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 FOR MERCK & CO., INC. AS AMICUS CURIAE SUPPORTING RESPONDENTS

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BRIEF FOR MERCK & CO., INC.
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INTEREST OF AMICUS CURIAE

Merck & Co., Inc. (Merck),[1] is a global leader in health care, committed to improving health and well-being around the world. As a leading manufacturer of pharmaceutical products, Merck has a substantial portfolio of patents that protect its inventions. Merck has considerable experience not only with defending its pa-

[1] Pursuant to Rule 37.6, Merck affirms that no counsel for a party authored this brief in whole or in part; no such counsel or a party made a monetary contribution to fund its preparation or submission; and no person other than Merck or its counsel made such a monetary contribution. The parties have consented to the filing of this brief, and copies of their letters of consent are on file with the Clerk's Office.

tents in litigation within the framework of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), but also with defending settlements of patent litigation in subsequent antitrust litigation.

In particular, Merck and its predecessor Schering-Plough Corporation (Schering) have spent more than a decade defending against antitrust actions brought as a result of Schering's settlements of patent litigation involving the brand-name drug K-Dur 20 (K-Dur). Those actions included an administrative action filed by the Federal Trade Commission (FTC) and a number of subsequent actions filed by private plaintiffs. Remarkably, two federal courts of appeals applied divergent legal standards in considering the legality of those very same settlements. Compare *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006), with *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012). Merck has filed a petition for a writ of certiorari from the Third Circuit's decision, which is currently pending before this Court. See *Merck & Co., Inc.* v. *Louisiana Wholesale Drug Co.*, No. 12-245 (filed Aug. 24, 2012).

Merck respectfully submits that the K-Dur litigation serves as a useful case study for this Court to consider in determining the appropriate antitrust standard applicable to settlements of pharmaceutical patent litigation between brand manufacturers and generic manufacturers, where the settlement includes a payment from the brand manufacturer to the generic manufacturer. Specifically, the K-Dur litigation illustrates why the Court should take no comfort in the FTC's assurance that the "quick look" standard it proposes would leave parties in pharmaceutical patent litigation with a range of meaningful settlement options. Under the FTC's standard,

any settlement term other than an agreement to allow the generic manufacturer to enter the market before the expiration of the patent will potentially subject the manufacturers to the kind of multi-year, multi-front antitrust litigation that Merck has endured in the wake of the K-Dur settlements. In practice, therefore, the FTC's "quick look" standard will operate no differently from a per se prohibition on any settlement term other than an early entry date. The end result will be fewer efficient patent settlements and a less competitive and dynamic pharmaceutical industry.

SUMMARY OF ARGUMENT

In its opening brief, the Federal Trade Commission purports to reject a rule of per se condemnation of pharmaceutical patent settlements that involve payments from the brand manufacturer to the generic manufacturer, and to offer as an alternative the so-called "quick look" mode of antitrust analysis. The FTC asserts that, unlike the scope-of-the-patent standard advocated by respondents, the "quick look" standard would prohibit those payments that are truly anticompetitive while, at the same time, leaving parties to pharmaceutical patent litigation with a broader range of meaningful settlement options than would be available under a per se regime. But given how antitrust litigation in this context actually plays out in practice—something Merck is all too qualified to comment upon—there is no meaningful difference between the FTC's proposed standard and per se condemnation of settlements containing payments. Indeed, the FTC's standard would effectively amount to per se condemnation of settlements on *any* terms except an early entry date. This Court should reject the FTC's aggressive and overbroad approach and adopt the scope-of-the-patent standard instead. The

scope-of-the-patent standard is the only standard that is both workable and capable of bringing a measure of certainty to this area of the law.

A. The FTC acknowledges two "primary" exceptions that parties could invoke under its proposed standard to attempt to overcome the presumption that a settlement containing a payment is illegal. The first is when the payment is made in exchange for "bona fide fair consideration," such as a license for intellectual property owned by the generic, or raw materials supplied by it. The second is when the payment is commensurate with the litigation costs avoided by settlement.

B. The FTC conveys the impression that these exceptions would leave parties in pharmaceutical patent litigation with a range of meaningful settlement options. That is unlikely to be the case in practice, however—as Merck's own experience in the K-Dur litigation amply demonstrates. The settlement that became the focus of the K-Dur litigation contained a payment that seemingly fit neatly into the first of the FTC's "primary" exceptions. The FTC nevertheless viewed the settlement as anticompetitive and issued an administrative complaint in an effort to enjoin it. And even after years of litigation in the FTC administrative action—culminating in a court of appeals decision rejecting the FTC's position and upholding findings that the payment at issue was supported by fair consideration—the K-Dur litigation was far from over. Private plaintiffs picked up where the FTC left off, commencing another multi-year round of litigation that continues to this day. And if this Court were to adopt the FTC's proposed standard and deny Merck's currently pending petition for certiorari, the K-Dur litigation would continue, possibly for years to come.

C. Merck's experience with the K-Dur litigation teaches that, if this Court were to adopt the FTC's pro-

posed standard, parties will be deterred from entering into any pharmaceutical patent settlements that contain payments—or, indeed, any terms other than an early entry date. Even when parties structure their settlements to fit within one of the FTC's exceptions, those settlements will remain vulnerable to attack in follow-on antitrust litigation, which (as in Merck's case) could come in two waves: the first initiated by the FTC, and the second by private plaintiffs. By the FTC's own admission, parties to such settlements will ordinarily be unable to terminate follow-on antitrust litigation through motions to dismiss. They will therefore face the prospect of enormous and asymmetric discovery costs—with no guarantee that they will be able to prevail at the summary-judgment stage or beyond.

Moreover, in both private actions and FTC actions, parties inevitably will face the prospect of a "trial within a trial" on the merits of the underlying patent litigation. In addition to increasing the costs and burdens associated with follow-on antitrust litigation, such relitigation of the patent merits would defeat the very point of the settlement. Prudent parties will forgo running those risks and simply avoid entering into settlements that involve payments from the brand manufacturer to the generic manufacturer, even in cases in which the payment would seemingly qualify for one of the FTC's exceptions. And without the ability to use payments as one tool to facilitate settlements, the inevitable result will be fewer settlements of pharmaceutical patent disputes.

D. Finally, the FTC's proposed standard will do more than effectively prohibit settlements that contain actual payments. As the FTC's statements in other forums (if not before this Court) make clear, the FTC appears to take the position that any settlement term except an early entry date is presumptively illegal. The

scope of the FTC's proposed rule is therefore breathtaking. If Congress had intended such a rule in the Hatch-Waxman Act, one might reasonably expect Congress to have said so. It did not do so then, and has not done so since—notwithstanding the FTC's repeated efforts to convince Congress to amend the Act to include a provision prohibiting settlements containing payments. This Court should reject the FTC's request that it adopt a rule that the political branches have thus far rejected. Instead, it should reaffirm that, under established principles of patent and antitrust law, settlements that do not exceed the scope of the patent are ordinarily valid.

ARGUMENT

THIS COURT SHOULD REJECT THE FTC'S PROPOSED 'QUICK LOOK' STANDARD, WHICH IS FUNCTIONALLY EQUIVALENT TO A PER SE PROHIBITION OF A VAST RANGE OF SETTLEMENT TERMS

A. Under The FTC's Proposed Standard, Pharmaceutical Patent Settlements That Contain Payments Are Unlawful, Subject Only To Narrow Exceptions

1. The FTC correctly recognizes that it would be inappropriate to treat pharmaceutical patent settlements that contain payments as "categorically unlawful," on the ground that "per se condemnation would foreclose consideration of possible legitimate justifications for the payment or procompetitive potential that some such agreements may have." Br. 33. The FTC, however, proposes the closest thing to a per se standard: a "quick look" standard, under which a pharmaceutical patent settlement that contains a payment is presumptively unlawful unless the parties to the settlement can demonstrate that "any money that changed hands was for something other than a delay." Br. 37 (quoting *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012)).

The FTC acknowledges two "primary" exceptions that parties can invoke in an effort to overcome the presumption of illegality. The first is when the payment "reflect[s] bona fide fair consideration" for "the generic manufacturer's provision of property or services unrelated to the brand-name manufacturer's monopoly." Br. 37. Such collateral transactions are in fact relatively common. Brand and generic manufacturers interact with each other across a range of different markets; separate and apart from their shared interest in the drug at issue in the patent litigation, they will often have complementary business models and genuine needs for each other's goods and services. When the parties cannot agree on an entry date for the generic version of a brand-name drug, therefore, it will naturally make sense for them to explore ways of bridging their differences that involve collateral transactions. Those transactions may involve a payment by the brand manufacturer to the generic manufacturer "for [intellectual property] licenses, for the supply of raw materials or finished products, [or] for helping to promote products" licensed by the brand manufacturer to the generic. Michael A. Carrier, *Review: A Response to Seven Critics*, 61 Ala. L. Rev. 597, 613 (2010).

The second exception acknowledged by the FTC is when the payment is "commensurate with the litigation costs that the brand-name manufacturer avoided by settling." Br. 38. As with collateral transactions, payments commensurate with litigation costs can help to bridge the gap between the parties on the entry date for the generic version of a brand-name drug, thereby facilitating settlement. As even critics of payments from brand manufacturers to generic manufacturers have recognized, there is nothing objectionable about payments that do not exceed litigation costs, because "the parties would

have been required to spend this money in any event." Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 76-77 (2009).

2. By identifying those two categories of payments that would remain permissible under a "quick look" rule, the FTC seeks to create the impression that parties to pharmaceutical patent litigation would be left with a wide range of tools to effectuate settlement. At the same time, however, the FTC makes clear that, even if parties structure their settlements so as to fall squarely within one of the FTC's exceptions, there is no guarantee that the settlements will be upheld. With regard to the exception for collateral transactions, for instance, the FTC takes the position that there is "no fixed formula" for determining whether a settlement qualifies for that exception. Br. 37. Instead, a court reviewing such a settlement "would need to consider the totality of the circumstances surrounding the agreement," taking into account such amorphous and subjective factors as "whether other terms of the side transaction comported with industry standards"; "a history of demonstrated interest in or need for the property or services on the part of the brand-name manufacturer"; and "the course and content of the manufacturers' negotiations over the agreements." Br. 37-38.

And as Merck's own experience in the K-Dur litigation amply demonstrates, practice belies the FTC's promise. If this Court were to adopt the FTC's standard, it is certain that parties seeking to invoke the exceptions to the rule of presumptive illegality will face extreme skepticism from the FTC. And even if the parties are successful in warding off the FTC—either by convincing it not to take action or by defeating any action after it is filed—the parties will likely have to defend

against antitrust actions filed by private plaintiffs. As a practical matter, therefore, it will be too expensive, and carry too many uncertainties, for parties to pharmaceutical patent litigation seriously to consider settling on terms other than an early entry date—with the result that, in many cases, parties will be unable to reach settlement at all.

The FTC's "quick look" standard will therefore function in much the same way as a per se prohibition. It will limit the range of settlements of pharmaceutical patent litigation to precisely one type: settlements consisting solely of an early entry date for the generic drug.

B. The K-Dur Litigation Illustrates Why The FTC's Proposed Standard Will Operate As The Functional Equivalent Of A Per Se Prohibition

The K-Dur litigation provides a vivid example of the protracted ordeal that will await parties under the FTC's proposed standard if they seek to resolve pharmaceutical patent litigation on terms other than an early entry date. The settlement that was the focus of the litigation included a payment that seemingly fit neatly into the FTC's first "primary" exception to the rule of presumptive illegality. As part of its settlement of patent litigation with the generic manufacturer Upsher-Smith Laboratories (Upsher), Schering agreed to pay Upsher $60 million payment for international rights to Upsher's promising cholesterol drug, Niacor-SR.

Schering presented substantial evidence that the payment served its stated purpose and was not a so-called "reverse payment" in disguise. Schering had a documented, preexisting interest in acquiring a sustained-release niacin drug such as Niacor-SR. In order to ensure that the Niacor-SR license was purchased for fair value, Schering had an employee with no knowledge of the patent litigation evaluate the drug's sales poten-

tial—and that employee determined that the value of the license was *four times* what Schering ultimately paid. The FTC nevertheless viewed the Upsher settlement as anticompetitive and issued an administrative complaint in an effort to enjoin it. And even after years of litigation in the administrative action—in which the parties to the settlement prevailed first before an administrative law judge and again before the Eleventh Circuit—the K-Dur litigation was far from over. Private plaintiffs picked up where the FTC left off, commencing another multi-year round of litigation that continues to this day—and that promises to continue into the future if this Court adopts the FTC's proposed standard. The history of the K-Dur litigation warrants tracing in some detail, because it demonstrates why the FTC's promise that some payments will remain permissible is entirely illusory.

1. Schering began developing K-Dur nearly thirty years ago as a treatment for potassium deficiency. In 1989, the Patent and Trademark Office issued a patent for the formulation of K-Dur. FDA subsequently approved Schering's application for K-Dur, and the drug became a commercial success. Pursuant to the Hatch-Waxman Act, Upsher filed an application with FDA for a generic version of K-Dur; in connection with that application, Upsher contended that Schering's patent for K-Dur was invalid and would not be infringed by their generic versions. Schering responded by filing a patent-infringement action against Upsher. See *In re K-Dur Antitrust Litig.*, Civ. No. 01-1652, 2009 WL 508869, at *4, *6-*8 (D.N.J. Feb. 6, 2009).

Upsher and Schering litigated fiercely, with extensive discovery over an eighteen-month period. Just hours before the trial was scheduled to begin, the parties reached a settlement. Under the terms of that settlement, Schering granted Upsher a license to market a

generic version of K-Dur starting on September 1, 2001, some five years before the expiration of the patent. Schering also agreed to pay Upsher $60 million over three years (plus additional amounts contingent on sales) for international rights to Niacor-SR. See *K-Dur*, 2009 WL 508869, at *6-*8.

2. The litigation over the validity of the Upsher settlement began in 2001, when the FTC issued an administrative complaint against Schering and Upsher.[2] The FTC alleged that their settlement constituted an unfair method of competition in violation of Section 5 of the FTC Act, 15 U.S.C. 45. The FTC's theory was that the settlement was invalid because the $60 million royalty payment was designed to "induce [the generic manufacturers] to agree to delay launching generic versions of K-Dur" and thus to "protect[] [Schering] from competition in the relevant markets." Compl. at 9, *In re Schering-Plough Corp.*, F.T.C. Dkt. No. 9297 (Mar. 30, 2001).

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[2] The FTC also sought to enjoin a second K-Dur-related settlement involving ESI-Lederle (ESI), a generic manufacturer that filed its application for approval after Upsher. Under the terms of that settlement, Schering granted ESI a license to market a generic version of K-Dur starting on January 1, 2004. At the urging of the federal magistrate judge who oversaw a court-ordered mediation of the dispute, Schering also agreed to pay $5 million to ESI, which the magistrate described as "nothing more than legal fees," plus an additional sum of up to $10 million contingent upon FDA approval. See *K-Dur*, 2009 WL 508869, at *9-*10. Although the payment to ESI seemingly implicated the second of the FTC's "primary" exceptions (for payments commensurate with litigation costs), and although the FTC itself admitted that there was "relatively limited evidence" that the ESI settlement was anticompetitive, the FTC nevertheless challenged the settlement along with the Upsher settlement. *In re Schering-Plough Corp.*, 136 F.T.C. 956, 1056 (2003). Before trial, the FTC entered into a settlement with American Home Products, ESI's parent. *Id.* at 962.

After the filing of the complaint, the parties engaged in months of intense and costly discovery and proceeded to trial before an administrative law judge (ALJ). The trial lasted nine weeks, with the trial transcript covering some 8,289 pages; the ALJ admitted thousands of exhibits into evidence and heard testimony from 41 fact and expert witnesses.

Rejecting the "emotional appeal" made by the FTC at trial, the ALJ ruled in the manufacturers' favor and dismissed the complaint. *In re Schering-Plough Corp.*, 136 F.T.C. 1092, 1096 (2002). In a detailed, 177-page opinion, the ALJ, applying a rule-of-reason standard, concluded that the FTC had failed to prove that "the challenged agreements had the effect of injuring competition." *Id.* at 1234. Critically for present purposes, the trial focused on whether the collateral transaction involving Niacor-SR was a bona fide, economically rational transaction, or a sham transaction with no meaningful consideration. The FTC's chief expert witness conceded that, if Schering had purchased Niacor-SR for "fair value," it would not raise competitive concerns. *Id.* at 1135.

The ALJ first determined that there was no evidence that, but for the Niacor-SR transaction, the parties would have agreed on an earlier entry date. The earliest entry date to which Schering was willing to agree was September 1, 2001. Upsher was unwilling to agree to a settlement consisting solely of that early entry date, because it was experiencing serious cash-flow problems and needed cash in order to remain competitive in the pharmaceutical market. The ALJ determined that the collateral transaction was necessary in order to bridge the gap between the parties' settlement positions; without that transaction, the ALJ found, the parties would have proceeded to trial. See 136 F.T.C. at 1122-1125, 1134-1135, 1250-1252.

The ALJ then determined that the collateral transaction involving Niacor-SR was a legitimate, fair-value transaction. In so doing, the ALJ made a number of relevant factual findings:

- Schering told Upsher during the negotiations that it was willing to consider a collateral transaction involving Niacor-SR, but that it would need to be an "arm's length" transaction that could "stand on [its] own two feet." 136 F.T.C. at 1124.
- Consistent with Schering's desire to enter into an "arm's length" transaction, Schering assigned the task of valuing the Niacor-SR license to an executive in Schering's global marketing unit, who, according to the ALJ, was "unaware that the Niacor opportunity had any connection to a patent suit." *Id.* at 1126. The executive ultimately concluded that the license would be worth more than $100 million in annual sales, for a total (at net present value) of $225 million to $265 million to Schering—roughly four times what Schering ultimately paid. *Id.* at 1126, 1132-1133, 1160.
- The executive's analysis was consistent with that of an internal Upsher report—prepared before the K-Dur patent litigation commenced—which stated that Niacor-SR was a "highly valued asset" with the potential for annual sales of $100 million to $400 million. *Id.* at 1139.
- Before entering into the settlement with Upsher, Schering had explored a deal with Kos Pharmaceuticals (Kos) for the rights to Niaspan, a sustained-release niacin drug nearly identical to Niacor-SR. The negotiations between Kos and Schering over Niaspan broke down only weeks

before Upsher offered the Niacor-SR license to Schering. A Schering sales forecast projected that annual sales of Niaspan could reach $134 million; an independent Wall Street analyst report estimated that annual sales could exceed $240 million. *Id.* at 1140-1141, 1147.

- The Niacor-SR license was contingent on approval from Schering's board. The board concluded that the transaction was "an agreement that would make sense in and of itself independent of anything else." *Id.* at 1133.

3. Notwithstanding the ALJ's detailed findings, the FTC reversed the ALJ's decision. *In re Schering-Plough Corp.*, 136 F.T.C. 956 (2003). The FTC held that the ALJ had erred by applying the rule-of-reason standard. *Id.* at 966. In the FTC's view, "[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for [a] payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *Id.* at 988 (footnote omitted).

In invalidating the settlement between Schering and Upsher, the FTC attacked the ALJ's determination that the collateral transaction involving Niacor-SR was a legitimate, fair-value transaction. To begin with, the FTC nitpicked Schering's contemporaneous valuation of the Niacor-SR license: the FTC noted that Schering personnel had hypothesized reasons why the market for niacin-releasing drugs might be smaller than originally thought, and it questioned whether the Schering executive tasked with the valuation analysis (who held an advanced degree in pharmacology) had adequately taken into account concerns about the safety and efficacy of

niacin-releasing drugs. See 136 F.T.C. at 1020-1022, 1151.

The FTC's determination that the collateral transaction involving Niacor-SR was a sham, however, was primarily driven by the "[i]nferences" that it claimed could be drawn from Schering's *post-settlement* conduct. See 136 F.T.C. at 1041. The settlement between Schering and Upsher took place on June 18, 1997. The evidence presented at trial showed that Schering personnel spent much of the summer of 1997 laying the groundwork to begin marketing Niacor-SR in Europe. In November 1997, however, Kos announced the results from the first full quarter of sales for Niaspan. Those results were disappointing—so much so that it caused Kos's share price to plummet to $5 per share, down from a high of $44. Schering understandably decided to put the launch of Niacor-SR "on hold," and ultimately never pursued it. See *id.* at 1163-1164.[3]

Even though there was a rational explanation for Schering's decision to suspend the Niacor-SR launch, the FTC seized upon that decision as evidence that Schering's *pre-settlement* conduct was nothing more than an elaborate ruse, designed to disguise the fact that the payment was being made for the purpose of restraining trade. See 136 F.T.C. at 1051.

4. The Eleventh Circuit vacated the FTC's order. *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (11th Cir.

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[3] As it turned out, Schering's sales projections for the market for sustained-release niacin drugs ultimately proved to be too low, rather than too high. Despite its disappointing launch, Niaspan proved to be a blockbuster drug, with annual sales of $600 million by 2008. In 2006, Abbott Laboratories purchased Kos—which was essentially a one-product company—for over $3 billion. See C.A. App. at 191, 1269, 1281, *K-Dur*, *supra*.

2005). Disagreeing with the FTC on the appropriate legal standard, the court concluded that "the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* at 1066. The court proceeded to determine that the record did not contain substantial evidence to support the conclusion that "the challenged agreements restrict competition beyond the exclusionary effects of [Schering's] patent." *Id.* at 1068.

The Eleventh Circuit did not stop there, however. It proceeded to criticize the FTC's factual determinations—and, in particular, its determinations regarding the Niacor-SR transaction. The court noted the evidence in the trial record that "Schering personnel evaluated Niacor, and forecast its profit stream with a net present value of $225-265 million"—a figure that far exceeded the amount of the royalty payments. See 402 F.3d at 1068-1069. The court also noted the evidence that "Schering had a long-documented and ongoing interest in licensing an extended-release niacin product." *Id.* at 1069. By contrast, the court viewed the evidence on which the FTC had relied in reaching its contrary determination as "forced," "unconvincing," and "meretricious." *Id.* at 1070.

Of note here, the Eleventh Circuit indicated that it was "troubled" by the inferences the FTC drew from Schering's post-settlement conduct. See 402 F.3d at 1069. The court described the expert testimony on which the FTC relied as an "unpersuasive appraisal" of Schering's post-settlement conduct that "blatantly ignored the parties' ongoing communications and the fact that the

niacin market essentially bottomed out" after the settlement was concluded. *Ibid.*[4]

The FTC filed a petition for certiorari. After the United States filed a brief opposing the petition, this Court denied review. 548 U.S. 919 (2006).

5. The Court's order denying certiorari brought the FTC administrative action to a close, some five years after it started. But it was by no means the end of the K-Dur story. Private plaintiffs filed a number of follow-on antitrust actions against Schering and Upsher. The Judicial Panel on Multidistrict Litigation transferred those actions filed in other districts to the District of New Jersey. As matters currently stand, there are three pending private actions, including a certified class action filed by direct purchasers of K-Dur. All of the complaints allege that, by virtue of the payment, Schering's settlement with Upsher constituted an unlawful restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

Much as in the FTC action, the parties engaged in eighteen months of intensive, costly discovery, involving numerous depositions and the production of millions of pages of documents. At the close of discovery, Schering and Upsher filed motions for summary judgment, which were referred to a special master. "[A]ppl[ying] an analysis consistent with the approach" taken by the Eleventh Circuit in the FTC proceedings, the special master rec-

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[4] A former official in the FTC's Bureau of Competition voiced similar criticism of the FTC's reliance on Schering's post-settlement conduct. As he put it, "[t]he legality of the settlement agreement should be tested by the facts as they appeared when the agreement was made and not by subsequent events." M. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 Geo. Mason L. Rev. 359, 398 (2002).

ommended that the motions be granted. *K-Dur*, 2009 WL 508869, at *27. He determined that "there is no evidence that any * * * aspects of the settlement exceeded the exclusionary scope of [Schering's] patent." *Ibid.*

The district court adopted the special master's report and recommendation and granted summary judgment to Schering and Upsher. See *In re K-Dur Antitrust Litig.*, Civ. No. 01-1652, 2010 WL 1172995 (D.N.J. Mar. 25, 2010).

6. The Third Circuit reversed in relevant part and remanded, creating a circuit conflict by becoming the first court of appeals to adopt the "quick look" standard. See *K-Dur*, 686 F.3d at 218. The court held that any pharmaceutical patent settlement that includes a payment from the brand manufacturer to the generic manufacturer is presumptively invalid, with the manufacturers bearing the burden of showing that the payment "was for a purpose other than delayed entry" or "offers some pro-competitive benefit." *Ibid.*

The K-Dur litigation therefore persists to this day—some sixteen years after the initial settlement between Schering and Upsher; twelve years after the FTC issued its administrative complaint; and six years after the patent for K-Dur actually expired. And if this Court were to adopt the FTC's proposed standard and deny Merck's petition for certiorari, the K-Dur litigation would continue, possibly for years to come. The district court would presumably conduct another round of briefing on renewed motions for summary judgment, in which Merck and Upsher would argue that they are entitled to invoke the exception for payments that are supported by fair consideration. Any order on those motions would likely be followed by yet another appeal to the Third Circuit. And if Merck and Upsher do not prevail on their mo-

tions, the case would be set for trial—potentially two decades after the settlement at issue was executed.

* * * * *

The moral of the K-Dur story is that, under the FTC's proposed standard, parties to pharmaceutical patent settlements that contain payments will likely face multiple rounds of costly and burdensome antitrust litigation. As we will explain in the next section, that will be true even where, as here, the parties have compelling evidence that the payment at issue falls within one of the FTC's exceptions to its rule of presumptive illegality. Entering into a settlement that subjects the parties to costly and uncertain antitrust litigation in the future defeats the very point of settlement, which is to achieve a complete and final resolution of the controversy at hand. For that reason, most parties will avoid entering into settlements on terms other than an early entry date—with the net result that pharmaceutical patent litigation will be much harder to resolve before trial. In practice, therefore, the FTC's standard will function in the same manner as the per se rule that the FTC purports to forswear—and that this Court has historically been "reluctan[t] to adopt." *State Oil Co.* v. *Khan*, 522 U.S. 3, 10 (1997).

C. Faced With The Prospect Of Protracted Litigation Like The K-Dur Litigation, Parties To Pharmaceutical Patent Settlements Will Avoid Entering Into Settlements That Involve Payments

Should this Court adopt the FTC's proposed standard, parties will be deterred from entering into pharmaceutical patent settlements that contain payments—or, indeed, any terms other than an early entry date. The practical consequence of such a standard will be to ren-

der it impossible to reach settlements in a substantial amount of pharmaceutical patent litigation.

1. To begin with, parties that enter into settlements containing payments will have to reckon with the FTC—which, as the K-Dur litigation demonstrates, has historically taken a dim view of such settlements, even in the face of overwhelming evidence that the payment is not anticompetitive. Particularly in light of the FTC's amorphous, totality-of-the-circumstances test for determining whether an exception to the rule of presumptive illegality has been satisfied, parties will never have any confidence that a settlement containing a payment will be acceptable to the FTC. And as the K-Dur litigation amply illustrates, if the FTC ultimately seeks to enjoin the settlement, the ensuing litigation burden will be substantial, even where the parties have compelling evidence that their settlement involves one of the categories of payments that would purportedly remain permissible under a "quick look" rule. See pp. 11-17, *supra*.

2. Whether or not the FTC takes action, parties that enter into settlements containing payments will face the prospect of antitrust actions filed by private plaintiffs. Notably, the FTC seemingly takes the position that, under its proposed "quick look" standard, the mere allegation that a pharmaceutical patent settlement contains a payment from the brand manufacturer to the generic manufacturer will be sufficient for a complaint to survive a motion to dismiss. See Br. 55-56. Such an allegation is all that would be needed to establish the presumptive illegality of the settlement—and therefore that the plaintiffs' allegation that the defendants unlawfully restrained trade is a "plausible" one. See *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 544, 565-566 (2007); cf. Mark Anderson & Max Huffman, *'Iqbal,' 'Twombly,' and the Expected Cost of False Positive Error*, 20 Cornell J.L. &

Pub. Pol'y 1, 38 (2010) (contending that, under the "quick look" standard, "the plaintiff's initial burden * * * is merely to demonstrate the existence of a suspect agreement").

The "naked assertion[]" that a settlement contains a payment would therefore be sufficient to "unlock the doors of discovery." *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678-679 (2009) (citation omitted). And the prospect of discovery is a particularly frightening one for defendants in private antitrust actions, where the costs of discovery are enormous and asymmetric.

This Court has previously noted the "unusually high cost of discovery in antitrust cases." *Twombly*, 550 U.S. at 558. That is because antitrust actions typically involve "voluminous documentary and testimonial evidence, extensive discovery, complicated legal, factual, and technical (particularly economic) questions, numerous parties and attorneys, and substantial sums of money." *Manual for Complex Litigation* § 30, at 519 (4th ed. 2004). Those burdens are only magnified where, as here, the court has certified a class of plaintiffs; one court has described antitrust class actions as "arguably the most complex action[s]" to litigate. *In re Linerboard Antitrust Litig.*, 296 F. Supp. 2d 568, 577 (E.D. Pa. 2003) (citation omitted). In such a case, the defendants can reasonably expect to be forced to defend scores of depositions of their personnel and to produce millions of pages of documents, whereas the named plaintiffs would need to do little more than to establish that they purchased the drug in question.

Because of the enormous and asymmetric costs of discovery in antitrust actions, parties contemplating settlements that contain payments will know that, if they enter into those settlements, they will likely have to make additional payments—to antitrust plaintiffs and

their lawyers. In the antitrust context, this Court has recognized that "the threat of discovery expense will push cost-conscious defendants to settle even anemic cases before reaching" the summary-judgment or trial stage. *Twombly*, 550 U.S. at 559. In the face of such enormous and asymmetric costs—to say nothing of the prospect of treble damages—most defendants will succumb to what Judge Friendly aptly termed "blackmail settlements." Henry J. Friendly, *Federal Jurisdiction: A General View* 120 (1973). And the irony of the FTC's approach is that fear of the costs of subsequent *antitrust* litigation will prevent parties from entering into efficient settlements of *patent* litigation, thus generating unnecessary litigation costs that will be passed on to consumers of brand and generic drugs alike.

3. Even if they are willing to endure the burdens of discovery, parties that enter into settlements containing payments will face uncertain prospects at the summary-judgment stage and beyond. For starters, given that "quick look" analysis places the burden on the *defendant* to establish that the conduct in question was procompetitive, a defendant's chances of prevailing at the summary judgment stage will be inherently more uncertain under the FTC's rule than in a typical antitrust case. To be sure, there will be some cases like the K-Dur litigation, in which the parties will be armed with compelling evidence to satisfy that burden. But in many other cases, it will be difficult for the parties to assess whether they will be able to prevail under the FTC's amorphous, totality-of-the-circumstances test for determining whether one of the exceptions has been satisfied. That is particularly true to the extent that the FTC's test ultimately requires an inquiry into the parties' intent at the time they entered into the settlement. See, *e.g.*, Br. 37 (suggesting that the relevant inquiry is whether "any

money that changed hands was *for* something other than a delay") (emphasis added; citation omitted).

At a minimum, the FTC's test would require an *ex post* analysis of whether the consideration provided in a collateral transaction was "fair," or whether the amount of a particular payment was "commensurate" with litigation costs. Br. 37, 38. The FTC itself has previously recognized that such *ex post* analysis "places parties contemplating settlement in the predicament of not knowing, at the time of settlement, whether particular settlement terms will appear unreasonable to a future antitrust tribunal." Pet. Supp. Br. at 4, *FTC* v. *Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273). And that uncertainty is only exacerbated by the fact that the *ex post* analysis will occur years, if not decades, after the settlement is reached. With regard to a collateral transaction, the value of the transaction may look very different in hindsight than it did at the time it was executed. If a brand manufacturer obtains a license from a generic manufacturer but the drug turns out to be unsuccessful, or the brand decides not to pursue it due to unforeseen changes in the market or the emergence of superior business opportunities, the parties to the settlement will run the risk that bad business judgment will be confused with an unlawful restraint of trade. See M. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 Geo. Mason L. Rev. 359, 398-399 (2002). Yet that is precisely what happened when the FTC sought to invalidate the settlement between Schering and Upsher based on Schering's subsequent decision to suspend the Niacor-SR launch. See pp. 14-15, *supra*.

4. One further point bears emphasis. The FTC concedes that any antitrust standard that would force the parties to litigate the merits of the underlying patent

dispute would be highly problematic. See Br. 54-55. As the court of appeals in this case noted, "deciding a patent case within an antitrust case about the settlement of the patent case" is an "[un]palatable" "turducken task." Pet. App. 36a. Inquiry into the patent merits "defeat[s] the point of settlement," Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 Tex. L. Rev. 283, 288 (2012), because it ensures that the parties simply "trad[e] the uncertainty of the outcome of the patent litigation, based on the patent merits, for the uncertainty of the outcome of the antitrust litigation, based again on the patent merits," Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 33-34 (2005).

Although the FTC acknowledges the problems with litigating the merits of the underlying patent action in a subsequent antitrust action, the FTC suggests in a footnote that "[q]uantification of damages in a private antitrust action might require an assessment of what sequence of events would likely have ensured in the absence of [the] payment." Br. 55 n.11. Notably, so too do the plaintiffs in the K-Dur litigation, in an amicus brief filed in this case. See Louisiana Wholesale Drug Co. Br. 33 (noting that "nothing would prohibit plaintiffs in an appropriate case from offering evidence of the outcome of the patent litigation but for the * * * payment").

It is far from clear exactly how a court would go about assessing the merits of the underlying patent litigation in a subsequent antitrust action; after all, by virtue of the settlement, the patent merits were never litigated to conclusion, and may not have been litigated extensively. What is clear, however, is that any consideration of the patent merits will inevitably add still more

complexity to the antitrust action. See Pet. 31 (noting that, in the briefing below in the K-Dur litigation, the parties had "addressed at length complex matters of chemistry and patent doctrine" relevant to the generic manufacturers' defense of noninfringement). And to the extent the patent merits are relevant at trial, it will permit plaintiffs to seek discovery relevant to the patent merits from defendants, thus exacerbating the asymmetric burdens of the discovery process. See pp. 21-22, *supra*. Resolving patent issues in this context will be all the more complicated because of the length of time that likely will have passed between the filing of the patent application and the commencement of the antitrust litigation.

Curiously, at the same time the FTC suggests that the patent merits may be relevant at the damages stage of a subsequent antitrust action, it takes the position that they are irrelevant at the liability stage. See Br. 53-54. But it is difficult to see why. Under the "quick look" standard of antitrust review—at least as it is ordinarily understood—the defendant may rebut the presumption that conduct of a particular type is anticompetitive by offering evidence "suggesting that the challenged restraint is 'justified' in that it * * * in fact increases output or reduces price." 11 Herbert Hovenkamp, *Antitrust Law* ¶ 1991, at 335-336 (3d ed. 2011). Indeed, it is the ability to do so that differentiates the "quick look" standard from a standard of per se condemnation. And the most direct way for a brand defendant to demonstrate that there will be no adverse effects on competition from a settlement containing a payment will be to show that it would have prevailed in the underlying patent litigation. See, *e.g.*, Gregory Dolin, *Reverse Payments as Patent Invalidity Signals*, 24 Harv. J.L. & Tech. 281, 284 (2011). By attempting to disable defend-

ants from making such a showing at the liability stage, the FTC makes clear that its "quick look" standard is a per se standard in all but name.

In sum, given the many risks of defending pharmaceutical patent settlements that contain payments from brand manufacturers to generic manufacturers, prudent parties will forgo running those risks and avoid including payments in settlements going forward. As a practical matter, therefore, the FTC's proposed standard will effectively take the option of including payments in settlements off the table.

D. The FTC's Proposed Standard Will Effectively Prohibit Not Only Payments, But Also A Vast Range Of Other Settlement Terms

Finally, the FTC's proposed standard will do more than effectively prohibit settlements that contain actual payments. It will similarly affect a broad array of other settlement terms, leaving only one type of settlement that can unambiguously pass antitrust muster: a settlement consisting solely of an early entry date for the generic drug.

1. In its brief before this Court, the FTC is coy about what, in its view, constitutes a "payment" triggering the rule that "reverse-payment agreements" are "presumptively unlawful." See, *e.g.*, Br. 19. The FTC has been more forthright, however, in other forums. In a recent amicus brief filed in district-court litigation shortly after the Third Circuit's decision in the K-Dur litigation, the FTC took the position that its "quick look" standard should apply not only to settlements that contain *actual* payments from the brand manufacturer to the generic manufacturer, but also to settlements that contain any term that "[f]unctions as a [p]ayment." See FTC Br. at 5, *In re Effexor XR Antitrust Litig.*, Civ. No. 11-5479 (D.N.J.) (filed Aug. 10, 2012). In the settlement

at issue in that case, no payment changed hands; the brand manufacturer simply agreed that it would not launch an authorized generic version of the drug during the generic manufacturer's 180-day period of exclusivity, thereby allowing the generic manufacturer to take advantage of the exclusivity period it already possessed as the first filer under the Hatch-Waxman Act. The FTC nevertheless took the position that the brand manufacturer's agreement not to launch its authorized generic version during that exclusivity period was the functional equivalent of a payment from the brand manufacturer to the generic manufacturer. See FTC Br. at 5-11, *Effexor*, *supra*.

Similarly, in a recent review of pharmaceutical patent settlements, the FTC took the position that royalty payments made *from* a generic manufacturer *to* a brand manufacturer could trigger the rule of presumptive illegality, where the settlement at issue provided that the royalties would be eliminated or reduced upon the brand manufacturer's launch of an authorized generic version. See FTC, *Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in Fiscal Year 2010: A Report by the Bureau of Competition* 1 (May 2011). The FTC has therefore taken the position that its rule purportedly concerning "reverse payments" applies in cases involving payments from brand manufacturers to generic manufacturers; payments from generic manufacturers to brand manufacturers; and no payments at all.

In order to understand the breadth of the FTC's position, one has to read between the lines of the FTC's brief. At one point, the FTC states that "[t]he extraordinary and distinguishing feature of reverse-payment agreements * * * is that the defendant generic manu-

facturers receive something * * * that they could not hope to obtain even if they *prevailed* in the litigation." Br. 30. The sole remedy that a generic manufacturer obtains if it prevails in patent litigation under the Hatch-Waxman Act, however, is the ability to enter the market earlier: *i.e.*, upon FDA approval (and expiration of any applicable exclusivity period), rather than upon the subsequent expiration of the patent. The inevitable implication of that statement, therefore, is that any settlement term except an early entry date is presumptively illegal.[5]

If that is really the FTC's position, it should at least have the courage of its convictions and explicitly say so, without forcing readers to take out their decoder rings. But it is perhaps not surprising that the FTC does not wish to expose the breathtaking scope of its proposed rule. Citing not a statutory provision but a law-review

[5] The breadth of the FTC's position is pernicious for an additional reason. If all that is required to trigger the rule of presumptive illegality is that the generic manufacturer "receive something," it would have the effect of shifting the burden to the defendants even as to cases in which no *net* consideration passes from the brand manufacturer to the generic manufacturer—*e.g.*, cases in which the generic manufacturer receives a payment, but the brand manufacturer receives fair consideration in return. The government has long recognized that settlements of that type are procompetitive. See, *e.g.*, U.S. Br. at 9, *Andrx Pharm., Inc.* v. *Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779). In the event this Court were to adopt some version of the "quick look" standard, it should make clear, at a minimum, that the rule of presumptive illegality is triggered only where the generic manufacturer receives net consideration—and that the plaintiff bears the burden of proving that the rule has in fact been triggered. See, *e.g.*, *United States* v. *Arnold Schwinn & Co.*, 388 U.S. 365, 374 n.5 (1967). In many cases, plaintiffs will be unable to meet that burden. Cf. *Schering-Plough*, 402 F.3d at 1071 (determining that "[t]here is nothing to refute" the proposition that Schering paid a "fair price" for the rights to Niacor-SR).

article (which, in turn, cites nothing at all), the FTC contends that the Hatch-Waxman Act "reflect[s] a strong congressional policy that favors testing the scope and validity of pharmaceutical patents, with a view to realizing the benefits of generic competition at the earliest appropriate time." Br. 30-31 (citing C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1614 (2006)). It is certainly true that the Hatch-Waxman Act provides a mechanism for the litigation of patent disputes before a generic manufacturer brings its product to market. See 21 U.S.C. 355(j)(5)(B)(iii); 35 U.S.C. 271(e)(2)(A). But that is as far as the Hatch-Waxman Act actually goes. Notably absent from the Hatch-Waxman Act is any provision that makes it presumptively illegal to enter into *settlements* of such litigation unless the settlements are based solely on an early entry date.

It is for that reason that the FTC has repeatedly, and unsuccessfully, asked Congress to amend the Hatch-Waxman Act to include a provision prohibiting settlements containing payments from brand manufacturers to generic manufacturers. See, *e.g.*, FTC, *Prepared Statement Before the Sen. Special Comm. on Aging on Barriers to Generic Entry* 20 (July 20, 2006) <tinyurl.com/ftcbarriers>. Now it asks this Court to adopt, by judicial fiat, a rule that is at least as broad as, if not broader than, the rule the political branches have refused to adopt—a rule that would effectively prohibit pharmaceutical patent settlements on any terms except early entry, and thereby render it impossible to reach settlements in a substantial amount of pharmaceutical patent litigation. This Court should reject the FTC's aggressive and overbroad approach to pharmaceutical patent settlements. Instead, it should reaffirm that settle-

ments that do not expand the scope of the patent are ordinarily valid under established principles of patent and antitrust law.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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