990) ("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."). As the Eleventh Circuit recognized below, "[r]ational parties settle to cap the cost of litigation and to avoid the chance of losing," because even a party likely to win has no guarantees. Pet. Cert. App. 30a. After all, "[n]o one can be *certain* that he will prevail in a patent suit." *Asahi Glass*, 289 F. Supp. 2d at 993 (emphasis in original). The *Amici* Generic Manufacturers know this well—over the past five years, they have brought over 100 patent challenges, many of which have resulted in

litigation. Of those suits litigated to conclusion, they have collectively lost more than they have won.

Settlement is a key tool for managing the expense and uncertainty of litigation. Having a full range of settlement options permits a party to enter litigation with the knowledge that it can avoid a costly and uncertain trial if the risk or expense outweighs the potential benefit. *See, e.g.*, D. Marie Provine, *Settlement Strategies for Federal District Judges* 1 (Fed. Judicial Ctr. 1986) ("Settlements are desirable, not just because trials are costly ... but because settlements allow parties to 'manage their own disputes' and avoid the uncertainties and limitations of the winner-take-all, imposed decisions that courts make in fully litigated cases."). Indeed, even when a generic manufacturer wins in district court, if it launches a product only to have the Federal Circuit reverse, the generic manufacturer faces crippling financial losses. *See, e.g.*, *supra* note 2. Given the threat of ruinous damages, unless a generic manufacturer wins—and sustains its win on appeal—settlement is the only way to routinely facilitate early entry.[3]

The rule proposed by FTC would limit the ability to settle by effecting a *per se* ban on the use of

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[3] A reversal on appeal of a patent case is no rarity. The Federal Circuit in recent years has reversed or vacated (at least in part) more than 40 percent of its patent appeals. *See U.S. Court of Appeals for the Federal Circuit, Affirmance and Reversal Rates for District Court Patent Infringement Appeals: 2001–2010*, *available at* http://www.patentlyo.com/files/caseload_patent_infringement_affirmance_and_reversal_rates_2001-2010.pdf.

monetary consideration in the settlement of patent cases. Although FTC argues that its presumption of illegality would be rebuttable, it offers no real explanation of how such a presumption could be rebutted, save for an artificial and arbitrary cap on the amount of consideration tied to litigation costs. *See* Pet. Br. 37-38. And it would leave a generic manufacturer with an untenable option: settle a patent case only to have the settlement litigated and reviewed after the fact, perhaps multiple times (as in the case of *Amicus* Upsher-Smith's settlement with Merck/Schering regarding K-Dur) in litigation against both regulatory authorities *and* the uninhibited private plaintiffs that "account for the overwhelming majority of antitrust litigation in the United States." *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 805 (D.C. Cir. 2001). And all this would come with the sword of antitrust treble damages hanging over the generic manufacturer's head.

Monetary consideration, however, is often a critical element *necessary* to achieve settlement, especially in the Hatch-Waxman context—it is not simply a *quid pro quo* for delay, as FTC presumes. Indeed, it has long been recognized that "[t]here are many circumstances where a reverse payment is necessary to resolve a patent litigation," *e.g.*, Schildkraut, *supra*, at 1034, and that, under many circumstances, the patent holder and patent challenger "cannot eliminate the payment and compromise on an earlier entry date, because no such date is acceptable to both the [patent holder] and the [patent challenger]," Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements That*

Settle Patent Litigation, 49 Antitrust Bull. 655, 677 (2004).

As explained by former Clinton National Economic Counsel members Jonathan Orszag and Laura Tyson, such circumstances include, among others, parties' differing views of the value of litigation, parties' differing views of their likelihood of success in litigation, and cash-strapped generic companies. Dickey, Orszag, & Tyson, *supra*, at 391-95. Indeed, one of FTC's own *amici*, Carl Shapiro, who has consulted for FTC and the Department of Justice and served as a plaintiff-side antitrust expert, agrees: "This is not to say that such payments are necessarily anticompetitive if other factors are brought into the analysis, such as risk aversion and asymmetric information about market conditions, as 'reverse cash payments' may be important in more complex settings for successful settlement." Carl Shapiro, *Antitrust Limits to Patent Settlements*, 43 RAND J. of Econ. 391, 408 (2003); *see also* John P. Bigelow & Robert D. Willig, *"Reverse Payments" in Settlements of Patent Litigation:* Schering-Plough*,* K-Dur*, and the FTC (2005)*, *in The Antitrust Revolution: Economics, Competition, and Policy* 248, 273 (5th ed. 2009) ("It also follows from economic logic that the opportunity to employ reverse payments may be necessary for socially beneficial and pro-competitive settlements to be reached, due to such common situations as asymmetric information, excess optimism, and

differential cash needs between the parties to the patent dispute.").[4]

FTC does not even attempt to address these real-world complexities that undermine the faulty premise of its entire argument. Rather, it blindly maintains that consideration passing to a patent challenger must be a *quid pro quo* for delay, and it simply asserts—without support—that branded and generic pharmaceutical manufacturers can just "negotiate a compromise date of entry," "with no money or similar consideration flowing from the brand-name to the generic manufacturer." Pet. Br. 22, 27. On this basis, FTC claims, its proposed rule would not significantly undermine the ability of

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[4] Throughout its brief, FTC relies heavily on the work of its former consultants, current antitrust enforcement authorities, plaintiff-side antitrust expert witnesses, and its own *amici*, and presents the conclusions of that work as undisputed fact. For example, Scott Hemphill, cited extensively by FTC, is Chief of the Antitrust Bureau of the New York State Attorney General's Office and has served as a consultant to the FTC; Carl Shapiro, an *amicus* in this case, has consulted for the FTC and the Department of Justice and serves as a plaintiff-side antitrust expert witness; and Mark Lemley (also an *amicus* in this case), Einer Elhauge, and Alex Krueger are also plaintiff-side antitrust expert witness. Indeed, some of this work has been criticized as "[u]nfortunately" simply "assum[ing] that reverse payments are anticompetitive payments for delay prior to evaluating their cost" and "provid[ing] no empirical analysis of the anticompetitive or procompetitive effects that reverse payments have." *See* Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 Iowa L. Rev. 57, 113 (2010).

parties to settle Hatch-Waxman patent litigation, and would eliminate only anticompetitive conduct.

But FTC's claims ignore the realities of Hatch-Waxman patent litigation—notably, the differing values of time to the patent holder and the patent challenger. For the generic company, an extra day of sales is worth only as much as it would gain at generic prices. For the branded company, however, each lost day of sales is calculated at the higher price of its branded drug. Each extra day will thus cost the branded manufacturer far more than the generic competitor will gain. In such a situation, the branded company's reservation date—"the earliest date at which [it] would be willing to allow the generic to enter the market rather than litigate"—may be later than the latest date at which the generic would agree to enter rather than litigate; there would be a gap between the parties' settlement ranges. *See* Schildkraut, *supra*, at 1043. "[W]ithout a payment from the branded manufacturer to the generic manufacturer, the parties may be unable to reach agreement on a settlement—even if a settlement would lower prescription drug costs by bringing a generic drug to market sooner than would occur if the case were resolved by a court decision." Bret Dickey, Jonathan Orszag, & Robert Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse Payment" Settlements* 4 (Aug. 10, 2010); *see also* Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B.J. 617, 618-19, 628-31 (2005) (explaining that there are multiple reasons "why a straightforward settlement that simply splits the remaining patent

term may not be available," including "asymmetric time horizons and asymmetric risk profiles or expectations" (emphasis omitted)). In short, absent monetary consideration, "due to the disparity between the brand-name manufacturer's and generic challenger's expected profits, there might not be any date that represents a reasonable litigation compromise for early (pre-patent expiration) entry by the generic challenger." *In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro II*"), 363 F. Supp. 2d 514, 536 (E.D.N.Y. 2005).

Monetary consideration may similarly be necessary to bridge the gap between the branded and generic companies' settlement ranges where the generic company is overly optimistic about its probability of success in litigation. *See* Dickey, Orszag, & Tyson, *supra*, at 394-95. In such a case, the "mismatch of beliefs and actual probabilities could create a situation ... where (absent a reverse payment) the generic manufacturer would not be willing to accept any settlement terms the brand-name manufacturer would be willing to offer due to the generic manufacturer's unrealistic belief about its chance of winning. ... [But] a reverse payment can potentially bridge the settlement gap and lead to a settlement that benefits consumers." *Id.*; *see also* Schildkraut, *supra*, at 1063-64.

The same is true in the case of a "cash-strapped generic" that heavily discounts future profits and will only accept settlements that allow for greatly accelerated entry but which would not be acceptable to the branded company. "The latest entry date to which the cash-strapped generic would be willing to agree is earlier than the earliest date to which the

brand-name manufacturer would be willing to agree. As a result, settlement talks would break down." Dickey, Orszag, & Tyson, *supra*, at 393-94. However, "[a] cash payment by the brand-name manufacturer may allow the brand-name and generic manufacturers to bridge the settlement gap ... lead[ing] to a range of settlements that would not have been otherwise feasible." *Id.*

In sum, monetary consideration often will permit a patent holder and a patent challenger to reach a settlement that otherwise could not be reached. As set forth below, this is critical for *enabling* competition and *promoting* consumer welfare.

B. Absent Settlement, Generic Competition Will Often Be Delayed Until Patent Expiration.

To perhaps state the obvious, settlement eliminates the possibility that the patent challenger litigates a case and *loses*, in which case no generic alternative can be marketed until *after the patent expires*. In such cases, settlement gives consumers access to generic drugs earlier than would otherwise be possible. Settlements thus often result in *accelerated* generic entry, and not "delay," as FTC claims. FTC wholly ignores this significant fact.

The examples of tamoxifen, previously the most widely prescribed cancer treatment drug in the world, and blockbuster antibiotic Cipro, are instructive. In the case of tamoxifen, four different generic manufacturers filed ANDAs with Paragraph IV certifications challenging the patent protecting Zeneca's branded tamoxifen drug, and Zeneca sued all four generic challengers. *Tamoxifen*, 466 F.3d at 194-95. Barr Laboratories, the first-filing generic,

and Zeneca reached a settlement that allowed Barr to introduce generic tamoxifen *nine years* prior to the expiry of Zeneca's patent and also included monetary consideration flowing to Barr. *Id.* The three other generic challengers opted to litigate their cases against Zeneca to conclusion, but "[i]n each case, the court ... upheld the validity of Zeneca's tamoxifen patent," and those challengers were prohibited from bringing generic tamoxifen to market until Zeneca's patent expired. *Id.* at 195. But because of—and only because of—Barr's settlement with Zeneca, consumers gained access to lower-cost generic tamoxifen *nine years earlier* than they otherwise would have.

Similarly, with regard to Cipro, Barr Laboratories filed an ANDA with a Paragraph IV certification challenging the patent protecting Bayer's branded Cipro drug, and Bayer sued Barr for infringement. *Cipro Fed. Cir.*, 544 F.3d at 1328. Barr, the first-filing generic, and Bayer subsequently reached a settlement that allowed Barr to market a generic version of Cipro before Bayer's patent expired, and also contained monetary consideration flowing to Barr. *Id.* at 1328-29. Thereafter, four other generic companies filed ANDAs with Paragraph IV certifications, seeking to market generic Cipro prior to patent expiry. *Id.* at 1329. Bayer sued each generic and prevailed in all four cases, thereby preventing any of those companies from selling generic Cipro until its patent expired. *Id.* But again, because of—and only because of—Barr's settlement with Bayer, consumers gained access to lower-cost generic Cipro prior to patent expiration.

At the other end of the spectrum, the case of Plavix (clopidogrel), the world's most highly prescribed blood-thinning medication, is equally instructive. Bristol-Myers held a patent covering Plavix. Apotex, seeking to market a generic version of that drug prior to expiration of the patent, filed an ANDA with a Paragraph IV certification as to that patent, and Bristol-Myers sued it for infringement. The parties reached two separate settlement agreements that would have allowed Apotex to market generic clopidogrel ten-and-a-half months prior to patent expiry. The regulatory authorities, however, rejected those settlements.[5] Apotex then litigated its patent challenge, lost, and was thus enjoined from marketing generic clopidogrel until Bristol-Myers's patent expired. *See Sanofi-Synthelabo v. Apotex Inc.*, 492 F. Supp. 2d 353 (S.D.N.Y. 2007), *aff'd* 550 F.3d 1075 (Fed. Cir. 2008); *see also Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 323-24 (S.D.N.Y. 2006). According to independent analysts, by rejecting the early-entry settlement, regulatory authorities cost consumers $2.6 billion. *See* Corey Davis et al., *FTC Call for Settlement Ban Is … Full of Sound and Fury, Signifying Nothing* 7 (Jan. 14, 2010).

FTC ignores this reality and instead attempts to generally discount the benefits of settlement by citing its own 2002 study claiming that generic

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[5] Because of an order entered in previous litigation, the settlement agreements between Apotex and Bristol-Myers were subject to approval by FTC and a consortium of state attorneys general. The state attorneys general rejected both settlements. *See Sanofi-Synthelabo*, 488 F. Supp. 2d at 324.

patent challengers prevail in 73% of cases. *See* Pet. Br. 6. Over and above the inherent unreliability of a litigant relying on its own self-serving study (which is based on non-public data) in litigation, this study and the others on which FTC relies have been roundly criticized by independent scholars.[6] An independent study citing more recent data indicates that the success rate of patent challenges in litigation is in fact far less—48%. RBC Capital Markets, *Pharmaceuticals: Analyzing Litigation Success Rates* 1, 4 (Jan. 15, 2010), *available at* http://amlawdaily.typepad.com/pharmareport.pdf. And yet another study of patent validity decisions over a nine-year period concluded that 73% of challenged pharmaceutical patents were held valid. *See* John R. Allison & Marc A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 217 (1998).

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[6] *See, e.g.*, Dickey, Orszag, & Willig, *supra*, at 3 (opining that FTC's study, on which it bases is claim that Hatch-Waxman settlements cost consumers $3.5 billion annually, is "unreliable"); Corey Davis et al., *FTC Call for Settlement Ban Is … Full of Sound and Fury, Signifying Nothing* 1-5 (Jan. 14, 2010) (concluding that the FTC study on which FTC bases its claims was "exceedingly flawed," relied on "grossly inaccurate data," improperly "presume[d] patent invalidity across the board," and assumed that settlement is always achievable without monetary payments); *see also* Xiang Yu & Anjan Chatterji, *Why Brand Pharmaceutical Companies Choose To Pay Generics in Settling Patent Disputes: A Systematic Evaluation of the Asymmetric Risks in Litigation*, 10 Nw. J. Tech. & Intell. Prop. 19, 37 (2011) ("[A]lthough the FTC holds the position that consumers suffer a loss up to $3.5 billion per year due to [so-called reverse-payment] settlements, its estimation method has recently been challenged on legal and economic grounds.").

Contrary to FTC's claim, in reality over half, and potentially up to three-quarters, of all patent challenges litigated to conclusion are not successful. In these cases, no generic competition is permitted and consumers are left with only the branded drug at branded drug prices. Consumers would be better off with a settlement that permits early entry, even if that settlement also contains consideration flowing to the patent challenger. FTC's proposed rule would eliminate this competition resulting from settlement, and is thus itself anticompetitive.

C. FTC's Approach Would Result In Fewer Patent Challenges And, Thus, Fewer Generic Drugs For Consumers.

Most fundamentally, by reducing generic companies' ability to settle patent litigation, FTC's proposed rule would cause generic companies to bring fewer patent challenges because, as numerous commentators and courts have recognized, a generic company's incentive to bring Hatch-Waxman patent challenges in the first place depends in significant measure upon having the flexibility to decide when, and on what terms, to resolve the litigation rather than fight "to the death" in every case. *See, e.g.*, *Valley Drug*, 344 F.3d at 1299, 1308; *Asahi Glass*, 289 F. Supp. 2d at 994.

The reason is simple. When deciding whether to file an ANDA challenging a patent, a generic company must weigh the cost of the litigation that will inevitably result from that ANDA filing. *See, e.g.*, Bret M. Dickey & Daniel L. Rubinfeld, *Would the* Per Se *Illegal Treatment of Reverse Payment Settlements Inhibit Generic Drug Investment?*, 8 J. Comp. L. & Econ. 615, 622 (2012). And, as noted

above, patent litigation is expensive and time-consuming.

Generic companies have finite resources—and these resources are stretched by the multiple patent challenges that such companies typically have ongoing at any given time. *See Cipro I*, 261 F. Supp. 2d at 256. If the expected cost of a patent challenge is increased, a generic company will necessarily be able to bring fewer challenges, meaning that the company will develop fewer low-cost generic drugs—all to the clear detriment of competition. As one recent report explains:

> [I]f antitrust policy towards patent settlements reduces the ability of generic manufacturers to settle litigation and therefore increases the cost and risk associated with bringing a generic version to market, generic manufacturers' investments in these challenges are likely to be diminished. That would reduce the number of generic drugs in the future "pipeline." In the long run, a reduction in the number of generic entrants would likely lead to higher average pharmaceutical prices.

Dickey & Rubinfeld, *supra*, at 619-20.

FTC's proposed rule would have precisely this detrimental, competition-reducing effect. By reducing generic companies' ability to settle litigation, FTC's proposed rule would present generic companies with a Hobson's choice. On the one hand, the company must be prepared to litigate its patent case to the bitter end—an expensive proposition for any generic company, especially when facing a branded company who has incentive to "go to the

mat" and to spare no expense in litigating against it. Or, on the other hand, it must trade that patent litigation for antitrust litigation (and the specter of treble damages). The result would necessarily be fewer patent challenges and the development of fewer generic drugs. *See, e.g.*, *Cipro I*, 261 F. Supp. 2d at 256 ("To maximize [the] incentives [for generic investment in product development and patent challenges], a generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it. Otherwise, the incentives to mount an ANDA IV challenge could be reduced."); Dickey & Rubinfeld, *supra*, at 624 ("Without the ability to settle, such substantial [litigation] uncertainties can dramatically chill the incentives of a generic manufacturer to develop generic drugs."). And, of course, fewer patent challenges and reduced generic drug development mean fewer generic drugs on the market, which will directly impact consumers.

That is why, as Judge Posner has recognized, "[a] ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive." *Asahi Glass*, 289 F. Supp. 2d at 994. By contrast, "[e]nsuring that generic manufacturers have a viable option to settle patent litigation"—which the scope of the patent test does—"reduces the uncertainty associated with investing in a new generic drug and, all else equal, increases generic manufacturers' incentives to invest in new drugs." Dickey & Rubinfeld, *supra*, at 624. And this "[i]ncreased competition from generic manufacturers leads to lower drug prices." *Id.*

Experience bears this out. When courts began to apply the scope of the patent test, the number of patent challenges increased dramatically: "a record 65 new first-to-file lawsuits [were filed] in 2009, up from 51 in the prior year and more than double the number just three years ago." RBC Capital Markets, *Pharmaceuticals: Analyzing Litigation Success Rates* 1 (Jan. 15, 2010). By contrast, in prior years, when settlements with monetary consideration were considered anticompetitive by certain courts, there were far fewer patent challenges. *See id.* In short, while the scope of the patent test promotes certainty and, with it, competition, FTC's proposed rule would reduce patent challenges and significantly harm consumers.

Apotex, an *amicus* supporting FTC, takes issue with the scope of the patent test and argues that FTC's proposed rule severely restricting settlements is justified because only one generic manufacturer has incentive to challenge a patent—the one that files the first ANDA with a Paragraph IV certification and is thereby eligible for a 180-day period of marketing exclusivity. Apotex also argues that provisions included in certain Hatch-Waxman settlements (referred to by Apotex by the misnomer "poison pill"), which permit a settling party to enter the market if any other party successfully challenges the patent, further disincentivize subsequent challengers. *See* Br. of Apotex, Inc. as *Amicus Curiae* Supporting Petitioner ("Apotex Br.") 7-21. But Apotex's arguments ignore the reality of Hatch-Waxman challenges and Apotex's own conduct.

As an initial matter, when a generic manufacturer makes the decision to devote resources

to develop a generic version of a branded drug, that manufacturer does not know which company will be the first to succeed and file an ANDA with a Paragraph IV certification—indeed, that is often discovered well *after* a Paragraph IV patent challenge is filed. But the generic manufacturer does understand, and takes into account, the probable costs of that challenge, including litigation. And, as explained above, if litigation costs increase (because settlement options are restricted), generic manufacturers will choose in some cases not to even attempt to develop a generic drug.[7]

But even if a generic manufacturer knew that it would not be the first Paragraph IV ANDA filer, that company would still be incentivized to challenge the branded company's patent. A subsequent filer, like a first-filer that is not sued by a branded company, can file a declaratory judgment action and trigger the first-filer's 180-day exclusivity period via the Hatch-Waxman Act's court-decision trigger, and thereafter launch its own generic product. Indeed, this is exactly what the Hatch-Waxman Act contemplates. *See, e.g.*, *Teva Pharm., USA, Inc. v. FDA*, 182 F.3d 1003, 1007-08 (D.C. Cir. 1999); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073-74 (D.C. Cir. 1998); *see also Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1294-96 (Fed. Cir. 2008). Numerous

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[7] Tellingly, Apotex has itself previously opined that "*[r]everse payments are not the cause of the settlement problem*." Apotex Inc., *Patent Settlements Between Brand and Generic Pharmaceutical Companies* 1 (2009) (emphasis in original), *available at* http://www.fdalawblog.net/files/apotex---parked-excl.pdf.

Hatch-Waxman cases are litigated between branded companies and generic companies that are not entitled to exclusivity.[8]

Moreover, Apotex's argument that such incentives are ineffective is belied by its own conduct. In the very case it references—*In re Modafinil*—Apotex was not one of the four first-filer generic manufacturers and the agreement contained a so-called "poison pill" provision; nevertheless, Apotex not only filed an ANDA, it later made a Paragraph IV patent challenge and filed a declaratory judgment action. *See* Apotex Br. 20. Likewise, as noted above, in the *Tamoxifen* and *Cipro* litigation, despite the fact that the first-filer entered into a settlement agreement, multiple other companies challenged the patents in court (and all subsequent challengers lost). *Tamoxifen*, 466 F.3d at 194-95; *Cipro Fed. Cir.*, 544 F.3d at 1328-29. In short, Apotex's arguments about incentives have no merit. Indeed, its real complaint is not with the settlement of litigation at all, but rather, with the operation of the Hatch-Waxman Act itself. But such allegations are not cognizable and are directed to the wrong forum. If Apotex dislikes the operation of the Hatch-Waxman regulatory regime, it must petition Congress, not the courts, to change it.

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[8] Furthermore, the term "poison-pill clause" is simply wrong. *See* Apotex Br. 17-18. The clause to which Apotex refers does no more than allow a settling generic company to enter the market *even earlier* than it otherwise could, thereby *increasing* the total number of competitors in the market if a patent is invalidated. Such clauses are the very definition of pro-competitive.

Ultimately, experience proves that the Hatch-Waxman regime is not broken, and the Court should reject FTC's flawed approach, which would reduce the incentives for generic manufacturers to bring patent challenges, reduce overall competition, and harm consumers.

CONCLUSION

For the foregoing reasons, the Court should affirm the decision below.

Respectfully submitted,

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