No. 12-416

Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

WATSON PHARMACEUTICALS, INC., ET AL.

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

BRIEF IN OPPOSITION

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QUESTION PRESENTED

This case is about settlements of patent litigation brought under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585. Flaws in the Hatch-Waxman Act, including those relating to settlements concluded thereunder, prompted Congress to enact remedial amendments in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, 117 Stat. 2066.

The settlements in this case involve Abbreviated New Drug Applications (ANDAs) governed by the pre-amendment law, and thus are known as "pre-MMA" settlements. The United States twice has advised this Court that the MMA's remedial changes counsel against granting certiorari in cases involving pre-MMA settlements to address antitrust questions concerning reverse payments.

The question presented here is the same as stated by the United States when it opposed the FTC's petition for a writ of certiorari in *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (CA11 2005), cert. denied, 548 U.S. 919 (2006):

> Whether the antitrust laws prohibit a brand name drug patent holder and a prospective generic competitor from settling patent infringement litigation by agreeing that the generic manufacturer will not enter the market before a future date within the term of the patent and that the patent holder will make a substantial payment to the generic manufacturer.

U.S. Br. I, *supra* (No. 05-273) (filed May 17, 2006).

PARTIES TO THE PROCEEDING

Petitioner is the Federal Trade Commission.

Respondents are Watson Pharmaceuticals, Inc. ("Watson"), Solvay Pharmaceuticals, Inc. ("Solvay"), Par Pharmaceutical Companies, Inc. ("Par"), and Paddock Holdings, Inc. (formerly known as Paddock Laboratories, Inc.) ("Paddock").

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, respondents Par and Paddock state as follows:

Par is wholly owned by Sky Growth Holdings Corporation, which has no parent corporation, and no publicly held company owns 10% or more of the stock of Sky Growth Holdings Corporation. (Sky Growth Holdings Corporation is privately held by individual investors and private investment firms affiliated with TPG Capital, L.P. (formerly Texas Pacific Group).)

Paddock has no parent corporation, and no publicly held company owns 10% or more of the stock of Paddock.

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STATEMENT

This case arises under pre-MMA Hatch-Waxman law, not current law. That matters because Congress's remedial MMA amendments have yielded steadily declining rates of reverse-payment settlements over the past five years (to a new recent low in FY 2011). Another indication that the amendments are working is that the government has not challenged any alleged reverse-payment settlement arising under post-amendment law. Although the United States previously advised the Court that the MMA's changes likely would reduce incentives for reverse-payment settlements and, therefore, counseled against granting certiorari in a pre-MMA case, the petition mentions the MMA only once, in a string-citation. Pet.20.

That new reticence may be due to the United States' switched position since the last administration. Compare, *e.g.*, U.S.Br.11, *Schering-Plough* ("[C]ompeting considerations suggest that the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful."), with Pet.22 ("The correct approach, taken by the Third Circuit, is to treat reverse-payment agreements as presumptively anticompetitive.").

The United States does not explain its reversal, but does concede it: "In those briefs [in 2004, 2006, and 2007], the United States did not endorse the FTC's view that reverse-payment settlements are presumptively anticompetitive." Pet.21 n.6.

The United States' new position is entitled to little, if any, deference. See Transcript of Oral Argument at 44, *Kiobel* v. *Royal Dutch Petroleum*,

No.10-1491 (Oct. 1, 2012) (Roberts, C.J.) ("[W]hatever deference you are entitled to is compromised by the fact that your predecessors took a different position.").

A. Background

Solvay sued Watson and Paddock, separately, for patent infringement in 2003 (pre-MMA). The cases proceeded in the Northern District of Georgia until 2006 when respondents settled separately. The court encouraged respondents to settle. B.I.O.App.2a ("[Solvay and Par/Paddock] consented to judgment through a final settlement, which was encouraged by the Court pursuant to its Local Rules"); Transcript of Proceedings, *Unimed Pharms.* v. *Paddock Labs.*, No.1:03-CV-2503-TWT (N.D.Ga. Feb. 26, 2004) ("This has all the appearances of a long, complicated, expensive, difficult case. Is there anything that I can do to prevent any of that from happening?").

Claim-construction briefs and partial summary judgment motions remained pending at settlement, and the court never made any substantive rulings in the three years of litigation. Complaint ¶90.

Respondents settled under circuit precedent expressly holding that final settlements of non-sham, Hatch-Waxman litigation that do not restrict generic competition beyond the patent's exclusionary grant do not violate the antitrust laws, regardless of reverse payments. *Andrx Pharms.* v. *Elan Corp.*, 421 F.3d 1227, 1235 (CA11 2005); *Schering-Plough*, 402 F.3d at 1065-1066; *Valley Drug* v. *Geneva Pharms.*, 344 F.3d 1294, 1308 (CA11 2003).

After investigating the settlements administratively for two years (taking twenty-one depositions),

the FTC filed this antitrust suit in the Central District of California. That court transferred this suit and follow-on private suits to the Northern District of Georgia:

> [T]he FTC's desire to create a circuit split for strategic reasons bears little weight on the determination of transfer in the interest of justice and convenience of the parties and witnesses.
>
> ****
>
> Although the FTC points out that Judge Thrash did not enter any substantive rulings in the case, to assert that there would be "little to no judicial economy in transfer" goes too far.

FTC v. *Watson Pharms.*, 611 F.Supp.2d 1081, 1087-1088 (C.D.Cal. 2009).

Additional follow-on suits were centralized before Judge Thrash. *In re Androgel Antitrust Litig. (No.II)*, 655 F.Supp.2d 1351 (J.P.M.L. 2009).

The district court dismissed the FTC's complaint relying on the same Eleventh Circuit precedents respondents settled under; the private cases survived dismissal on claims of sham litigation. *Androgel*, 687 F.Supp.2d 1371 (N.D.Ga. 2010); Pet.App.37a-61a.

The FTC did not seek leave to amend, and the court entered final judgment on April 20, 2010. The FTC noticed its appeal on June 10, 2010.[1]

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[1] Thus, during Justice Kagan's tenure as Solicitor General, the United States may have participated in the FTC's decision whether to appeal.

The court of appeals affirmed on April 25, 2012, relying on the same Eleventh Circuit precedents respondents settled under. *FTC* v. *Watson Pharms.*, 677 F.3d 1298 (CA11 2012); Pet.App.1a-36a. It denied rehearing en banc on July 18, 2012. Pet.App.62a-63a. The FTC did not seek to stay the mandate, which issued on July 27, 2012.

The district court subsequently granted summary judgment in the private cases, holding that neither the patent litigations nor the settlements were a sham. *Androgel*, 2012 WL 5352986, at *7-16. The private plaintiffs have noticed their appeal.

These litigations ensued from the FTC's collateral attack on respondents' settlements. Respondents have been defending those settlements, which undisputedly conform with Eleventh Circuit law, for over six years—twice as long as the patent litigation itself.

B. Regulatory Regime

1. *The Hatch-Waxman Act: balanced goals, flawed implementation.* "The Hatch-Waxman Act establishes procedures designed to facilitate the market entry of lower-priced generic drugs while maintaining incentives to invest in new drug development." U.S.Br.2, *Joblove* v. *Barr Labs.*, 551 U.S. 1144 (2007) (No.06-830) (filed May 23, 2007). That description of Hatch-Waxman's balanced goals appears in each of the United States' prior briefs to the Court. U.S.Br.2, *Schering-Plough*; U.S.Br.2, *Andrx Pharms.* v. *Kroger*, 543 U.S. 939 (2004) (No.03-779) (filed July 9, 2004) (verbatim minus "market").

The petition, however, never mentions Hatch-Waxman's balancing of short-term consumer-welfare

interests in lower-priced drugs with long-term consumer-welfare interests in rewarding research and development. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 217 (CA3 2012) ("[I]n passing the Hatch-Waxman Act, Congress drew a careful line between patent protection and the need to provide incentives for competition in the pharmaceutical industry.").

But Hatch-Waxman is all about balance. Generics can provoke patent litigation through a "highly artificial act of infringement," *Eli Lilly* v. *Medtronic*, 496 U.S. 661, 678 (1990), by filing a Paragraph-IV ANDA without risking treble damages. Brand-names, in turn, can obtain a thirty-month stay on generic marketing while litigating the infringement case. To incentivize generics to file Paragraph-IV ANDAs, the first-to-file obtain 180-day exclusivity, which delays other generic entry and maintains higher drug prices.

Petitioner neglects to mention two other important features of Hatch-Waxman. First, the "highly artificial act of infringement" results in asymmetrical risks between brand-name and generic companies:

> Because the generic manufacturer will not have made infringing sales (that would give rise to claims for damages) or incurred production and marketing costs at the time of the infringement suit, its litigation risk will be minimal, whereas the patent holder faces potentially devastating consequences if it loses the litigation. The resulting disparity in the litigants' respective risks may tend to increase the cost of settlement

> for a patent holder and make reverse payments more likely, even when the patent holder's legal claims are relatively strong.

U.S.Br.10, *Joblove*.

Second, before the MMA's remedial changes, settlements between brand-names and generic first-filers could easily bottleneck entry of subsequent filers:

> [T]he 180-day exclusivity period created an incentive for the parties to settle the litigation with a non-entry payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market indefinitely.

U.S.Br.11, *Joblove* (internal quotation marks and alterations omitted).

The exclusivity provision, designed to incentivize generics by rewarding first-filers, thus had erected a barrier to entry for subsequent filers.

2. *The MMA's remedial amendments:* "Prompted by concern over the anticompetitive effects of agreements such as those at issue here, Congress amended Hatch-Waxman as part of the 2003 Medicare Amendments." FTC C.A.Br.8, *K-Dur*; see U.S.Br.18, *Andrx* ("[T]he 2003 amendments may reduce the number of agreements containing reverse payments.").

Among other remedial changes, the MMA addressed the bottlenecking of subsequent ANDA filers under Hatch-Waxman's first-filer exclusivity

provisions: "In 2003, Congress provided for forfeiture of the exclusivity period in various circumstances, and also provided that any generic manufacturer that filed an ANDA with a paragraph IV certification on the same day as the first filer would be treated as a first filer itself." U.S.Br.3 n.2, *Joblove*.

Beyond the MMA's new provisions on forfeiture and shared-exclusivity, the FTC recommended five additional remedial changes, and Congress enacted all five.[2]

The petition does not arise under the current landscape for Hatch-Waxman settlements because the settlements here involve ANDAs filed before the MMA became effective. Complaint ¶23. "[T]here are two separate exclusivity frameworks—one for first-filed ANDA applications submitted before December 8, 2003 (pre-MMA) and one for first-filed ANDA applications submitted on or after December 8, 2003 (post-MMA)." *ANDA Litigation: Strategies and Tactics for Pharmaceutical Patent Litigators* 68 (Kenneth L. Dorsney et al. eds., 2012).

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[2] Compare FTC, *Generic Drug Entry Prior to Patent Expiration* i-xi (July 2002), http://www.ftc.gov/os/2002/07/genericdrug study.pdf, with MMA amendments codified at 21 U.S.C. 355(j)(5)(B)(iii) (limiting brand-name company to one thirty-month stay per ANDA); 355 note (requiring settlements and related agreements to be filed with FTC and DOJ); 355(j)(5)(B)(iv)(I) (adding trigger for first-filer's 180-day exclusivity period for first-filer's marketing of brand-name product, including authorized-generics); 355(j)(5)(B)(iii)(I) (lowering "court decision" trigger for first-filer's exclusivity period to district court decisions); *ibid.* (adding "court decision" trigger for first-filer's exclusivity period for brand-name company's failure to contest a declaratory judgment action).

C. Facts

1. *Under the old Patent Act, Solvay's patent application was not public.* The FDA approved Solvay's New Drug Application (NDA) for AndroGel® in February 2000, and Solvay began sales without patent protection. Complaint ¶¶33-34, 39. Solvay's sales nonetheless were exclusive for three years under FDA regulation—an important fact because it explains (to us now as well as to the watchful generic industry then) why AndroGel® had exclusive, growing sales without patent protection. Complaint ¶34; Pet.App.39a.

Solvay subsequently applied for a patent in August 2000. Complaint ¶39. But that application was confidential under then-existing law; Congress amended the Patent Act three months later to make future applications public. 35 U.S.C. 122(b)(1)(A) (effective Nov. 29, 2000) ("[E]ach application for a patent shall be published ***.").

AndroGel®'s growing sales and apparent lack of patent protection, along with the publicly discernible sunset on its three-year exclusivity, attracted generic attention. Separate from "Paragraph-IV," Hatch-Waxman enables generics to "piggy-back[] on the brand's NDA" by filing an ANDA under Paragraphs-I, -II, or -III, when, respectively, (I) there is no patent on the brand-name's drug, (II) the patent has expired, or (III) the generic company certifies that it will not market its product during the patent's term. *Caraco Pharm. Labs.* v. *Novo Nordisk*, 132 S.Ct. 1670, 1676-1677 (2012) (citing 21 U.S.C. 355(j)(2)(A)(vii)(I)-(III)).

In December 2000, more than two years before Solvay's regulatory exclusivity would expire in February 2003, Paddock undertook to copy AndroGel® "as close as humanly possible," intending to file a Paragraph-I ANDA. *Androgel*, 2012 WL 5352986, at *3.

Paddock's world changed in January 2003 when, one-month before the three-year exclusivity would expire, the PTO issued Solvay's patent. Complaint ¶42; *Androgel*, 2012 WL 5352986, at *3 n.4 ("The Generics did not realize that AndroGel was patent protected because Solvay's patent application was not public."). Paddock stopped its bioequivalence work, later resuming with the fallback hope of becoming the first Paragraph-IV filer. See *Androgel*, 2012 WL 5352986, at *3. Paddock filed its Paragraph-IV in May 2003, not knowing that Watson had filed one days earlier. *Ibid.*; Complaint ¶¶44-45; Pet.App.41a.

Paddock never had been involved in a Paragraph-IV case and had not anticipated one, so it partnered with Par in July 2003 to take charge of the inevitable litigation, and its expense, in exchange for a share of potential generic profits. Complaint ¶¶46, 69; Pet.App.41a.

When Solvay subsequently sued Watson and Paddock in August 2003, the ANDA-filing numbers in the complaints were the first public indication that there were two Paragraph-IV filers, and that Watson was first-filer. Complaint ¶47; *ANDA Litigation*, *supra*, at 138 ("A key driver for nonlitigation alternatives is whether the generic party is a Paragraph IV first-filer, and this may not be known until around the time of the initial pleadings.").

2. *As the second ANDA filer, Par/Paddock were subject to Watson's exclusivity.* Throughout the litigations, Par/Paddock were blocked by Watson's first-filer exclusivity. Complaint ¶45. When the Hatch-Waxman thirty-month stay expired in January 2006, Watson, as first-filer, was free to launch its product, but FDA regulation barred Par/Paddock from marketing until 180-days after Watson. Complaint ¶¶2, 22-23, 52-54. Because Watson never launched, Par/Paddock never could. *Ibid.*

After three years of litigation, Solvay reached settlement terms with Watson, permitting Watson to enter no later than August 31, 2015 (five years before patent expiration). Complaint ¶¶60-67. After concluding its settlement terms with Watson, Solvay separately offered Par/Paddock the same entry terms subject to Watson's exclusivity. Complaint ¶71. Because that was the earliest settlement-entry date possible for a second-filer, Par/Paddock quickly accepted. *Ibid.*

When Par/Paddock settled with Solvay, Watson's 180-day exclusivity still applied. Complaint ¶45. Thus, Par/Paddock could obtain the same entry date as Watson "only if Watson did not assert its 180-day generic exclusivity period." Pet.App.44a. After the parties executed separate, confidential settlement agreements, Watson relinquished its first-filer exclusivity with the FDA, furnishing Par/Paddock an unanticipated windfall: the same entry date as the first-filer. B.I.O.App.4a ¶6.

The FTC alleges that the 2015 entry date had little value:

> *Watson* agreed not to market generic AndroGel until 2015 even though it knew of Solvay's plans to introduce a "line extension" product that would eliminate or substantially reduce potential sales of generic AndroGel by 2015. *** *Solvay told Watson* of its plans for a line extension product during settlement negotiations.

Complaint ¶¶62-63 (emphasis added); see Pet.6.

Conspicuously absent from these allegations is any mention of Par/Paddock, who were in the pre-MMA backseat throughout.

3. *Respondents settled under Eleventh Circuit precedent.* The scope-of-the-patent test was governing law in the Eleventh Circuit when respondents settled: absent allegations of sham-litigation or fraud in obtaining the patent, Hatch-Waxman settlements that do not restrict generic competition beyond the patent's exclusionary grant do not violate the antitrust laws, regardless of reverse payments. See p.2, *supra*.

Petitioner does not allege that: either settlement entails restrictions beyond the patent's exclusionary grant, Solvay's patent was obtained by fraud, or the patent litigations were shams. Complaint ¶¶65, 76, 86. The settlements undisputedly qualify for the safe harbor under which respondents settled.

Contemporaneous with the settlements, Solvay and Watson, and Solvay and Par/Paddock, entered into separate co-marketing agreements for AndroGel®. Complaint ¶¶66, 77. Eleventh Circuit law undisputedly permitted such transactions contemporaneous with Hatch-Waxman settlements. Furthermore, no legal objection to the co-marketing

agreements exists beyond petitioner's objection to the simultaneity with settlement. See generally *Sorrell* v. *IMS Health*, 131 S.Ct. 2653, 2659 (2011) ("Speech in aid of pharmaceutical marketing *** is a form of expression protected by the Free Speech Clause of the First Amendment."). Solvay and Paddock entered a manufacturing agreement, without which Solvay's sole source for AndroGel® was a company in Europe. Complaint ¶¶32, 84.

4. *Solvay and Par/Paddock are bound by the district court's Consent Judgment and Order of Permanent Injunction.* Solvay and Watson ended their litigation with a voluntary stipulation of dismissal. Solvay and Par/Paddock took a different path: asking the court to enter a consent judgment. Complaint ¶¶68, 80. The resulting Consent Judgment and Order of Permanent Injunction (B.I.O.App.1a-6a) is a final judgment with the force of res judicata and currently binds Solvay and Par/Paddock to their compromise terms on generic entry.

5. *After the Eleventh Circuit affirmed dismissal of this case, the Third Circuit decided an unrelated case.* "The key allegation in the FTC's complaint is that [Solvay] was 'not likely to prevail' in infringement actions that it brought against the generic manufacturers and then settled." Pet.App.3a; see Complaint ¶86. The Eleventh Circuit affirmed dismissal relying on its same precedents under which respondents had settled. It held that petitioner's allegation that Solvay was "not likely to prevail" did not state an antitrust claim against settlements undisputedly within the scope-of-the-patent. Pet.App.28a-30a. That decision accorded with the

other circuits that had adjudicated antitrust challenges to final Hatch-Waxman settlements. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (CAFC 2008) (*Cipro*); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (CA2 2006).

Three months later, in an unrelated case, the Third Circuit became the only circuit to reject the scope-of-the-patent test in favor of a presumption that "treat[s] any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade." *K-Dur*, 686 F.3d at 218.

REASONS FOR DENYING THE PETITION

The MMA remedial amendments demarcate the old Hatch-Waxman world from the new. This case falls on the wrong side of that line. Driven by some of the same concerns asserted in the petition, Congress recalibrated Hatch-Waxman's competitive landscape, resulting in sharply declining reverse-payment settlement rates. That this case arises under pre-amendment law is reason alone to deny the petition. *Verizon Commc'ns* v. *Law Offices of Curtis V. Trinko*, 540 U.S. 398, 412 (2004) ("One factor of particular importance is the existence of a regulatory structure designed to deter and remedy anticompetitive harm. Where such a structure exists, the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny.").

In *Schering-Plough*, the United States opposed the FTC's petition, advising the Court: "The decision below does not conflict with any decisions of this Court ***." U.S.Br.1. *Schering-Plough* is the precedent respondents settled under, and the precedent the Eleventh Circuit followed in upholding their settlements. The United States continued: "[T]he public policy favoring settlements, and the *statutory right of patentees to exclude competition within the scope of their patents*, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation." U.S.Br.10-11 (emphasis added). Petitioner argues that under this Court's precedents it stated a claim "by alleging the existence and circumstances of a presumptively anticompetitive reverse-payment agreement." Pet.24. There is no principled basis for reconciling these positions. Respondents' reliance and repose interests in settlements concluded in 2006, undisputedly in conformity with Eleventh Circuit law, should not depend on the outcome of an election any more than this Court's antitrust jurisprudence should.

The Eleventh Circuit's decision here is no less correct than *Schering-Plough* despite petitioner's allegation that "[h]ad the patent suit proceeded, Solvay's patent was unlikely to prevent generic entry." Complaint ¶3. This Court has never exposed litigants to antitrust liability on such flimsy allegations. *Prof'l Real Estate Investors* v. *Columbia Pictures Indus.*, 508 U.S. 49, 62 (1993) (denying antitrust claim because "sham litigation must constitute the pursuit of claims so baseless that no reasonable litigant could realistically expect to secure

favorable relief"); *Walker Process Equip.* v. *Food Mach. & Chem.*, 382 U.S. 172, 173 (1965) (holding that "enforcement of a patent obtained by fraud on the Patent Office may be the basis of an action under §2 of the Sherman Act"); *Standard Oil* v. *United States*, 283 U.S. 163, 171 (1931) ("Where there are *legitimately conflicting* [patent] claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act.") (emphasis added); cf. *Whitmore* v. *Arkansas*, 495 U.S. 149, 159-160 (1990) ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case."), cited in *Watson*, Pet.App.32a.

That the Third Circuit created a conflict only *subsequent* to the Eleventh Circuit's decision here is reason to deny (and not hold) this petition. Petitioner's contention that the Third Circuit's decision "has already led to inconsistent results in separate challenges to the same reverse-payment agreements," Pet.11, refers exclusively to the K-Dur settlements and is demonstrably false even as to those. There has not been (and may never be) any inconsistent result involving the K-Dur settlements: the Eleventh Circuit upheld them against the FTC's challenge based on the evidence taken at trial before the ALJ, Pet.30-31; the Third Circuit reversed summary judgment and remanded for further proceedings, which may offer the private plaintiffs the same trial opportunity the FTC had.

And petitioner can hardly complain of a circuit split that it sought to create: "We are looking to find cases so that we can create, for example, a split in the circuits that would militate toward the Supreme

Court taking a case. I can't discuss any of our individual investigations publicly, but we are looking to find a case." Testimony of Jon Leibowitz, Commissioner, FTC, *The Generic Drug Maze: Speeding Access to Affordable Life-Saving Drugs, Hearing Before Senate Special Committee on Aging*, 109th Cong. 51 (2006) (testifying a few months before FTC began investigating respondents' settlements and ultimately sued in California).

Indeed, petitioner prefers the Third Circuit's rule and plans to litigate there: "If [certiorari is denied], of course, we'll simply be forced to bring pay-for-delay cases in the Third Circuit for years to come." Remarks of FTC Chairman Jon Leibowitz, Sixth Annual Georgetown Law Global Antitrust Enforcement Symposium (Sept. 19, 2012), at 4, http://www.ftc.gov/speeches/leibowitz/120919jdlgeorgetownspeech.pdf. Petitioner's litigation options similarly belie its contention that it will be harmed by "flexible venue provisions" for appeal of Commission administrative decisions. Pet.11; see U.S.Br.19, *Schering-Plough* (disputing same forum-shopping argument by the FTC).

Significantly, the Third Circuit created the circuit split by misapplying one of this Court's abrogated former precedents, which was plain error. The panel also ignored that "while the federal patent laws favor full and free competition in the use of ideas in the public domain over the technical requirements of contract doctrine, settlement of litigation is more strongly favored by the law." *Flex-Foot, Inc.* v. *CRP, Inc.*, 238 F.3d 1362, 1369 (CAFC 2001), cited in *Watson*, Pet.App.33a; *Cipro*, 544 F.3d at 1333-1334;

Tamoxifen, 466 F.3d at 202-203; *Schering-Plough*, 402 F.3d at 1072.

This case is not needed to address the Third Circuit's error subsequent to the decision in this case. Petitioner concedes that the *K-Dur* petitions "would be adequate vehicles for deciding the question presented," Pet.29, and this Court rarely grants certiorari in a civil case due to a later-developing conflict. See pp.26-27 & n.6, *infra*.

I. Reverse-Payment Rates Are Declining After The MMA, And Neither This Case Nor *K-Dur* Arises Under Current Law.

The question presented is confined to Hatch-Waxman settlements. Pet.27 ("Payments from the plaintiff to the defendant are scarcely an essential or traditional feature of settlement practice—to the contrary, they appear to be largely unknown outside the Hatch-Waxman context.").[3] Steadily declining reverse-payment rates over the past five years cabin the issue further. The United States predicted that decline, twice advising the Court that the MMA amendments likely would reduce incentives for reverse-payment settlements and, therefore, coun-

[3] See U.S.Br.24 n.9, *K-Dur* ("[S]uch payments are essentially unknown in the settlement of other patent litigation."); U.S.Br.10, *Joblove* ("The Hatch-Waxman Act provides particular incentives for reverse payments in the context of settlements of patent infringement claims involving pharmaceutical products."); U.S.Br.10, *Schering-Plough* ("[T]he Hatch-Waxman Act may also create unique justifications for reverse payments ***."); U.S.Br.15-16, *Andrx* ("Settlements with reverse payments *** appear to be rare outside the Hatch-Waxman context.").

seled against granting certiorari in cases arising under pre-MMA law, like this one.

A. Reverse-payment rates have been declining since 2006.

Since the MMA, the FTC issues annual reports on Hatch-Waxman settlements. The latest report indicates that in FY 2011 there were 156 "final settlements," of which 28 (18%) were "potential pay-for-delay" settlements. See *Agreements Filed with FTC under MMA Act of 2003: Overview of Agreements Filed in FY 2011*, at 2, http://www.ftc.gov/os/2011/10/1110mmaagree.pdf.

The FTC defines "potential pay-for-delay" as settlements: (i) providing for anything other than immediate generic entry upon settlement, regardless of how long prior to patent expiration the settlement permits entry; and (ii) conferring any value to the generic apart from the value of early entry. *Ibid.*; see S. 27, 112th Cong. § 3(a)(2) (reported out of Judiciary Committee July 22, 2011) (pending FTC-proposed amendment to FTC Act establishing violation for Hatch-Waxman settlements where the "ANDA filer receives anything of value" and "agrees to limit *** sales of the ANDA product for any period of time"). (To whatever extent the remnants that do not make it out of the sausage factory are meaningful, the current bill prohibiting reverse-payment settlements is preceded by others in prior Congresses that have not become law. See U.S.Br.20 n.9, *Joblove* (citing bills pending in 2007).)

The FTC's latest annual report, *supra*, also indicates that while "potential pay-for-delay" rates

peaked at 50% in FY 2006, they have declined to a recent low in FY 2011.[4]

The declining rates of even "potential" reverse-payment settlements counter the government's contention that they "are increasingly common in the drug industry." Pet.16. Because such settlements occur only under Hatch-Waxman and rates are falling steadily, the question presented appears to be of waning importance after Congress's remedial amendments.

Declining rates during 2006-2011 are particularly significant because that period coincides with the "scope-of-the-patent" test being the unanimous rule among circuits that had adjudicated antitrust challenges to final Hatch-Waxman settlements

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[4] Overview of Final Settlements (2004-2011)

Fiscal Year	2004	2005	2006	2007	2008	2009	2010	2011
Final Settlements	14	11	28	33	66	68	113	156
Potential Pay-for-Delay	0	3	14	14	16	19	31	28
	0%	27%	50%	42%	24%	28%	27%	18%

From presentation by Bradley S. Albert, Deputy Assistant Director, FTC, *"Are Reverse Payments Dead?"* program sponsored by ABA Section of Antitrust Law, Healthcare and Pharmaceuticals Committee (Nov. 10, 2011).

(CA11, CA2, CAFC). Reverse-payment rates continued falling despite favorable case law.

The industry largely has resolved to forgo reverse payments. Empirically, this natural experiment debunks the government's newly cynical prediction that "[i]f reverse-payment agreements are treated as presumptively lawful, such arrangements will be highly attractive to both brand-name manufacturers and their would-be generic competitors." Pet.19. No doubt, there will be even fewer reverse-payment settlements given the Third Circuit's recent decision.

B. The FTC has not challenged any settlement arising under current law.

The government has litigated only three reverse-payment cases. Those settlements occurred in a discrete era (1997-2006) and involved pre-MMA ANDAs. This enforcement history is another reality check on petitioner's contention that the issue is exceptionally important.

1. *K-Dur® settlements (1997)*: The K-Dur settlements occurred fifteen years ago. The Third Circuit's recent decision concerns private-litigation challenges to those settlements. Separately, the FTC challenged the K-Dur settlements administratively, and after a two-month trial, the ALJ upheld the settlements. The Commission reversed, but the Eleventh Circuit vacated the Commission's decision. The FTC's challenge is over, and the Third Circuit's reversal of summary judgment in the private cases may provide those plaintiffs the same trial opportunity the FTC had.

Significantly, the private plaintiffs survived a motion to dismiss even though the district court

applied the scope-of-the-patent test. *In re K-Dur Antitrust Litig.*, 338 F.Supp.2d 517, 532-533 (D.N.J. 2004).

2. *Provigil® settlements (2005-2006)*: The FTC next litigated against settlements concluded in late 2005 and early 2006. The FTC survived a motion to dismiss even though the district court applied the scope-of-the-patent test. *King Drug of Florence* v. *Cephalon*, 702 F.Supp.2d 514, 528-529 (E.D.Pa. 2010). The FTC and private cases are stayed pending resolution of the *K-Dur* petitions.

3. *AndroGel® settlements (2006)*: The settlements in this case occurred in 2006.

The government has not challenged any alleged reverse-payment settlement occurring since. See *Overview of FTC Antitrust Actions in Pharmaceutical Services and Products* 13-19 (June 2012), http://www.ftc.gov/bc/healthcare/antitrust/rxupdate.pdf.

All three challenges involve Paragraph-IV ANDAs filed *before* the December 8, 2003 effective date of the MMA amendments and, therefore, are governed by pre-MMA law. See Complaint ¶23; Pet.App.27a n.9. Because of the time lag between a generic's Paragraph-IV filing and any subsequent litigation settlement, a settlement occurring after the MMA amendments (in 2006 for example) may still involve a pre-MMA ANDA. That is the case here, but is decreasingly likely for settlements occurring in 2007 and later. This lag explains the decline in reverse-payment rates since 2006. See p.19 & n.4, *supra*. The MMA's remedial changes just took time to affect ensuing settlements.

The MMA amendments are working. Intervention by the Court at this time is unwarranted, particularly in a case arising under pre-amendment law.

C. The United States twice advised the Court not to take cases arising under pre-MMA law.

In 2004, the United States advised the Court in *Cardizem/Andrx* (CA6): "This Court's review also may be unwarranted in light of certain amendments to the Hatch-Waxman Act that were enacted by Congress in 2003 ***." U.S.Br.18, *Andrx*. The pre-MMA origin of this case (and *K-Dur*) is important because declining reverse-payment rates and the fact that the government has not challenged any post-MMA settlements appear to be consequences of those remedial amendments—two of which the United States specifically advised the Court were likely to reduce incentives for reverse-payment settlements.

First, the MMA increases the likelihood that *multiple* ANDA filers will be awarded 180-day exclusivity. See 21 U.S.C. 355(j)(5)(B)(iv)(II)(bb). The United States invoked this shared-exclusivity amendment as counseling against certiorari for a pre-MMA case: "[A]llowing multiple ANDA applicants to obtain the 180-day exclusivity period[] may increase the transaction costs for pioneer drug companies that seek to enter into agreements with those applicants. On balance, therefore, the 2003 amendments may reduce the number of agreements containing reverse payments." U.S.Br.18, *Andrx*.

The Eleventh Circuit echoed that point here (albeit without addressing the MMA amendment) when discussing the infeasibility of a brand-name

company shielding a weak patent by buying off multiple generic challengers:

> If the patent actually is vulnerable, then presumably other generic companies, which are not bound by the first challenger's reverse payment settlement, will attempt to enter the market and make their own challenges to the patent. Blood in the water can lead to a feeding frenzy. Although a patent holder may be able to escape the jaws of competition by sharing monopoly profits with the first one or two generic challengers, those profits will be eaten away as more and more generic companies enter the waters by filing their own paragraph IV certifications attacking the patent.

Pet.App.35a-36a.

Second, the MMA added forfeiture provisions that can deprive a first-filer of 180-day exclusivity. In 2007, the United States advised the Court in *Tamoxifen/Joblove* (CA2):

> Congress amended the Hatch-Waxman Act to provide for forfeiture of the 180-day exclusivity period for various reasons ***. As a practical matter, therefore, it may now be more difficult for a first-filing generic manufacturer to enter into a settlement and then use the 180-day exclusivity period effectively to lock other generic manufacturers out of the market ***.

U.S.Br.19-20, *Joblove*.

Thus, because the MMA amendments significantly impair the ability of settlements under current law to bottleneck other potential generic challengers,

anticompetitive incentives for reverse payments are diminished. See U.S.Br.9-10, *Schering-Plough* (discussing pre-MMA bottlenecking potential and resulting incentives for reverse payments).

As the United States twice advised the Court, Congress's significant remedial changes in the MMA (including those proposed by the FTC, see p.7 & n.2, *supra*) have created a new competitive landscape for Hatch-Waxman litigation and settlements that counsels against granting certiorari in a case arising under pre-amendment law. The merits briefs and any ensuing decision in this case would be strewn with digressions about how things used to be pre-MMA versus how things might maybe would be or probably ought to be in a case arising under current law.

II. This Case Has Other Atypical Facts That Are Unlikely To Recur.

This case not only fails to present the Court with a Hatch-Waxman settlement governed by current law, it also has unusual facts that render it an unsuitable vehicle for the question presented.

A. The generics were unaware of Solvay's pending patent because of a flaw in the Patent Act that Congress subsequently remedied.

This case presents the unusual situation in which generics spent years copying a brand-name drug without attempting to "design around" any patent because, under then-existing law, patent applications were not public. See pp.8-9, *supra*. This anachronistic fact insulates this case from one of petitioner's principal arguments, namely, that Hatch-Waxman settlements harm consumer welfare when

brand-names use reverse payments to settle challenges from generics who themselves have innovated by designing around the brand-name's patent:

> In particular, a generic competitor may be able to design its product to satisfy FDA regulations regarding generic drugs yet avoid infringing a patent ***. Some scholars have concluded that the patent portfolios of brand-name drug manufacturers have grown in recent years with the addition of patents that may be particularly susceptible to being avoided, in whole or in part, by generic competitors.

Pet.17 (citations omitted).

Under current law, a generic makes its Paragraph-IV certification after endeavoring to design around the patent or undertaking to copy the product based on the generic's *a priori* determination that the patent is ripe for an invalidity challenge. Because this case involves a "patent surprise" resulting from a provision of the Patent Act no longer in effect, it is a poor vehicle for addressing the current Hatch-Waxman environment where generics make choices fully informed about pending patents.

B. Respondents settled under circuit precedent expressly permitting reverse payments.

In September 2006, after three years of litigation with no substantive rulings, respondents took the court's advice and executed final settlements. See p.2, *supra*. They relied on Eleventh Circuit precedent holding that a final settlement of patent litigation within the scope of the patent does not violate the antitrust laws, regardless of reverse payments.

See p.2, *supra*. The Eleventh Circuit also had held concerning Hatch-Waxman settlements that the "reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into." *Valley Drug*, 344 F.3d at 1306.

The only reason this petition is arguable under Rule 10 is due to the happenstance that in an unrelated case, the Third Circuit, following the guidance of the government as amici curiae,[5] subsequently diverged from unanimous circuit law and issued an opinion supporting the FTC's favored rule—three months after the Eleventh Circuit's decision in this case and six years after respondents settled.

Further review under these circumstances would deprive respondents of any modicum of repose. The Court rarely grants certiorari in a civil case where a conflict develops only after that case was decided. The Court did so in *Tidewater Oil Co.* v. *United States*, 409 U.S. 151 (1972): "Because this decision raises an important question of federal appellate jurisdiction and because a conflict among the circuits subsequently developed on this question, we granted certiorari." *Id.* at 153 (footnote omitted). But there, the petitioner in the subsequent case that created the conflict did *not* seek review of that question. See Petition for Writ of Certiorari at 2, *Fisons Ltd.* v.

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[5] In addition to amicus briefs from the FTC and United States, a deputy solicitor general argued for forty-seven minutes at the *K-Dur* oral argument, available at http://www.ca3.uscourts.gov/oralargument/ListArgumentsAll.aspx (No.10-2077) (Dec. 12, 2011); see *id.* at 00:32-00:35 (Sloviter, J.) ("Yeah, well you can go, I mean, it's the government we want to hear.").

United States, 405 U.S. 1041 (No.71-971) (filed Jan. 31, 1972). Therefore, the Court had to take the case that was decided before the conflict arose if the Court hoped to address the conflict at all.

Not so here, where this case is unnecessary to address the subsequent conflict created by the Third Circuit. The *K-Dur* petitions (filed before this one) present the issue.[6]

It cannot be right that parties can litigate for three years over a "highly artificial act of infringement," *Eli Lilly*, 496 U.S. at 678, with no substantive rulings, then, with the court's encouragement, settle their litigations under circuit law expressly holding that settlements within the scope-of-the-patent are legal regardless of reverse payments, and endure the FTC's six-year collateral attack on the settlements—yielding a decision and mandate from the court of appeals upholding the settlements under the same precedent on which the parties relied when they settled—only to find themselves whipsawed into extraordinary review because of a subsequently conflicting decision from another circuit in an unrelated case.

Even if petitioner were to prevail on the merits, there would be no closure but potentially years more litigation over whether, factually, there was even a

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[6] Research yielded only three examples since *Tidewater* where the Court granted certiorari in a civil case to resolve a later-developing conflict. See *Merrill Lynch, Pierce, Fenner & Smith* v. *Curran*, 456 U.S. 353, 356 (1982); *United States* v. *Consumer Life Ins.*, 430 U.S. 725, 727 (1977); *United States* v. *ITT Cont'l Baking*, 420 U.S. 223, 225 (1975).

reverse payment in this case. (*K-Dur*, however, presents an undisputed reverse payment. Pet.30-31.)

Respondents' reliance and repose interests, which are absent in *K-Dur* because petitioners there are the settling parties, warrant prompt denial of this petition even if the Court were to grant the *K-Dur* petitions. For the same reasons, holding this petition would be unjust.

C. The district court imposes the alleged restraint on Par/Paddock's generic entry.

Respondents' private settlement agreements (between Solvay and Watson on one hand, and Solvay and Par/Paddock on the other) could not of their own force end the patent litigations. Instead, Solvay and Watson dismissed their litigation "without prejudice" by filing a stipulation of dismissal "without a court order." Fed.R.Civ.P.41(a)(1)(A)(ii).

Solvay and Par/Paddock took the road less-traveled. They asked the court to enter the Consent Judgment and Order of Permanent Injunction, and the court did so. That order: (i) terminated Solvay and Par/Paddock's litigation "with prejudice"; (ii) enjoins Par/Paddock from selling its generic version of AndroGel® until 2015 at the latest; (iii) guarantees Par/Paddock's right to practice the patent after that date; and (iv) retains continuing jurisdiction to enforce these terms. B.I.O.App.4a-5a ¶¶6, 9-11, 13.

The order binds Solvay and Par/Paddock to their generic-entry compromise and achieves finality and repose (or, at least it was supposed to) in ways that a settlement agreement alone could not. See *United States* v. *Swift*, 286 U.S. 106, 115 (1932) ("We reject

the argument *** that a decree entered upon consent is to be treated as a contract and not as a judicial act."); *SEC* v. *Randolph*, 736 F.2d 525, 528 (CA9 1984) ("A consent decree offers more security to the parties than a settlement agreement where the only penalty for failure to abide by the agreement is another suit."), quoted in *EEOC* v. *Product Fabricators*, 666 F.3d 1170, 1173 (CA8 2012); see also *Schering-Plough*, 402 F.3d at 1072 ("Veritably, the Commission's opinion would leave settlements, including those endorsed and facilitated by a federal court, with little confidence.").

Because Solvay and Par/Paddock successfully *petitioned* the court for an order governing their compromise generic-entry terms, they are immune from antitrust liability under *Noerr-Pennington*:

> We conclude that it would be destructive of rights of association and of petition to hold that groups with common interests may not, without violating the antitrust laws, use the channels and procedures of state and federal agencies *and courts* to advocate their causes and points of view respecting *resolution of their business and economic interests* vis-à-vis *their competitors*.

Cal. Motor Transp. v. *Trucking Unlimited*, 404 U.S. 508, 510-511 (1972) (emphasis added); see *Andrx Pharms.*, 421 F.3d at 1234 (CA11 2005) ("[A]s the Supreme Court has noted, engaging in litigation to seek an anticompetitive outcome from a court is First Amendment activity that is immune from antitrust liability."); *Columbia Pictures Indus.* v. *Prof'l Real Estate Investors*, 944 F.2d 1525, 1528 (CA9 1991) ("A decision to accept or reject an offer of settlement is

conduct incidental to the prosecution of the suit and not a separate and distinct activity which might form the basis for antitrust liability."), aff'd, 508 U.S. 49 (1993); cf. *Valley Drug*, 344 F.3d at 1309 ("The failure to produce the competing [generic] drug, rather than the payment of money, is the exclusionary effect ***.").

Noerr-Pennington immunity trumps the question presented as to the settlement between Solvay and Par/Paddock because petitioner seeks to undo the order that Solvay and Par/Paddock successfully petitioned the court to enter as a continuing injunction enforcing their compromise terms on Par/Paddock's generic entry.

D. As the second ANDA filer, Par/Paddock could not have obtained an earlier settlement-entry date.

Petitioner's theory is that but-for alleged reverse payments, each generic would have obtained an earlier entry date. Complaint ¶¶93-94; Pet.22-23. That theory is inapplicable to second-filer Par/Paddock, whose settlement enabled entry on the *same day* as Watson, 180-days earlier than Watson's pre-MMA exclusivity period otherwise would have permitted. Pet.App.12a. Par/Paddock's settlement is pro-competitive.

Even under petitioner's theory that a settlement enabling generic entry before patent expiration may nonetheless cause anticompetitive "delay," there could only be a purported delay if the second-filer were to enter more than 180-days *after* the first-filer. In the three reverse-payment cases litigated by the FTC (all involving pre-MMA ANDAs), Par/Paddock is

the only second-filer that obtained the same entry date as the first-filer.[7]

Given that Par/Paddock could not have obtained an earlier settlement-entry date than the first-filer, petitioner is left to allege: "If Solvay had settled with Watson only, Par had ample financial incentive to continue to challenge Solvay's patent." Complaint ¶95. Petitioner's theory thus morphs from one alleging a hypothetical, earlier settlement-entry date into one alleging a duty on second-filer Par/Paddock to have continued litigating based on an allegation of "ample financial incentive."

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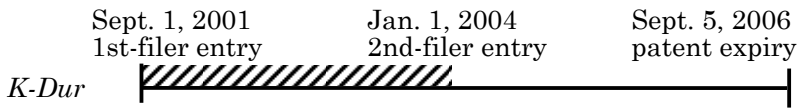
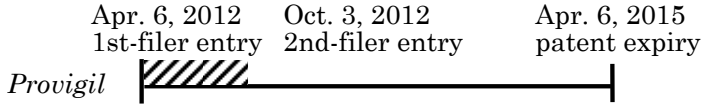
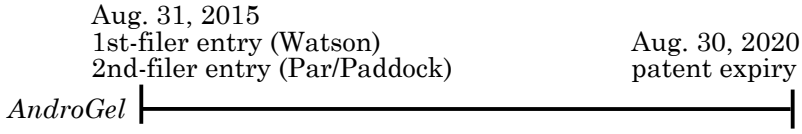


"Delay" between first- and second-filer entry = 28 months



"Delay" between first- and second-filer entry = 180 days



"Delay" between first- and second-filer entry = zero

From FTC complaints susceptible of judicial notice. See *Tellabs* v. *Makor Issues & Rights*, 551 U.S. 308, 322 (2007).

But under pre-MMA rules for subsequent ANDA filers, success in a continued litigation by Par/Paddock would have required winning "a final decision of a court from which no appeal *** has been or can be taken." 21 U.S.C. 355 note (explaining pre-MMA rule). And, pre-MMA, *Watson* would have reaped the reward—with Par/Paddock having to wait dutifully to enter 180-days later.

Petitioner's complaint against Par/Paddock dangles by an allegation of "ample financial incentive" for continued litigation (after Watson settled) when Congress changed the statutory scheme precisely because such incentives were lacking. See *Mova Pharm.* v. *Shalala*, 140 F.3d 1060, 1073 (CADC 1998) ("One difficulty is that the 180-day exclusivity period will seemingly always go to the *first* applicant, no matter whose suit satisfies the court-decision trigger ***. It seems odd to reward the first applicant if some later applicant was the party that actually prevailed in the patent-infringement litigation.").

As a Hatch-Waxman practice manual observes:

> If the generic is not a first-filer, it will obtain no exclusivity even if the patent is held invalid or not infringed. Thus, there is little to gain by remaining a party to the litigation and continuing to pay litigation costs and endure discovery burdens. Nonlitigation alternatives should, therefore, be considered all the more seriously to avoid unnecessary litigation costs.

ANDA Litigation, *supra*, at 138.

Rather than presenting a suitable opportunity to address the question presented, petitioner's case as to

the Par/Paddock settlement is bound-up in the old problems with first- versus subsequent-filer settlements addressed by the MMA.

III. The Third Circuit Misapplied *Katzinger*, Which This Court Abrogated In *Lear*.

A. In rejecting the unanimous decisions of three circuits, the Third Circuit purported that its "practical analysis is supported by a long line of Supreme Court cases recognizing that valid patents are a limited exception to a general rule of the free exploitation of ideas." *K-Dur*, 686 F.3d at 215. But the only decision of this Court that the Third Circuit addressed beyond mere citation is *Edward Katzinger Co.* v. *Chicago Metallic Mfg.*, 329 U.S. 394 (1947), abrogated by *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969), overruling in part *Automatic Radio Mfg.* v. *Hazeltine Research*, 339 U.S. 827 (1950). Tellingly, neither petitioner nor any of the courts adjudicating antitrust challenges to Hatch-Waxman settlements cites *Katzinger*.

Laboring under this Court's now-overruled patent-licensee estoppel rule, *Katzinger* concerned whether a commercial licensee of a patent could be estopped, by virtue of the licensing agreement, from challenging the validity of the patent. 329 U.S. at 395. *Katzinger* held that because the licensing agreement contained a price-fixing clause for product sold under the license, the licensee was not estopped from challenging patent validity. *Id.* at 399-401. On the same day, the Court decided *MacGregor* v. *Westinghouse Elec. & Mfg.*, 329 U.S. 402, 407 (1947) (likewise holding that in a suit for royalties, a patent licensee can assert invalidity where the commercial-

licensing agreement contains a price-fixing provision). *Katzinger* and *MacGregor* extended the then-existing "anti-trust exception" to the now-overruled patent-licensee estoppel rule. *Lear*, 395 U.S. at 666 ("Five years later [after *Sola Elec.* v. *Jefferson Elec.*, 317 U.S. 173 (1942)], the 'anti-trust exception' was given an even more extensive scope in the *Katzinger* and *MacGregor* cases.").

Sola, *Katzinger*, and *MacGregor* became dead-letter exceptions when this Court finally overruled the patent-licensee estoppel rule itself in *Lear*. *Id.* at 671 ("We are satisfied that [*Automatic Radio* v. *Hazeltine*], itself the product of a clouded history, should no longer be regarded as sound law with respect to its 'estoppel' holding, and that holding is now overruled."). To recap, the law now is that a commercial-licensing agreement *cannot estop* a patent licensee from challenging patent validity, regardless of whether the licensing agreement includes a price-fixing clause.

When *Lear* overruled the estoppel rule, the Court abrogated the patchwork of exceptions to that rule that had accreted over the years in cases like *Sola*, *Katzinger*, and *MacGregor*. That was *Lear*'s point: "During this period, each time a patentee sought to rely upon his estoppel privilege before this Court, the majority created a new exception to permit judicial scrutiny into the validity of the Patent Office's grant." *Id.* at 664. *Lear* continued: "The result has been a failure. *** [T]here has been a chaos of conflicting case law, proceeding on inconsistent premises." *Id.* at 668.

Lear could not have been plainer that it was giving a decent public burial to the former exceptions to the estoppel rule along with the rule itself.

The Third Circuit's decision never mentions any of this, nevermind that *Katzinger*'s holding no longer has any meaning in the law. It simply plucks convenient language from *Katzinger* and moves on. *K-Dur*, 686 F.3d at 216. The Third Circuit concludes its reliance on *Katzinger* with a further leap: "This logic is persuasive with respect to the situation at bar because reverse payments permit the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid." *Ibid.*

But *Katzinger* concerned ordinary patent-licensing agreements. It had nothing to do with settling patent litigation. Even post-*Lear*, a patent-litigation settlement *can estop* a settling alleged infringer from challenging the patent:

> *Lear*, however, did not involve a settlement of litigation, but only the right of a patent licensee to challenge the validity of the licensed patent. The enforcement of settlement of litigation involves another public policy totally absent in *Lear*: the encouragement of settlement of litigation and the need to enforce such settlements in order to encourage the parties to enter into them.

Hemstreet v. *Spiegel, Inc.*, 851 F.2d 348, 350 (CAFC 1988) (holding that settling alleged infringer was estopped from challenging patent and obligated to continue paying royalties under the settlement license even though a third party subsequently invalidated the patent).

Because of these overriding interests in achieving finality and repose in litigation settlements, every circuit that has addressed the issue post-*Lear* agrees that patent-litigation settlement agreements (as opposed to ordinary patent-licensing agreements) can estop settling alleged infringers from challenging the patent.[8]

Thus, the Third Circuit not only misrelied on *Katzinger*'s abrogated "anti-trust exception" to the now-overruled estoppel rule, the court misapplied that orphaned exception to the patent-litigation settlement context. If settling alleged infringers can

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[8] *E.g.*, *Flex-Foot*, 238 F.3d at 1368-1369 ("The license agreement in *Lear* was not created as part of a litigation settlement. *** *Hemstreet* was premised on the policy that while the federal patent laws favor full and free competition in the use of ideas in the public domain over the technical requirements of contract doctrine, settlement of litigation is more strongly favored by the law."); *Wallace Clark & Co.* v. *Acheson Indus.*, 532 F.2d 846, 849 (CA2 1976); *Interdynamics* v. *Firma Wolf*, 653 F.2d 93, 97-98 (CA3 1981); *Schlegel Mfg.* v. *USM Corp.*, 525 F.2d 775, 781 (CA6 1975) (per curiam); *Am. Equip.* v. *Wikomi Mfg.*, 630 F.2d 544, 546-549 (CA7 1980); *United States ex rel. Shell Oil* v. *Barco Corp.*, 430 F.2d 998, 1001-1002 (CA8 1970); see also *Rates Tech.* v. *Speakeasy*, 685 F.3d 163, 167 (CA2 2012) (holding that licensee was not estopped from challenging patent because the "no-challenge clause in this case *** was entered into prior to any litigation between the parties"), petition for cert. filed, 81 U.S.L.W. 3199 (Sept. 28, 2012) (No.12-402) (seeking review of whether patent-settlement estoppel can apply to pre-suit agreements); *Massillon-Cleveland-Akron Sign Co.* v. *Golden State Adver.*, 444 F.2d 425, 425-426 (CA9 1971) (holding that licensee was not estopped from challenging patent where the "covenant[] to refrain from directly or indirectly contesting or questioning the validity of the patent" did not settle patent litigation).

be estopped from challenging a patent post-*Lear*, *Katzinger* has nothing to add.

In creating the circuit split, the panel was untroubled that none of the circuits adhering to the scope-of-the-patent test had cited *Katzinger*. Indeed, the panel patted itself on the back for finding the answer key that no other court had. *K-Dur*, 686 F.3d at 216 ("It appears that these aspects of the Supreme Court's general patent jurisprudence had been overlooked by the Special Master and others adopting the scope of the patent test.").

But beyond the panel's discussion of *Katzinger*, its reliance on this Court's "general patent jurisprudence" consists merely of a string-citation piling on additional convenient language without analyzing whether those cases' holdings support the panel's conclusion that antitrust law regulates settlements of non-sham patent litigation that do not exclude competition beyond the patent's exclusionary grant. See *id.* at 215-216. Not surprisingly, none of the four cases cited remotely supports that conclusion.[9]

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[9] See *Cardinal Chem.*, 508 U.S. at 96, 102 (reversing the Federal Circuit's rule that it lacked jurisdiction to address patent validity "after affirming [a] finding of noninfringement," reasoning that "[t]he Federal Circuit's practice denies the patentee such appellate review"); *Bonito Boats*, 489 U.S. at 161 (holding that federal patent law preempts conflicting state law that mimics patent rights: "[A]llowing the states to create patent-like rights in various products in public circulation would lead to administrative problems of no small dimension."); *Masonite*, 316 U.S. at 280 (holding that price-fixing agreements exceeded the patent's exclusionary grant: "In this case, the price regulation was based on mutual agreement among distributors of competing products, some of whom had competing patents, as we have noted. None of these patents ***

B. The Third Circuit ignored most of this Court's precedents on which the Eleventh, Second, and Federal Circuits had relied in adopting the scope-of-the-patent test. The panel's decision contains nary a citation to:

1. *Standard Oil*, 283 U.S. at 171, discussed in *Schering-Plough*, 402 F.3d at 1072 ("That the parties to a patent dispute may exchange consideration to settle their litigation has been endorsed by the Supreme Court."); *Tamoxifen*, 466 F.3d at 202; *Cipro*, 544 F.3d at 1333.

2. *Walker Process*, 382 U.S. at 177, discussed in *Valley Drug*, 344 F.3d at 1307 ("The only time the Supreme Court has addressed the circumstances under which the patent immunity from antitrust liability can be pierced, it held that the antitrust claimant must prove that the patentee enforced a patent with the knowledge that the patent was procured by fraud on the Patent Office."); *Cipro*, 544 F.3d at 1336; cited in *Watson*, Pet.App.4a.

3. *United States* v. *Singer Mfg.*, 374 U.S. 174, 196-197 (1963) ("'[T]he possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act *beyond the limits of the patent monopoly*.'") (emphasis added) (quoting *United States* v. *Line Material*, 333 U.S. 287, 308 (1948)), cited in *Watson*, Pet.App.24a; *Schering-*

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had been held to conflict with or infringe the Masonite patents."); *Pope*, 144 U.S. at 224 (120-year-old case concerning the estoppel rule overruled by *Lear*); *see also Studiengesellschaft*, 670 F.2d at 1135 ("None of the anti-competitive effects of the challenged restriction found by the district court exceed the anticompetitive effects which the patent authorized.").

Plough, 402 F.3d at 1067; *Tamoxifen*, 466 F.3d at 202; see *Valley Drug*, 344 F.3d at 1307 (quoting *Line Material*, 333 U.S. at 309).

4. *Dawson Chem.* v. *Rohm & Haas*, 448 U.S. 176, 215 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."), discussed in *Watson*, Pet.App.18a; *Schering-Plough*, 402 F.3d at 1066; *Tamoxifen*, 466 F.3d at 201-202; *Cipro*, 544 F.3d at 1333; *Valley Drug*, 344 F.3d at 1304.

C. The Third Circuit's decision is a solitary outlier, the first ever to diverge from the scope-of-the-patent test. The Third Circuit initially said that "five other circuits have addressed the question," but subsequently conceded that decisions from the Sixth and D.C. Circuits (both concerning the same 1997 interim-litigation agreement) "did not involve a settlement resolving patent litigation." *K-Dur*, 686 F.3d at 209-210; see Pet.13 (conceding that "the Sixth and D.C. Circuits have not adopted specific standards to determine the legality of reverse-payment agreements").

As the United States previously advised the Court: "[*Cardizem/Andrx*] involves the relatively rare situation in which the parties entered into an *interim* agreement that did not resolve the parties' underlying patent dispute. *** The distinction is important because the calculus of competitive costs and benefits is substantially different for interim settlements and final settlements." U.S.Br.7, 17, *Andrx*.

The Sixth and D.C. Circuits are not involved in the conflict single-handedly created by the Third

Circuit's misapplication of *Katzinger*. The panel's plain error—subsequent to the Eleventh Circuit's decision in this thoroughly litigated case—is not a basis for further review here.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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Paddock Holdings, Inc.

NOVEMBER 2012

APPENDIX

APPENDIX

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

No. 1:03-CV-2503

UNIMED PHARMACEUTICALS, INC.,
A DELAWARE CORPORATION, AND
LABORATORIES BESINS ISCOVESCO,
A DELAWARE CORPORATION,
PLAINTIFFS,
v.
PADDOCK LABORATORIES, INC.
A MINNESOTA CORPORATION,
DEFENDANT

[Filed: September 15, 2006]

CONSENT JUDGMENT AND ORDER OF PERMANENT INJUNCTION

This action for patent infringement (the "Litigation") has been brought by Plaintiff Unimed Pharmaceuticals, Inc. ("Unimed") (a wholly-owned subsidiary of Solvay Pharmaceuticals, Inc. ("Solvay")), and Laboratories Besins Iscovesco ("Besins"), against Defendant Paddock Laboratories, Inc. ("Paddock") for infringement of United States Patent No. 6,503,894 (the "'894 Patent"), covering a pharmaceutical transdermal gel sold under the trademark Androgel® (the "Unimed Product"). Each

of Unimed, Solvay, and Besins (the "Plaintiffs") and Paddock, together with its assignee Par Pharmaceutical Companies, Inc. ("Par"), acknowledge there is significant risk to each of them associated with the continued prosecution of this Litigation and have consented to judgment through a final settlement, which was encouraged by the Court pursuant to its Local Rules, and as reflected in the consent judgment set forth herein.

Plaintiffs and Paddock, together with Par, have agreed to enter into a good faith final settlement agreement regarding this Litigation on the expectation and belief that this would result in a number of public interest benefits. Pursuant to a settlement agreement and ancillary patent license agreement (the "Agreements") entered into for the final resolution of this Litigation, Par will be able to market the Paddock Product, as defined herein, by no later than 2016, allowing entry of a generic version of the Unimed Product in advance of the 2020 expiration of the '894 Patent, which competition otherwise might not have occurred or been allowed to continue had Plaintiff prevailed on any one of the numerous claims brought against Paddock in the Litigation.

The proposed settlement also would eliminate the substantial litigation costs that would otherwise be incurred by both Plaintiffs and Paddock during the Litigation, while also serving the public interest by saving judicial resources and avoiding the risks to each of the parties associated with infringement. This will afford Plaintiffs and Paddock the opportunity to more productively use money and other resources that would have been spent in the

continued prosecution and defense of this Litigation, to the benefit of the Parties and consumers alike, such as by investing more money in marketing, research and development and education of physicians and patients regarding use and benefits of the Unimed Product, that will facilitate competition and the benefits therefrom approximately five years earlier than could be achieved if the Paddock Product were permanently enjoined during the life of the '894 patent.

In order to effectuate this settlement, Par consents to the jurisdiction of this Court.

Plaintiffs and Paddock now consent to this Judgment and Order of Permanent Injunction (the "Judgment") and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

1. This Court has jurisdiction over the parties and subject matter of this action.

2. The '894 Patent is owned by Plaintiffs (or its affiliates) and is valid and enforceable, as asserted in their Complaint against Paddock, in all respects.

3. Paddock and Par acknowledge that the claims of the '894 Patent are valid and enforceable in all respects.

4. Paddock and Par acknowledge that the sale of the product described in its Abbreviated New Drug Application No. 76-744 (the "Paddock Product") would infringe the claims of the '894 Patent, as asserted in the Complaint against Paddock.

5. Paddock assigned its rights in the Paddock Product to Par and Par has assumed certain obligations to defend Paddock in the Litigation.

6. As a result, Paddock and Par are barred from practicing the '894 Patent until

> the earliest of (a) August 31, 2015, provided there is no commercialization sufficient to trigger Hatch-Waxman 180 day exclusivity; (b) the date any Generic Testosterone Gel Product (as defined in the relevant Agreements) is offered for sale in the Territory (as defined in the relevant Agreements); or (c) in any other event, February 28, 2016, by manufacturing, marketing or selling the Paddock Product, pursuant to the terms of the parties' Agreements that permit the practice of the '894 Patent.

7. The submission of Paddock's Abbreviated New Drug Application No. 76-744 under Section 505(j) of the Federal Food, Drug and Cosmetic Act is an act of infringement of the '894 Patent under 35 U.S.C. 271(e)(2)(A).

8. Paddock and Par would infringe the '894 Patent by selling, offering to sell, importing and/or using the Paddock Product.

9. All affirmative defenses, claims and counterclaims, which have been or could have been raised by Paddock in this action with respect to the validity or enforceability of the '894 Patent, are dismissed with prejudice.

10. Except as agreed to by the parties pursuant to the Agreements in settlement of this Litigation or otherwise, Paddock and Par are also hereby enjoined

and estopped during the term of the '894 Patent, from making any challenge to the validity or enforceability of the '894 Patent with respect to the claims asserted against Paddock, or from marketing and selling the Paddock Product.

11. The foregoing injunction against Paddock and Par shall take effect immediately upon entry of this Judgment, and shall continue generally with respect to the '894 Patent coterminous with the license grant provided by the Agreements, unless earlier terminated or modified by further order of this Court.

12. The parties waive all right to appeal from this Judgment.

13. This Court shall retain jurisdiction of this action and over the parties for purposes of enforcement of the provisions of this Judgment.

14. Each party is to bear its own costs and attorney's fees.

Dated: September 14, 2006

By:

/s/ Bradley W. Grout

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SO ORDERED, this 15th day of September, 2006

/s/Thomas W. Thrash
Thomas W. Thrash Jr.
United States District Judge