

Supreme Court US.
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No. 12-416

IN THE
Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,

v.

WATSON PHARMACEUTICALS, INC., ET AL.,
Respondents.

**On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Eleventh Circuit**

**BRIEF FOR RESPONDENT
SOLVAY PHARMACEUTICALS, INC.**

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QUESTION PRESENTED

Whether the settlement of bona fide Hatch-Waxman patent litigation in which the accused generic infringer is licensed to come to market before the expiration of the brand-name drug company's patent and which does not exceed the exclusionary potential of the patent is not rendered presumptively illegal merely because it also includes a business deal that is alleged to provide additional value to the accused infringer.

RULE 29.6 STATEMENT

Respondent Solvay Pharmaceuticals, Inc., now known as AbbVie Products LLC, is a wholly owned indirect subsidiary of Abbott Laboratories. No person beneficially owns 10% or more of the outstanding shares of Abbott Laboratories.

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--	---

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**BRIEF FOR RESPONDENT
SOLVAY PHARMACEUTICALS, INC.**

Respondent Solvay Pharmaceuticals, Inc. (Solvay) respectfully acquiesces in the petition for a writ of certiorari. Because this case is a better vehicle for resolving the circuit split than is the *K-Dur* case (Nos. 12-245 and 12-265), Solvay agrees with the FTC that the Court should grant certiorari in this case rather than in *K-Dur*. Alternatively, Solvay respectfully suggests that the Court grant certiorari in both cases.

INTRODUCTION

The FTC's petition identifies a clear circuit split on an issue of national importance. Although Solvay believes that the decision below by the Eleventh Circuit was correct, and thus disagrees with the FTC on the merits, Solvay agrees that the petition should be granted.

This case presents the question whether holders of some types of pharmaceutical patents have fewer rights to enforce their patents than do other patentees, merely because their patents cover new pharmaceuticals. Here, the manufacturer of an innovative drug covered by a patent expiring in 2020 sued would-be generic manufacturers for infringement. That bona fide dispute was settled, after years of hard-fought litigation, by splitting the remaining patent term: the innovator licensed the would-be generic manufacturers to market their allegedly infringing products five years early, in 2015, and the generic manufacturers agreed to respect the patent and not launch their allegedly infringing drugs until then. The FTC does not quarrel with this patent term split. Rather, the FTC contends that the

settlement should be presumed anticompetitive solely because the parties also simultaneously entered into promotion and manufacturing agreements.

In the decision below, the Eleventh Circuit held, in agreement with every appellate court that had confronted this issue, that this litigation settlement did not violate the antitrust laws' prohibition of unreasonable restraints of trade because the patent had the *potential* to exclude the allegedly infringing generic competition from the market for five years longer than the settlement will. In other words, the only supposed anticompetitive effect of the settlement—restricting allegedly infringing competition until 2015—is within the rights granted by issuance of the patent. This holding correctly reflected the exclusionary right that is at the heart of a presumptively valid patent.

Since then, however, the Third Circuit has articulated a directly contrary rule, holding in a different case that a settlement of Hatch-Waxman patent litigation that is accompanied by a “payment” presumptively violates the antitrust laws and subjects the settling parties to treble-damage liability. The impact of the Third Circuit’s decision will be enormous because the FTC and private plaintiffs can choose to bring many antitrust challenges to pharmaceutical patent settlements within the Third Circuit. That decision threatens to slow the development of both innovative products and low-cost generics. The decision also creates the potential for massive and punitive liability based upon conduct that, when taken, had been sanctioned by the federal courts. This issue warrants this Court’s intervention. The FTC’s petition should be granted.

STATEMENT OF THE CASE

1. Unimed Pharmaceuticals, Inc. (Unimed), which Solvay has since acquired, and its joint-development partner, Besins Healthcare, S.A. (Besins), invented AndroGel and discovered through years of clinical testing that AndroGel is a safe and effective treatment for men who suffer from symptoms of low testosterone. AndroGel has been available since 2000, when the FDA approved Unimed's New Drug Application (NDA). Second Amended Complaint (Complaint) ¶¶ 31-33. In January 2003, the U.S. Patent and Trademark Office (PTO) issued U.S. Patent No. 6,503,894 ('894 patent), which expressly discloses the AndroGel formulation. The patent expires in August 2020. *Id.* ¶¶ 39-43. AndroGel has become a great medical and commercial success, providing needed treatment to millions of patients and generating nearly \$875 million in sales in 2011.¹

2. Although Unimed invested significant time and money establishing in clinical trials that AndroGel is safe and effective, a manufacturer seeking to introduce a generic version of AndroGel need not do so. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly called the Hatch-Waxman Act, changed the law to permit a generic manufacturer to obtain FDA approval by filing an Abbreviated New Drug Application (ANDA) relying on the innovator's proprietary clinical trial data to establish safety and efficacy, as long as the generic manufacturer shows that its proposed drug has the same active ingredient

¹ Abbott Labs., *2011 Annual Report* 52, www.abbott.com/static/content/microsite/annual_report/2011/downloads/Abbott_AR2011_Full.pdf.

as and is bioequivalent to the innovator drug. 21 U.S.C. § 355(j)(2)(A) (2000); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011).² Companies thus can develop generic drugs much more quickly and cheaply than if they had to conduct their own clinical trials. *PLIVA*, 131 S. Ct. at 2574.

The Hatch-Waxman Act encourages patent disputes between innovator and generic drug companies to be resolved quickly and before the generic company has come to market. The Act requires innovator companies to provide public notice of any patents that cover their drugs, by listing those patents in an FDA publication commonly called the Orange Book. 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53. The FDA may not approve the marketing of a generic before expiration of any patent listed in the Orange Book as covering the drug unless the ANDA contains a “paragraph IV certification” alleging that the listed patent is invalid or unenforceable, will not be infringed by the proposed generic drug, or both. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute encourages paragraph IV certifications by making the first filer for a generic drug eligible for 180 days of market exclusivity against other generic applicants. *Id.* § 355(j)(5)(B)(iv). This exclusivity can be worth millions of dollars.

The Hatch-Waxman Act also deems the mere filing of a paragraph IV certification an act of patent infringement, so that the innovator can file an

² Portions of 21 U.S.C. § 355 were amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, 2448, but the amendments generally do not apply to the ANDAs at issue in this case. *Id.* §§ 1101(c), 1102(b), 117 Stat. at 2456, 2460 (effective date provisions).

immediate patent lawsuit against the ANDA filer. 35 U.S.C. § 271(e)(2)(A). To further encourage these pre-marketing lawsuits, the Hatch-Waxman Act imposes a 30-month stay on FDA approval of an ANDA if, but only if, the innovator company sues within 45 days of receiving notice of a paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iii). If the innovator prevails in such a lawsuit, it is entitled as a matter of right to an injunction prohibiting ANDA approval before the patent expires. *Id.* § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A). The innovator cannot recover damages unless the generic company has commercially launched its product before the district court's judgment—a rare occurrence because FDA approval is stayed for 30 months and because a generic company typically will be deterred by the potential for a ruinous damages award if it ultimately were to lose the patent suit. 35 U.S.C. § 271(e)(4); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

3. In May 2003, Watson Pharmaceuticals, Inc. (Watson) and Paddock Laboratories, Inc. (Paddock) each filed an ANDA seeking FDA approval to market a generic version of AndroGel. Each ANDA contained a paragraph IV certification against the '894 patent, and Unimed and Besins promptly filed patent infringement lawsuits against Watson and Paddock in the United States District Court for the Northern District of Georgia. Complaint ¶¶ 44, 47.

The patent litigations proceeded vigorously for more than three years. The parties produced hundreds of thousands of pages of documents, took nearly 40 depositions, and retained numerous scientific experts. Pet. App. 33a. Paddock's litigation was so resource-intensive that it had to seek litigation funding from a larger generic drug company, Par

Pharmaceutical Companies, Inc. (Par), and in exchange gave Par the exclusive right to distribute Paddock's generic version of AndroGel if and when it received FDA approval and could come to market. Complaint ¶ 46.

Unimed's patent was specifically intended to cover AndroGel and described AndroGel's composition. Watson and Paddock each conceded that its respective product used the same ingredients in very nearly the same amounts as AndroGel. As is common in high-stakes patent litigation, however, each defendant raised numerous other defenses. Each contended, for example, that the patent's claims did not actually cover AndroGel because of technical errors in claim drafting, even though the PTO had issued a certificate of correction resolving those errors, and even though the patent stated that AndroGel was the preferred embodiment. *Cf. Topliff v. Topliff*, 145 U.S. 156, 171 (1892) ("The object of the patent law is to secure to inventors a monopoly of what they have actually invented or discovered, and it ought not to be defeated . . . by the application of artificial rules of interpretation."); *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (construing a patent's claims to exclude the preferred embodiment "is rarely, if ever, correct"). Watson and Paddock also contended that the patent was invalid. They filed partial summary judgment motions, but those motions did not address every asserted claim of the patent and therefore could not have disposed of the cases even if they had been granted.

The district court has since expressly held, in the subsequent antitrust class-action litigation discussed below, that Unimed's claims in the patent litigation were bona fide, and that Unimed's litigation

positions were objectively reasonable. *In re AndroGel Antitrust Litig. (No. II)*, 2012 WL 5352986 (N.D. Ga. Oct. 30, 2012), *appeal docketed*, No. 12-15562-B (11th Cir. Oct. 30, 2012).

4. In September 2006, after three years of hard-fought litigation and before the district court decided any substantive motions, the parties settled. As part of each settlement, Solvay (Unimed's parent company) agreed to license the respective generic company to launch its generic version of AndroGel in August 2015—five years before the '894 patent will expire. Complaint ¶¶ 65, 76. In exchange, each generic company agreed to respect the '894 patent by not marketing its generic drug before 2015. Also, Watson, Paddock, and Par each agreed to provide services to Solvay—Watson to promote AndroGel to urologists, Paddock to provide manufacturing capacity for AndroGel, and Par to promote AndroGel to primary care physicians—and Solvay agreed to pay for those services. *Id.* ¶¶ 66, 74. Although the FTC alleged that Solvay overpaid for these services, there was no allegation that the services were not provided.

5. After the settlements, the FTC began what became a two-year investigation into whether the settlements violated the antitrust laws. Following extensive discovery, the FTC filed a lawsuit against respondents in the United States District Court for the Central District of California. Shortly thereafter, several private plaintiffs brought putative class actions involving substantively identical allegations. Over the FTC's and the private plaintiffs' objection, the court transferred the litigation to the United States District Court for the Northern District of

Georgia, which had presided over the patent litigation.

Following the transfer, the FTC filed its operative complaint. The FTC alleged that Solvay's business agreements with Watson, Par, and Paddock were not "independent business transactions," and that Solvay overpaid. The FTC alleged that Solvay entered into the business arrangements because Watson, Par, and Paddock otherwise would have insisted on an earlier date for their licenses to market generic AndroGel. Complaint ¶¶ 81-85. The FTC did not allege that Solvay's patent suits were unreasonable "sham" litigation, but instead only that Solvay was "not likely to prevail" in its patent infringement lawsuits. *Id.* ¶ 86. The FTC alleged that both settlements violated section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a). Complaint ¶¶ 106-112. The FTC calls any "compensation" given by an innovative drug manufacturer to a generic company as part of a settlement of Hatch-Waxman Act patent litigation—other than a license to enter with a generic version before expiration of the patent—a "reverse payment." Pet. 2.

6. The district court rejected the FTC's argument that "it should be presumptively unlawful for companies to settle a patent dispute with reverse payments," Pet. App. 51a, and dismissed the FTC's complaint. The court noted that "neither the rule of reason nor the per se analysis is appropriate when a patent settlement is involved" because these approaches "look at whether the challenged conduct had an anticompetitive effect on the market." *Id.* at 47a-48a (internal quotation marks omitted). The entire purpose of a patent, however, is to "create an environment of exclusion" and "cripple competition"

within the patent's exclusionary scope; "[t]he anti-competitive effect is already present" by virtue of the patent's existence. *Id.* at 48a (internal quotation marks omitted). Because the FTC did not allege that the settlements exceeded the '894 patent's exclusionary potential, the district court concluded that the FTC did not state an antitrust claim.³

7. The court of appeals affirmed. The court began its opinion by observing that the business of innovator drug companies is to participate in an innovation lottery. These companies typically spend billions of dollars and many years on research for each product they bring to market. Protecting their ability to generate profits by obtaining patents and charging commensurate prices for the life of their patents is vital to the development of new pharmaceutical products because "[n]o rational actor would take that kind of a risk over that period of time without the prospect of a big reward." Pet. App. 2a.

With due regard for the "tension between the pro-exclusivity tenets of patent law and the pro-competition tenets of antitrust law," *id.* at 16a, the court of appeals noted that "antitrust laws typically prohibit agreements where one company pays a potential competitor not to enter the market." *Id.* at 17a. But it also observed that patent litigation

³ The district court also dismissed the private plaintiffs' claims that respondents' litigation settlements violated the Sherman Act, but it did not dismiss the private plaintiffs' claims that alleged, unlike the FTC, that Unimed's '894 patent litigation was a sham, brought without any reasonable basis and for an improper purpose. As noted above, the district court has since granted summary judgment to respondents, holding that the patent litigation was not a sham. *AndroGel*, 2012 WL 5352986.

settlements are “atypical cases” because a patent is “a ‘lawful right to exclude others’ from the market.” *Id.* (quoting *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003)). The court held that there cannot be antitrust liability for a supposed “exclusionary” effect that is within the exclusionary potential of the patent. The appropriate antitrust rule of decision, therefore, “is an evaluation of whether the settlement agreements contain provisions that restrict competition beyond the scope of the exclusionary potential of the patent” because that rule “giv[es] full force to the exclusionary rights [the patent] potentially conveyed.” *Id.* at 23a-24a.

The court of appeals rejected the relevance of the FTC’s allegation that Solvay was “not likely to prevail” in the patent litigation. The FTC proposed that antitrust liability turn on the “likely exclusionary effect” of the patent, rather than its “potential exclusionary effect.” *Id.* at 30a. The court explained that this “retrospective predict-the-likely-outcome-that-never-came” standard would be impractical because it would require courts in antitrust cases challenging patent litigation settlements to undertake the “turducken task” of “attempt[ing] to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to [a] judgment” that was never rendered. *Id.* at 33a, 36a. Such a task would require re-litigating the entire patent case in an effort to determine who the likely winner would have been. The court of appeals explained that this would be burdensome for the parties and the court, would “undo much of the benefit of settling the patent litigation” in the first place, and so would “discourage settlements.” *Id.* at 33a. More importantly, such a “retrospective prediction” of success is “unlikely to be

reliable,” as the FTC had itself “recognized . . . in the past.” *Id.* Treble-damage antitrust liability should not turn on what essentially would be guesswork.

The court of appeals emphasized that the “reality of patent litigation and the risks it presents to the patent holder” are likely to motivate the patent holder to prefer settling “even if it might well prevail.” *Id.* at 31a. The court recognized that “[e]ven the confident patent owner knows that . . . prevailing in patent litigation” is rarely if ever assured, *id.* at 32a, and that even “[a] party likely to win might not want to play the odds for the same reason that one likely to survive a game of Russian roulette might not want to take a turn,” *id.* at 30a.

The court of appeals also rejected the FTC’s alternative argument, *see* FTC Opening Br. at 43-56, *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012) (No. 10-12729-DD) (filed July 26, 2010), that all “reverse-payment” settlements should be presumed unlawful. Pet. App. 4a.

The FTC sought rehearing en banc, which the court of appeals denied. *Id.* at 62a-63a. The FTC’s petition followed.

ARGUMENT

A. The Petition Presents A Question On Which A Circuit Conflict Has Arisen Since The Decision Below Was Rendered And On Which National Uniformity Is Critically Important

1. The decision below accorded with the decisions of every appellate court in the country to have addressed the question presented, as well as every non-appealed district court decision on the subject. These

courts uniformly held that a company's agreement not to market its generic drug in settlement of Hatch-Waxman patent litigation does not violate the antitrust laws—regardless of whether it is accompanied by an alleged “reverse payment”—so long as the limitation on marketing is within the exclusionary potential of the patent, the patent was not procured by fraud, and the patent litigation was not a sham.⁴ Although some courts did hold that particular “reverse-payment” settlements were or might have been unlawful, these courts did so because the particular settlements restrained competition beyond the exclusionary potential of the patent.⁵

⁴ See *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 105 (2d Cir. 2010); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 205-09 (2d Cir. 2006); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1327, 1336-37 (Fed. Cir. 2008); *King Drug Co. of Florence v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 528 (E.D. Pa. 2010); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003) (Posner, J., by designation); *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165, 184-86 (Ct. App. 2011), *review granted*, 269 P.3d 653 (Cal. 2012); see also *In re K-Dur Antitrust Litig.*, 2009 WL 508869, at *24 (D.N.J. Feb. 6, 2009), *adopted by* 2010 WL 1172995 (D.N.J. Mar. 25, 2010), *rev'd*, 686 F.3d 197 (3d Cir. 2012).

⁵ See *Andrx Pharms., Inc. v. Elan Corp., PLC*, 421 F.3d 1227, 1231 (11th Cir. 2005) (settling generic company's retention of its 180 days of exclusivity “had the effect of preventing any generic competition,” even by companies not party to the litigation); *Valley Drug*, 344 F.3d at 1311-12 (settlement agreement was not limited to potentially infringing products and used 180-day exclusivity to block other potential entrants); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907-08 & n.13 (6th Cir. 2003) (same); *King Drug*, 702 F. Supp. 2d at 530-33 (same); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 806-15 (D.C. Cir. 2001) (involving the same settlement agreement as *Cardizem*); see also U.S. Br. at 16-18, *FTC v. Schering-Plough*

Two months after the decision below, this judicial uniformity came to an end. In *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), the Third Circuit rejected the holdings of the Second, Eleventh, and Federal Circuits—including an Eleventh Circuit decision regarding the same settlement agreements the Third Circuit was evaluating. After relying on selected bits of legislative history to conclude that “[t]he goal of the Hatch-Waxman Act is to increase the availability of low cost generic drugs,” the Third Circuit further concluded that “reverse-payment” settlements tend to undermine that goal and that the uniform holdings of the other circuits reflected “bad policy.” *Id.* at 217. The court held that “reverse payments” should be subjected to a “quick look rule of reason analysis” and be regarded “as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.” *Id.* at 218. Remarkably, the Third Circuit stated that its condemnation of “reverse-payment” patent settlements did not have general application, but instead was specifically “limited to reverse payments between patent holders and would be generic competitors in the pharmaceutical industry.” *Id.* at 216.

2. The Court should grant the petition and resolve the question presented because the Third Circuit’s novel holding, if allowed to stand, will have nationwide effects on respondents and on the pharmaceutical industry generally. Because of the antitrust laws’ permissive venue provisions, *see* 15 U.S.C. §§ 22, 53(a), governmental and class-action plaintiffs will

Corp., 548 U.S. 919 (2006) (No. 05-273) (filed May 17, 2006) (noting the absence of a circuit conflict at the time).

engage in forum shopping by filing all antitrust litigation regarding Hatch-Waxman patent settlements in the Third Circuit. *See, e.g.*, Jon Leibowitz, Chairman, FTC, Remarks Prepared for Delivery at the Sixth Annual Georgetown Law Global Antitrust Enforcement Symposium 4 (Sept. 19, 2012), www.ftc.gov/speeches/leibowitz/120919jdlgeorgetown_speech.pdf (announcing that the FTC will “simply be forced to bring pay-for-delay cases in the Third Circuit for years to come” if this Court does not grant certiorari). There will also be a flood of venue-transfer litigation, at least until the circuit conflict is resolved.

Moreover, a large number of settlement agreements may be subject to challenge by the FTC and class-action plaintiffs under the Third Circuit’s rule. *See Bureau of Competition, FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, at 2 (2011), www.ftc.gov/os/2011/10/1110mmaagree.pdf (characterizing 78 settlements between 2009 and 2011 as potentially involving “reverse payments”). Many of the class-action challenges will include astronomical damages claims, in light of the antitrust laws’ provision for treble damages and the generally higher pricing of brand-name drugs that is necessary to recoup the billions of dollars invested in researching and developing them. In the private suits that followed this case alone, the direct purchasers of AndroGel claimed in the district court that they were entitled to billions of dollars on their federal antitrust claims. The sum claimed dwarfs the cumulative profits Solvay has made on AndroGel since its launch, and far exceeds the combined 2011 profits of all four respondents. The companies would be exposed to this massive liability for

settling time-consuming, expensive, and difficult patent cases, even though those settlements accorded with legal standards adopted by every circuit that had considered the issue at the time the settlements occurred.

B. The Decision Below Should Be Affirmed

1. The Eleventh Circuit's decision correctly reflects the exclusionary right that is at the heart of a presumptively valid patent

In deciding whether the antitrust laws prohibit the owner of a patent from entering into a contract that would be illegal absent the patent, this Court held over half a century ago that a patentee is exempt from the antitrust laws so long as the patentee does not use its patent to reach “beyond the limits of the patent monopoly.” *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948). Within the patent’s limits, however, the “right to exclude others” is the “essence of a patent grant.” *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). That grant, moreover, is presumed valid until affirmatively proved otherwise. 35 U.S.C. § 282(a).

The antitrust laws proscribe “misuse of patent rights.” *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 176 (1965). But they do not “reach monopolies practiced under patents” even if the patents “may turn out to be voidable under one or more of the numerous technicalities” of patent law. *Id.* at 180 (Harlan, J., concurring). Moreover, when the true scope of a patent is subject to “legitimately conflicting claims . . . , a settlement by agreement, rather than litigation, is not precluded”

by the antitrust laws. *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931).

The Eleventh Circuit followed these well-established principles.⁶ If Unimed had won its patent infringement lawsuits, the district court would have ordered the FDA not to approve Watson and Paddock's generic versions of AndroGel until at least August 2020. See 35 U.S.C. § 271(e)(4)(A). Such a court order—the epitome of lawful exclusion—was entirely within the realm of realistic outcomes in the litigation, as the district court has since explicitly found and as the FTC has not contested.

The settlement agreements that the FTC has challenged here plainly permit more generic competition, and create less exclusion, than would have been ordered if Unimed had won its lawsuits. The allegation that Solvay paid for this result does not alter that Solvay agreed to *less* exclusion than it lawfully and realistically might have obtained in the exercise of its constitutionally protected right to assert its patent reasonably. Because the settlements are no more exclusionary than the exclusionary potential of the patent, they do not violate the antitrust laws.

2. The rule advocated by the FTC and adopted by the Third Circuit in *K-Dur* is wrong and unworkable

a. The FTC reasons, as did the Third Circuit, that “reverse-payment” patent settlements are found only in the pharmaceutical industry and merit a unique antitrust rule of decision. Pet. 27 (arguing that “reverse payments” are “scarcely an essential or tra-

⁶ The Eleventh Circuit also properly identified many practical difficulties with the FTC's proposed rule. Pet. App. 31a-36a.

ditional feature of settlement practice” and “largely unknown outside the Hatch-Waxman context”); *K-Dur*, 686 F.3d at 208 (stating that “reverse payments” are “unique to the Hatch-Waxman context”). This view is incorrect. Many if not most patent litigation settlements entail consideration that flows from the patentee to the alleged infringer—“reverse payments,” in the FTC’s lexicon—with no antitrust ramifications at all. Settlements in Hatch-Waxman litigation may differ in appearance, but they do not differ in economic substance, and only the latter should be legally significant. See *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 887-88 (2007) (criticizing antitrust rules that are “based on ‘formalistic’ legal doctrine rather than ‘demonstrable economic effect’” (quoting *Cont’l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 58-59 (1977))).

In a traditional patent infringement lawsuit brought under 35 U.S.C. § 271(a)-(c), the patentee seeks damages, *id.* § 284, among other possible remedies. Such litigation commonly settles with the patentee’s giving up all or part of its damage claim in exchange for the infringer’s agreeing to respect the plaintiff’s patent and exit the market for some or all of the patent term. Settlement on these terms rarely if ever implicates the antitrust laws. See 1 Herbert Hovenkamp et al., *IP and Antitrust* § 7.4a, at 7-23 (2d ed. 2003 & Supp. 2010) (litigation settlements in which “the plaintiff settles by giving the defendant a nonexclusive license to practice the patent in exchange for royalties or other consideration . . . almost never harm[] competition”). Yet even in this ordinary circumstance, the patentee has provided consideration: the release of the defendant from a greater potential liability. From an economic perspective, releasing a party from potential liability is

as much consideration or a “payment” as is cash. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) (“in the traditional context, implicit consideration flows from the patent holder to the alleged infringer”); Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 *Annals Health L.* 367, 389 (2010) (“the patent holder pays the infringer to settle the lawsuit by accepting lower damages”); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 *Antitrust L.J.* 1033, 1033 (2004) (“the patent holder ‘pays’ to settle by accepting less in damages from the infringer than it expects to get from litigating”); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., by designation) (“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”).

Hatch-Waxman settlements often have a different appearance for the simple reason that the Hatch-Waxman statutory framework encourages patent litigation before any allegedly infringing products have been sold, and thus before there is any potential damages award for the patentee to compromise. But Hatch-Waxman settlements are *economically* no different from traditional patent settlements. In each context, the economic substance of the settlement is that the plaintiff is providing consideration to the defendant in exchange for the defendant’s agreement not to market its allegedly infringing product for a portion of the patent term. See 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, 621 (2006) (Hatch-Waxman “creates a context in which payments from the patent owner to the infringer become explicit,” but “does not change the underlying nature of the payments or make them more anticompetitive”).

Nonetheless, the FTC has for years urged Congress to prohibit such settlements in the context of pharmaceuticals. Ten times within the past decade, bills have been introduced to make “reverse-payment” Hatch-Waxman settlements either presumptively or *per se* illegal.⁷ Not one of these bills has been enacted. While Congress would have the authority to enact legislation that engages in line-drawing or adopts industry-specific rules, the courts should not endorse an antitrust rule of decision based on an industry-specific distinction that is purely formalistic, especially in the face of Congress’s repeated refusal to enact the distinction legislatively.

b. Another lynchpin of the FTC’s argument is the claim that its analysis shows that settlements accompanied by “payments”—which the FTC defines to include business deals in which any amount of money or other consideration flows from the patent holder to the generic company—result in a later license date for the generic drug than settlements without “payments.” Pet. 20. The FTC’s analysis, however, simply assumes its conclusion, by taking it

⁷ See S. 27, 112th Cong. (2011) (presumption of unlawfulness); S. 3677, 111th Cong. § 746 (2010) (same); S. 369, 111th Cong. (2009) (same); H.R. 3995, 112th Cong. (2012) (rule of *per se* unlawfulness); H.R. 3962, 111th Cong. § 2573 (2009) (same); H.R. 1706, 111th Cong. (2009) (same); H.R. 1902, 110th Cong. (2007) (same); H.R. 1432, 110th Cong. (2007) (same); S. 316, 110th Cong. (2007) (same); S. 3582, 109th Cong. (2006) (same).

as given that the cases that settled with payments would have settled without those payments.

There is no basis for that assumption. It is a fundamental tenet of dispute resolution that disputes often will not be resolved at all if the parties can negotiate only by compromising on a single term, such as the date on which a product will be marketed. When parties “negotiat[e] along a single dimension” and are prohibited from introducing other sources of value into the negotiation, there may be “no way to split the pie that leaves both parties satisfied.” Roger Fisher et al., *Getting to Yes* 58 (3d ed. 2011). This dynamic is at least as true in Hatch-Waxman litigation as in any other context. Bernard & Tom, *supra*, at 630 (noting that “asymmetric time horizons” and “asymmetric expectations about litigation success can make it impossible to settle within the cashless, patent-term-splitting paradigm”).⁸ Settlement by negotiating along one dimension is possible only if the parties share a view of what is likely to

⁸ The *K-Dur* respondents challenge this proposition by citing their proffered expert’s opinion that Schering and Upsher *could* have settled their patent case without a “reverse payment.” BIO at 14, *Merck & Co. v. La. Wholesale Drug Co.*, No. 12-245 (filed Nov. 7, 2012). That opinion was based on the assumption that Upsher had, and that both Schering and Upsher *agreed* Upsher had, a 90% chance of winning. Making predictions only about what *could* have happened, and doing so based on supposedly precise soothsaying about the likelihood of a particular litigation outcome, however, is a “discipline [that] itself lacks reliability,” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151 (1999), and thus is not a “fact” that could be appropriately relied upon in determining the relevant legal standard for evaluating Hatch-Waxman settlements. Moreover, that this purported evidence is contained in the *K-Dur* record does not make *K-Dur* a better vehicle for resolving the present circuit split.

happen if the case is pursued to judgment and place the same value on that outcome. Without other sources of value, there may be no way to “bridge th[e] gap” between the parties’ irreconcilable bargaining positions. *Id.*⁹

c. In limiting parties in Hatch-Waxman patent litigation to negotiating only a licensed entry date, the FTC’s proposed rule and the *K-Dur* holding would lead to fewer settlements of Hatch-Waxman cases. The deleterious consequences would be substantial.

First, public and private resources would be wasted. The courts have long favored private settlements of disputes. *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994) (“public policy wisely encourages settlements”); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005) (noting the “public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements”). Paragraph IV filers should not be conscripted as “unwilling private attorneys general.” *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 532 (E.D.N.Y. 2005) (internal quotation marks omitted). The resources that would be consumed by unnecessarily protracted lawsuits are better used in productive endeavors: innovator companies’ investing in research and development of new products, generic companies’ bringing

⁹ The conclusions the FTC draws from its statistics are misleading for other reasons as well. For instance, the FTC measures “delay” in absolute terms—number of months from the settlement—without regard for the remaining length of the patent. When all else is equal, however, a patent with a longer term creates more litigation risk and thus more pressure to settle, including on terms that involve a “reverse payment” if needed to bridge the gap between the parties’ positions.

other low-cost generics to market, and the courts' resolving disputes between parties who genuinely cannot do so themselves.

Second, the FTC's and Third Circuit's approach would reduce innovation. As a result of prolonged litigation and the inherent unpredictability of adjudication, the costs and uncertainty of patent enforcement would increase. For innovator companies, the increased cost and uncertainty surrounding pharmaceutical patent enforcement would in turn reduce the value of patents, which provide critical incentives for innovation. See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 203 (2d Cir. 2006) ("restricting patent settlements" would "heighten the uncertainty surrounding patents and might delay innovation"); *Valley Drug*, 344 F.3d at 1308 ("restricting settlement options, which would effectively increase the cost of patent enforcement," would "impair the incentives for disclosure and innovation"); Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 Tex. L. Rev. 503, 512-13 (2009) ("patents appear to be a prerequisite for the vast majority of pharmaceutical innovation").

Investment in the future development of new life-saving and life-enhancing medicines that strong patent protection fuels is critically important to consumer welfare. In rejecting the FTC's proposed rule, Congress declined to find that such future investment is less important than quickly decreasing the price levels of some of the current stock of patent-protected drugs. The courts should not impose a contrary judgment in the guise of interpreting the antitrust laws. As Judge Easterbrook has explained regarding the importance of maintaining incentives for innovation: "An antitrust policy that reduced

prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovation lowers the costs of production would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses.” Frank H. Easterbrook, *Ignorance and Antitrust*, in *Antitrust, Innovation, and Competitiveness* 119, 122-23 (Thomas M. Jorde & David J. Teece eds., 1992). The FTC’s and Third Circuit’s analyses focus exclusively on short-term static prices, ignoring completely the long-range effect on innovation. Such an analysis is at odds with overall consumer welfare and, therefore, is an inappropriate basis for antitrust liability. *Reiter v. Sonotone Corp.*, 442 U.S. 330, 343 (1979) (“Congress designed the Sherman Act as a ‘consumer welfare prescription.’”).

Third, the FTC’s and Third Circuit’s approach would likely *reduce* generic competition for pharmaceuticals. A rule that drives up the cost and uncertainty of patent litigation would drive up cost and uncertainty not just for innovator pharmaceutical companies, but also for generic pharmaceutical manufacturers. This in turn would reduce generic manufacturers’ incentive to challenge patents by making paragraph IV certifications in the first instance. *Asahi*, 289 F. Supp. 2d at 994 (“A ban on reverse-payment settlements would reduce the incentive to challenge patents . . . and so might well be thought anticompetitive.”). As a result, the rate at which generic drugs are brought to market could well slow under the Third Circuit’s rule—directly contrary to the FTC’s stated objective of lowering the cost of pharmaceuticals. See Br. for Generic Pharm. Ass’n at 4, *Upsher-Smith Labs. Inc. v. La. Wholesale Drug Co.*, No. 12-265 (filed Oct. 1, 2012) (“Legal rules that limit the ability to settle drive up the cost of

patent challenges, meaning that fewer generic drug applications that would trigger a patent challenge will be filed.”). That is why not just the brand-name pharmaceutical industry, but also the generic drug industry has uniformly opposed this rule and any rule like it.

Ultimately, the point is not that the magnitude of the pernicious expected effects of the FTC’s and Third Circuit’s approach can be easily measured and weighed, but that the FTC and the Third Circuit have made no effort to account for those effects. The FTC and the Third Circuit characterize their approach as application of “quick look” antitrust scrutiny. But “quick look” scrutiny is justified only when the “experience of the market” has shown that the conduct at issue has an anticompetitive tendency “so clear” that antitrust condemnation is warranted without full analysis. *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 779-81 (1999). Here, there is no such experience of the market, just the overly simplistic insistence by the FTC and the Third Circuit that consumers will benefit from outlawing dozens of settlements of Hatch-Waxman patent cases.

d. The FTC’s and the Third Circuit’s rule also would be unworkable. Under that rule, the settling parties can supposedly rebut the presumptive unlawfulness of a “reverse-payment” settlement by showing that the “reverse payment” did not result in “delayed entry.” *K-Dur*, 686 F.3d at 218 (the presumption “could be rebutted by showing that the payment . . . was for a purpose other than delayed entry”). But neither the FTC nor the Third Circuit discusses the baseline from which a “delay” should be measured. It is far from obvious that there would have been earlier entry in the “but for” world in

which no settlement “payment” had been made. It may be that there would have been no settlement at all absent an accompanying business deal, in which case determining whether the settlement delayed generic competition would require determining the outcome of the underlying patent case if it had been litigated to judgment. If the innovator drug company would have prevailed, there would not have been any delay because the generic drug would not have entered the market until the expiration of the patent.

But even if the FTC were correct that every patent case that has been or would be settled with a “reverse payment” could and would alternatively be settled without a “reverse payment,” the licensed entry date under the latter hypothetical settlement could be determined only by evaluating the likelihood of success of the patent case, as the FTC appears to acknowledge. Pet. 22-23 (settlement is “likely to reflect the parties’ assessment of their respective prospects of success in the infringement suit”). This in turn would be a truly Herculean task, more difficult even than determining what the final judgment in the patent case would have been absent a settlement.

To be sure, *K-Dur* proclaimed that “there is no need to consider the merits of the underlying patent suit.” *K-Dur*, 686 F.3d at 218. But that comment was part of the court’s discussion of whether the presumption of unlawfulness should apply in a particular instance, not whether and how such a presumption—if applied—can be rebutted. Notably, the United States has agreed that analysis of “reverse-payment” settlements ultimately would involve retrospectively predicting what the outcome in the patent case would have been had it proceeded to judgment. See Pet. 21 n.6 (acknowledging that the

United States has argued to this Court in three previous briefs that “the antitrust inquiry should include an assessment of the likelihood that the brand-name manufacturer would have prevailed in the underlying infringement suit”).¹⁰ Several commentators have advanced this view as well.¹¹ It is hard to see how causation or damages in an antitrust challenge to a patent settlement could be resolved without essentially re-litigating the merits of the underlying patent case to evaluate the “but for” world.

Requiring trial courts, juries, and settling parties to engage in this exercise would be untenable. This Court has observed that “[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case.” *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990). This is particularly true in patent cases, which are

¹⁰ See also U.S. Br. at 12, *Joblove v. Barr Labs., Inc.*, 551 U.S. 1144 (2007) (No. 06-830) (filed May 23, 2007) (“In determining whether the exclusionary effect of a settlement involving a reverse payment renders the settlement unreasonable and anti-competitive, a court at a minimum should take into account the relative likelihood of success of the parties’ claims, viewed *ex ante*.”); U.S. Br. at 11, *Schering*, *supra* note 5 (“[A]n appropriate legal standard should take into account the relative likelihood of success of the parties’ claims, viewed *ex ante*.”).

¹¹ See, e.g., Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1759 (2003) (arguing that the “infringement plaintiff can defend [against the presumption of unlawfulness] by showing” that “the *ex ante* likelihood of prevailing in its infringement lawsuit is significant”); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 41 (2009) (“If the parties can demonstrate that the payments represent a reasonable assessment of litigation success, then they can rebut this presumption.”).

notoriously unpredictable.¹² The task would be further complicated because the antitrust evaluation of patent litigation might be reviewed by the regional circuits. *See Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807-09 (1988). The resulting state of affairs would have the regional circuits attempting to discern the “likelihood” of how the Federal Circuit would have decided the hypothetical appeal from the hypothetical judgment in the settled patent case.

Brand-name and generic pharmaceutical companies, like most litigants, settle to avoid the uncertainty of adjudication. *Hertz Corp. v. Friend*, 130 S. Ct. 1181, 1193 (2010) (“Predictability is valuable to corporations making business and investment decisions.”); *Carson v. Am. Brands, Inc.*, 450 U.S. 79, 87 (1981) (“Settlement agreements may thus be predicated on an express or implied condition that the parties would, by their agreement, be able to avoid the costs and uncertainties of litigation.”). The legality of their efforts in doing so should not be subject to the magnified uncertainty of how a judge or jury, years later, handicap how a different judge, jury, and the Federal Circuit would have resolved the supposedly settled case.

e. If allowed to stand, *K-Dur* would also wreak years of litigation over what constitutes a “reverse payment.” The *K-Dur* court referred in passing to “money that changed hands” in connection with a

¹² See U.S. Court of Appeals for the Fed. Circuit, *Affirmance and Reversal Rates for District Court Patent Infringement Appeals*, www.patentlyo.com/files/caseload_patent_infringement_affirmance_and_reversal_rates_2001-2010.pdf (showing that over 40% of patent appeals result in reversal or vacatur at least in part).

settlement, 686 F.3d at 218 (emphasis added), but otherwise did not define “reverse payment.” The FTC has made clear that it views a “reverse payment” as anything of “economic value” that an innovator provides a generic—a concept far broader than payment of money. See FTC Pet. for Reh’g En Banc at 13, *Watson*, 677 F.3d 1298 (No. 10-12729-DD) (filed June 11, 2012) (“[The] burden-shifting approach should apply whenever the patent holder provides economic value to the challenger in any form in connection with delayed entry.”); FTC Br. at 24 n.26, *K-Dur*, 686 F.3d 197 (No. 10-2077) (filed May 18, 2011) (“The rule we urge should apply whenever the patent holder provides economic value to the challenger in any form.”).

Disputes over the definition of “reverse payment” have already arisen in district courts within the Third Circuit. When an innovator company and a generic company settle Hatch-Waxman litigation by agreeing on a future date for licensed generic entry, the innovator company sometimes agrees that the innovator will not itself launch an “authorized generic” for some period of time after the agreed-upon entry date.¹³ An agreement of this form is essentially a time-limited exclusive license and does not involve any exchange of money. Yet the FTC has repeatedly advanced the view that such an agreement, when

¹³ An authorized generic is a drug manufactured in accordance with the innovator’s own FDA approval but sold, by either the innovator or a licensee, using a different product name and at a reduced price. John M. Rebman, *Dr. Strange Drug, Or: How I Learned to Stop Worrying and Love Authorized Generics*, 12 DePaul J. Health Care L. 159, 159 (2009). Introducing an authorized generic allows an innovator to capture a portion of the market for generic drugs rather than cede it to generic manufacturers. *Id.* at 168.

contained in a settlement of Hatch-Waxman patent litigation, is a “reverse payment” because the innovator’s promise not to authorize a generic constitutes “economic value.” See, e.g., FTC Br. at 6-12, *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-cv-995 (D.N.J.) (filed Oct. 5, 2012); FTC Br. at 5-11, *In re Effexor XR Antitrust Litig.*, No. 11-cv-5479 (D.N.J.) (filed Aug. 10, 2012). If a cashless promise that maintains the 180-day exclusivity promised to generics under Hatch-Waxman can be a forbidden “reverse payment,” it is difficult to see any limiting principle for the FTC’s proposed rule.

C. The Court Should Grant The FTC’s Petition

1. This case is a better vehicle than *K-Dur*

Solvay agrees with the FTC that this case is a better vehicle for resolving the circuit split than is the *K-Dur* case (Nos. 12-245 and 12-265).

a. This case is a better vehicle than the *K-Dur* case because it arises from a final dismissal with a simple record, whereas *K-Dur* reaches this Court in an interlocutory posture from reversal of a grant of summary judgment on a fact-intensive record. In *K-Dur*, the court of appeals remanded for further proceedings under the new standard it announced. If the case proceeds on remand, there are many ways in which the case could be resolved that would render the choice of legal standard irrelevant.

For example, the parties in *K-Dur* dispute whether the innovator company, Schering, made any payments to the generic in exchange for the agreed-upon date of generic entry when it bought licenses from Upsher (one of the ANDA filers) for unrelated drugs.

K-Dur, 686 F.3d at 205. The antitrust defendants in *K-Dur* argue that the licenses were priced at fair market value, and thus there was no “reverse payment.” See BIO at 10, *Merck*, *supra* note 8. The Third Circuit did not address this issue, but the Eleventh Circuit, in evaluating the same settlement, found the “payments [were] a fair price” for the licenses and that Schering had “made a stand-alone determination that it was getting as much in return from these products as it was paying.” *Schering*, 402 F.3d at 1071. If the licenses are found on remand to reflect fair value, then the settlement would not include a “reverse payment,” or, put another way, the only payments would have been for “a purpose other than delayed entry” and thus not anticompetitive even under the Third Circuit’s test. See *K-Dur*, 686 F.3d at 218.

Similarly, *K-Dur* involves disputes about the strength of the antitrust defendants’ positions in the underlying Hatch-Waxman patent litigation. See *In re K-Dur Antitrust Litig.*, 2009 WL 508869, at *29 (D.N.J. Feb. 6, 2009). If it were found on remand that, in the absence of a settlement, Schering would have won the patent litigation and kept the generics off the market, then the settlement could not have delayed generic entry. This would mean that the settlement caused no injury to the antitrust plaintiffs, so their case would fail even under the Third Circuit’s test.

When, as in *K-Dur*, the interlocutory posture of a case means the question presented in a petition may “become quite unimportant by reason of the final result, or of intervening matters,” the Court has held that it “should not issue a writ of certiorari . . . unless it is necessary to prevent extraordinary

inconvenience.” *Am. Constr. Co. v. Jacksonville, Tampa & Key West Ry. Co.*, 148 U.S. 372, 384 (1893); see also *Bhd. of Locomotive Firemen & Enginemen v. Bangor & Aroostook R.R. Co.*, 389 U.S. 327, 328 (1967) (per curiam) (“[B]ecause the Court of Appeals remanded the case, it is not yet ripe for review by this Court.”). In contrast to *K-Dur*, in which the question presented could be made irrelevant by proceedings on remand regardless of whether this Court grants certiorari to resolve the current circuit split, this case arises from a complete dismissal, so there will be no further proceedings unless this Court grants certiorari.

b. The underlying patent litigation in this case included disputes over patent validity and infringement, whereas the underlying patent litigation in *K-Dur* involved only disputes over infringement. Solvay does not believe it should matter to the antitrust analysis of a patent settlement whether validity or infringement or both were contested in the settled litigation. But the antitrust plaintiffs in *K-Dur* have urged the courts to adopt an antitrust analysis that distinguishes between validity and infringement defenses in the underlying patent litigation—on the ground that a patent is presumed valid but there is no similar presumption of infringement. See Appellants’ Opening Br. at 35-38, *K-Dur*, 686 F.3d 197 (No. 10-2077) (filed May 11, 2011). Granting certiorari in this case would enable the Court to consider cases in which the generic manufacturer challenges the validity of the patent as well as those in which the generic manufacturer contests infringement.

2. Alternatively, the Court should grant the petitions in *K-Dur* along with the petition in this case

In the alternative, as the FTC also suggests (Pet. 29, 32-33), the Court could grant the petitions for writs of certiorari in this case as well as in *K-Dur*.

a. Granting certiorari in both cases would allow the Court to consider a greater variety of business arrangements when considering whether—and if so, how—business arrangements entered at the time of a patent litigation settlement are relevant to the antitrust analysis.

As discussed above, the Third Circuit's presumption of illegality is not as clear as the Third Circuit and FTC have portrayed it. The concepts of what constitutes a "reverse payment" and how the presumption can be rebutted are unclear under the Third Circuit's test. Having examples of several different types of business deals—including for co-promotion and back-up manufacturing in this case, and for licenses to unrelated products in *K-Dur*—could be helpful in considering the implications of that test.

b. That the FTC seeks only prospective relief in this case and the *K-Dur* plaintiffs seek only damages is also a reason why the Court may wish to grant certiorari in both cases. Doing so would allow the Court to consider the difficulty of applying the Third Circuit's test to both kinds of claims for relief. In the FTC's view, the fact that the FTC seeks only prospective relief means that, by granting certiorari in only this case, the Court could avoid considering "whatever uncertainties may arise in fixing the damages caused by a reverse-payment agreement." Pet.

31. But whether the potential legal tests would create unmanageable uncertainties with respect to causation and damages is important to consider. As explained above, one serious problem with the Third Circuit's test is that, to determine what damages (if any) are owed, the parties would have to re-litigate the underlying patent suit to determine when generic entry would have occurred absent the settlement. *See supra* pp. 24-27.

Contrary to the FTC's suggestion, the Third Circuit's test faces essentially the same uncertainties in a case, like this one, in which the plaintiff seeks only prospective relief. Rebutting the Third Circuit's presumption would involve determining whether a settlement in fact delayed generic entry, which in turn would involve determining when the generic product would have entered the market absent the settlement. And resolving that question would require re-litigating the underlying patent case to determine the likelihood that the generic product would have been found to infringe. This need to re-litigate patent cases follows from the Third Circuit's rule, not from the form of relief sought. Granting certiorari in this case and in *K-Dur* would permit the Court to consider the Third Circuit's test, and the need to re-litigate the underlying patent case resulting from that test, in the context of claims for damages and injunctive relief.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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