Nos. 12-245 & 12-265

IN THE

Supreme Court of the United States

MERCK & CO., INC.,

Petitioner,

v.

LOUISIANA WHOLESALE DRUG CO., ET AL.,

Respondents.

UPSHER-SMITH LABORATORIES, INC.,

Petitioner,

v.

LOUISIANA WHOLESALE DRUG CO., ET AL.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

AMICI BAYER AG & BAYER CORP.'S BRIEF IN SUPPORT OF PETITIONERS

PHILLIP A. PROGER
KEVIN D. MCDONALD
LAWRENCE D. ROSENBERG
VICTORIA DORFMAN
MARK R. LENTZ
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001

September 24, 2012

PETER B. BENSINGER, JR.
Counsel of Record
MICHAEL J. VALAIK
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 West Hubbard St.
Chicago, IL 60654
(312) 494-4400
Peter.bensinger@bartlit-beck.com

Counsel for Amici Bayer AG & Bayer Corp.

CORPORATE DISCLOSURE STATEMENT

Bayer Corporation is a wholly-owned subsidiary of Bayer AG. There is no publicly-held company that owns more than 10% of Bayer AG.

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STATEMENT OF INTEREST OF BAYER AG AND BAYER CORPORATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

Bayer AG and Bayer Corporation research and manufacture patented pharmaceutical products. [1] The question presented in the Petitions significantly affects Bayer because it is involved in litigation as to those products, and sometimes settles such litigation.

In 1997, Bayer entered into a so-called reverse-payment settlement with a generic manufacturer arising out of litigation regarding Bayer's patent on Ciprofloxacin. Various plaintiffs challenged that settlement in several federal and state courts. After Bayer won summary judgment in federal district court, the Second and Federal Circuits ultimately heard appeals from two groups of plaintiffs. Both courts adopted the same "scope of the patent" test – holding that a settlement of patent litigation within the exclusionary scope of a patent is legal unless the patent owner committed fraud on the Patent Office or the patent litigation was a sham. *Ark. Carpenters Health & Welf. Fund v. Bayer AG*, 604 F.3d 98, 106, 110 (2d Cir. 2010) (per curiam) (*Cipro IV*), *cert. denied*, 131 S. Ct. 1606 (2011); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed.

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[1] Pursuant to this Court's Rule 37.6, *amici curiae* affirm that no counsel for any party authored this brief in whole or in part, that no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief, and that no person other than amici or their counsel made a monetary contribution intended to fund the preparation or submission of this brief. The parties have consented in writing to the filing of this brief.

Cir. 2008) (*Cipro III*), *cert. denied*, 557 U.S. 920 (2009). There was then no circuit split, and this Court denied certiorari in both cases.

Bayer currently is a defendant in a case pending in the California Supreme Court challenging the same settlement that was at issue in the Second and Federal Circuit rulings. *In re Cipro Cases I & II*, 269 P.3d 653 (Cal. 2012). California's Cartwright Act largely follows the Sherman Act. *See, e.g.*, *Asahi Kasei Pharma Corp. v. CoTherix, Inc.*, 204 Cal. App. 4th 1, 12 (2012). Bayer's *Cipro* case has some, but not all, of the elements of the present case because the parties in *Cipro* stipulated that there was infringement and disputed only patent validity. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 518 (E.D.N.Y. 2005) ("*Cipro II*"). Nonetheless, there is no doubt that the issues raised in this petition will be relevant to the decision of the California Supreme Court. Indeed, the California Supreme has – on its own motion – stayed its proceedings in the *Cipro* cases pending the outcome of these certiorari petitions. Stay Order (9/12/12).

The Third Circuit's decision in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), undermines the established law governing a core legal right of any patent holder – the right to enter into agreements no more exclusionary than the patent itself, including agreements that settle patent litigation.

SUMMARY OF ARGUMENT

Bayer agrees with petitioners in *Merck & Co. v. Louisiana Wholesale Drug Co.*, No. 12-245, and *Upsher-Smith Laboratories, Inc. v. Louisiana*

Wholesale Drug Co., No. 12-265, that this Court should grant review.

1. The scope of the patent rule is fully consistent with this Court's decisions on the intersection of patent and antitrust law. Those cases demonstrate that the exclusionary effect of a patent cannot be ignored in an antitrust case; that there is no antitrust violation so long as the challenged conduct is within the scope of a valid patent. The scope of the patent rule is based on these principles and has evolved in a series of thoughtful circuit court decisions.

The Third Circuit ignored these precedents, relying instead on dicta from inapposite cases. In departing from the holdings and reasoning of its sister Circuits, the *K-Dur* court below made numerous mistakes of fact and law that should not be permitted to disrupt otherwise uniform law governing the essential right to settle a patent suit.

2. The scope of the patent rule benefits consumers. That rule respects and fosters innovation leading to the creation of life-saving drugs, which is a lengthy, expensive and risky undertaking. The grant of a patent monopoly bestows on the innovator the ability to charge higher prices thereby recouping investment in creating new drugs. Without such innovation, there would be no drug prices to lower. The rule also embraces, just as the Third Circuit's rule undermines, the universal policy in favor of judicial settlement.

Finally, in rejecting the scope of the patent rule, the Third Circuit relied on two flawed studies, neither of which actually supports the result below.

ARGUMENT

The Third Circuit's decision creates a square conflict in the circuits as to when a settlement of patent litigation within the exclusionary scope of the patent may be declared illegal under the antitrust laws. The Second, Eleventh and Federal Circuits have rejected antitrust challenges to reverse payment settlements where those settlements did not exceed the scope of the patent. *See FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012); *Cipro IV*, 604 F.3d 98; *Cipro III*, 544 F.3d 1323; *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004). The Third Circuit below expressly disagreed with those decisions and rejected the so-called "scope of the patent" rule. Pet. App. 31a.

Instead, the Third Circuit effectively created a rule of presumptive liability. The decision threatens the fundamental stability of research and innovation in the pharmaceutical industry in which *amici* actively participate. Given the reality that even pharmaceutical patents that innovators believe to be the strongest and most secure are routinely challenged by generic manufacturers, the decision below dramatically undermines innovation by changing the rules governing settlement, and may require innovators and generics to engage in costly and uncertain litigation to its ultimate conclusion. The result will make consumers worse off, as there will be fewer settlements that guarantee at least

some generic entry before the patent expires, and fewer challenges by generic companies because most are unwilling to litigate to the death.

I. THIS COURT SHOULD GRANT REVIEW TO CONFIRM THAT THE "SCOPE OF THE PATENT" TEST IS CORRECT

A. The Scope of the Patent Rule Is Firmly Grounded In This Court's Precedent

This Court first considered the application of antitrust law to agreements within the scope of a patent in 1902, and flatly declared that "[t]he first important and most material fact in considering this question is that the agreements concern articles protected by letters patent …." *Bement v. Nat'l Harrow Co.*, 186 U.S. 70, 88 (1902). As was the case in *Bement*, when the agreements exclude no more competition than the patent itself, they do not restrain lawful competition. *Id.* at 91. The Court subsequently confirmed that the rule applies even to setting prices under a license, which is "the essence of that which secures proper reward to the patentee." *United States v. General Elec. Co.*, 272 U.S. 476, 493 (1926).

As the Court recognized, the antitrust laws were never intended to restrict this fundamental right unless and until the agreement in question exceeded the patent's exclusionary effect: "But [the Sherman Act] clearly does not refer to that kind of a restraint of interstate commerce which may arise from reasonable and legal conditions imposed upon the assignee or licensee of a patent …." *Bement,* 186 U.S. at 92. The Court's decision in *Bement* was critical for two reasons. First, it occurred at a time when the antitrust laws were thought to condemn

per se "any restraint of commerce, whether reasonable or unreasonable." *Id.* at 92. Acknowledging the point, the Court still found that because the agreements were within the patent's scope, they did not restrain lawful commerce at all. *Id.*

The second critical aspect of *Bement* is that the agreements in question were entered into to settle patent litigation. "This execution of these contracts did in fact settle a large amount of litigation regarding the validity of many patents …. This was a legitimate and desirable result in itself." *Id.* at 93.

Underlying these decisions is a principle so fundamental that it seldom needs to be stated expressly: the antitrust laws protect only *lawful* competition. *See, e.g.*, *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790-92 (8th Cir. 2006) (no antitrust liability for conspiring to preclude the importation of illegal drugs); *Access Telecom, Inc. v. MCI Telecomms. Corp.*, 197 F.3d 694, 712-13 (5th Cir. 1999) ("If there is no legal U.S. export market …, then there is no antitrust injury."). Thus, the antitrust plaintiff alleging exclusion bears the burden of showing that the "excluded" competition was, in fact, lawful. *See, e.g.*, *In re Canadian Import Antitrust Litig.*, 470 F.3d at 790-92. And that principle applies fully to competition that infringes a valid patent. "[T]he public [i]s not entitled to profit by competition among infringers." *Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358, 364 (7th Cir. 1907).

In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Co.*, 382 U.S. 172, 177 (1965), this Court applied its precedent to an antitrust

challenge based on the simple assertion of a patent in litigation. As the Eleventh Circuit has noted, *Walker Process* represents "[t]he only time the Supreme Court has addressed the circumstances under which the patent immunity from antitrust liability can be pierced" when the defendant's conduct is within the scope of a patent. *Valley Drug*, 344 F.3d at 1307. The *Walker Process* Court held that proof of actual fraud in securing a patent "would be sufficient to strip [the patentee] of its exemption from the antitrust laws," and thus allow an antitrust claim for wrongful enforcement. 382 U.S. at 177. The Court stressed, however, that beyond such intentional misconduct in obtaining the patent, the patentee's "good faith would furnish a complete defense" to antitrust claims. *Id.* And Justice Harlan emphasized that antitrust liability requires actual fraud, not merely invalidity "under one or more of the numerous technicalities attending the issuance of a patent." *Id.* at 180 (Harlan, J., concurring).

B. Prior To *K-Dur*, The Circuit Courts Properly Applied The Law To Hatch-Waxman Settlements

Applying both this Court's precedent and the relevant statutes, the lower courts have long held that, when patents are involved, "the protection of the patent laws and the coverage of the antitrust laws are not separate issues." *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981) (discussing *Bement*, 186 U.S. at 91). The antitrust analysis of patent agreements must always begin with the exclusionary effect of the patent. *Id.* ("[T]he conduct at issue is illegal if it threatens competition in areas other than those

protected by the patent, and is otherwise legal."); *accord, e.g.*, *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) ("Should the restriction be found to be reasonably within ... the scope of the patent claims, that ends the [antitrust] inquiry."); *USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 513 (7th Cir. 1982) (Antitrust liability may lie "only upon proof of an anticompetitive effect beyond that implicit in the grant of the patent."); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) ("[W]here a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger [antitrust] liability ….").

The *Cipro* MDL suit against Bayer was one of the first to apply these principles to so-called reverse-payment settlements under the Hatch-Waxman Act. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 187, 251 (E.D.N.Y. 2003) (*Cipro I*). Bayer owned the patent on the sole active ingredient of the antibiotic Cipro. When Barr Laboratories sought permission from the Food and Drug Administration to market a generic version of Cipro, Bayer sued. Barr stipulated that its product would infringe the patent, but asserted that the patent was invalid and unenforceable. In January 1997, the parties settled. *Id.* After the settlement, Bayer's patent was upheld on reexamination by the Patent Office and in three separate litigations challenging the patent. *Id.* at 197.

In 2000, private plaintiffs filed suit alleging that Bayer's "reverse payment" settlement with Barr violated the antitrust laws. Twenty-six federal cases were consolidated in a multi-district litigation. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*,

166 F. Supp. 2d 740 (S.D.N.Y. 2001). In 2003, Judge Trager denied plaintiffs' motions for partial summary judgment, in which plaintiffs argued that the settlement was per se unlawful. *Cipro I*, 261 F. Supp. 2d 188. Judge Trager explained that "the proper analysis in this case is whether the … challenged agreements restrict competition beyond the exclusionary effects of the [Cipro] patent." *Id.* at 249.

In rejecting the argument that settlement payments were a sign of patent weakness, Judge Trager noted that "the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from infringing commercial sales. This statutory scheme affects the parties' relative risk assessments and explains the flow of settlement funds and their magnitude." *Id.* at 251 (citation omitted). "Accordingly, *so-called reverse payments are a natural by-product of the Hatch-Waxman process*." *Id.* at 252 (emphasis added). In 2005, Judge Trager granted summary judgment for defendants on all claims: "Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." *Cipro II*, 363 F. Sipp. 2d at 535.

Six federal appellate opinions have applied these principles to reject antitrust claims based on Hatch-Waxman settlements within the patent's exclusionary effects. Three have been in the Eleventh Circuit: *Watson*, 677 F.3d at 1312 ("Our …

decisions establish the rule that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall *within the scope of the exclusionary potential of the patent*.") (emphasis added); *Schering-Plough*, 402 F.3d at 1076 (vacating FTC order because "the agreements fell well within the protections of the '743 patent, and were therefore not illegal."); *Valley Drug*, 344 F.3d at 1306 (reversing finding that a reverse payment settlement was per se unlawful because "the district court failed to consider the exclusionary power of Abbott's patent in its antitrust analysis.").

The Second Circuit decided *Tamoxifen* soon after Judge Trager granted summary judgment in *Cipro II,* adopting his formulation of the controlling rule verbatim. 466 F.3d at 213 ("[T]here is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.") (quoting *Cipro II*, 363 F. Supp. 2d at 535). The Second Circuit later applied the *Tamoxifen* rule to one of the two federal appeals from Judge Trager's decision in *Cipro II*. *Cipro IV*, 604 F.3d at 105-06 (The Cipro settlements "fall within the terms of the exclusionary grant conferred by the branded manufacturer's patent.").

In the other *Cipro* appeal, brought by a proposed class of indirect purchasers, the Federal Circuit affirmed Judge Trager as well. *Cipro III*, 544 F.3d at 1336 ("The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent.").

In sum, until the *K-Dur* decision, the federal appellate courts were in harmony. Indeed, with the

exception of the Third Circuit, every circuit court to consider "reverse payments" has cited Judge Trager's analysis of the *Cipro* settlement with approval. *E.g.*, *Watson*, 677 F.3d at 1313; *Tamoxifen*, 466 F.3d at 213; *Schering-Plough*, 402 F.3d at 1068; *Valley Drug*, 344 F.3d at 1306; *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 n.13 (6th Cir. 2003) (expressly distinguishing *Cipro* and finding liability because the settlement in *Cardizem* imposed restraints beyond the exclusionary effect of the patent), *cert. denied*, 543 U.S. 939 (2004).

C. The Third Circuit's Departure From The Governing Principles of Patent and Antitrust Law Is Erroneous

The Third Circuit's decision below is remarkable. The court based its holding on two "policies" – one based on the desire of the public to "test" weak patents and the other based on the desire of Congress to provide consumers with generic drugs. Pet App. 28a, 31a. The *K-Dur* court failed to note that the sources from which it derived each of these unexceptional goals expressly acknowledged an equal and opposite policy as a counter-balance. Thus, the opinions of this Court that cite an interest in testing patents also cite, in the same passages, an equal interest in protecting patent holders from infringing rivalry: "'It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention *should be protected in his monopoly* ....'" *Lear, Inc. v. Adkins,* 395 U.S. 653, 663-64 (1969) (quoting *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892)) (emphasis added). Similarly, both the language and history of the Hatch-Waxman Act –

from which the court below derived its "antitrust" policy in favor of generic drugs – demonstrate unequivocally that the interest in promoting generic drugs was not intended to undermine, much less fundamentally change, the patent holder's right to exclude:

> Hatch-Waxman amended both the FFDCA and the patent laws in an effort to strike a balance between two conflicting policy objectives: *to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products*, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.

aaiPharma Inc. v. Thompson, 296 F.3d 227, 231 (4th Cir. 2002) (quotation marks and citation omitted; emphasis added).

Equally remarkable is that the court below announced a rule of striking novelty without analysis. The court simply declared that settlements with cash payments would be presumed anticompetitive and evaluated under a "quick look" analysis. The court shifted the burden to the defendants and apparently rendered any infringement inquiry irrelevant.[2] Pet. App. 32-33a. The court also did not consider or explain how a settlement providing an early entry license tests the strength of a patent any better than

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[2] In *K-Dur*, the generic defendants contested infringement. Pet. App. 26a. It is unclear whether the rule the Third Circuit adopted in *K-Dur* would apply equally where the generic challenger stipulates to infringement.

a settlement with cash payments. Nor did the court explain why the desire for *non-infringing* generic drugs reflected in Hatch-Waxman compels a conclusion that the Sherman Act condemns certain settlements, *whether or not* the generic drug infringed a valid patent.

The *K-Dur* court erred in its analysis and misconstrued the authority it cited.

1. The *K-Dur* Court Cited Inapposite Precedent of This Court While Ignoring *Walker Process*

The *K-Dur* court chided the district court for "overlook[ing]" the "aspects of the Supreme Court's general patent jurisprudence" that call for testing weak patents. Pet. App. 30a. But the court failed to cite this Court's decisions in *Bement*, *General Electric*, or even *Walker Process* – a case on which the other circuit courts expressly relied. *Cipro III*, 544 F.3d at 1336. Instead, *K-Dur* cited several inapposite cases, none of which held that the exercise of rights within the scope of a patent could be limited by antitrust law. Pet. App. 28-29a. For example, *United States v. Masonite Corp.*, 316 U.S. 265 (1942), concerned patent exhaustion. Its holding relied on the express finding that "the patentee exhausts his limited privilege when he disposes of the product to the *del credere* agent" and any further restrictions would be "an enlargement [or beyond the scope] of the limited patent privilege." *Id.* at 279. The attempt to impose conditions on a patented good after all rights have been exhausted is the very definition of going beyond the patent's scope.

K-Dur cites several other cases for the unremarkable proposition that being party to a

license agreement does not estop a licensee from challenging patent validity. *See, e.g.*, *Lear*, 395 U.S. 653; *Edward Katzinger Co. v. Chi. Metallic Mfg. Co.*, 329 U.S. 394 (1947); *Sola Elec. Co. v. Jefferson Elec. Co.*, 317 U.S. 173 (1942), *Pope Mfg. Co.*, 144 U.S. 224. But in none of those cases did this Court insinuate, let alone hold, that a licensee *must* challenge validity and that parties cannot settle. Similarly, in *Cardinal Chemical Co. v. Morton International Inc.*, 508 U.S. 83 (1993), this Court did not address settlements at all, but held that deciding non-infringement did not moot a separate question of patent invalidity.

Unlike *Bement* and *Walker Process*, none of those cases is directly relevant to the question presented here.

2. *K-Dur* Undermines The Patentee's Right To Exclude Infringing Competition

K-Dur is the first court of appeals to hold that antitrust liability can be imposed on settling parties without considering whether the patentee had the right to exclude the generic product altogether. The court contended: "[T]here is no need to consider the merits of the underlying patent suit because '… it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.'" Pet. App. 33a. This statement is erroneous.

First, the statement is grounded on the false premise that the generic and branded companies can always limit their settlement to negotiation over a single term: the date of generic entry. But that ignores the fact that generic and branded companies value the time period of a license differently. Due to

the difference in prices charged, the value of each month (or year) of a license to the generic is much less than the amount the brand-name manufacturer would have to sacrifice during the same period. In such a case, money can bridge the gap, making a settlement possible where negotiating only on the length of the license would not. *See, e.g.*, Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1062 (2004). In such a case, it is incorrect to say that the money caused the entry date to be delayed: without the payment, there would be no settlement at all.

Second, the *K-Dur* court's excuse for ignoring the patentee's right to exclude is also incorrect under the law. Antitrust liability does not attach simply because a court can hypothesize a "better" settlement than the one actually reached. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004) ("The Sherman Act is indeed the Magna Carta of free enterprise, but it does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition.") (internal quotation marks and citation omitted); *Am. Motor Inns, Inc. v. Holiday Inns, Inc.*, 521 F.2d 1230, 1249 (3d Cir. 1975) ("Application of the rigid 'no less restrictive alternative' test in cases such as this one would place an undue burden on the ordinary conduct of business."); *see also Buffalo Broad. Co. v. ASCAP*, 744 F.2d 917, 933 (2d Cir. 1984) (similar). Accordingly, as long as the settlement excludes no more competition than does the patent itself, "consumers have no right to second-guess whether some different agreement would have been more

palatable." *Cipro II*, 363 F. Supp. 2d at 536 (citing *Trinko*, 540 U.S. at 415-16).

3. *K-Dur*'s Rule That Liability May Be Based On The Parties' Failure to Keep Litigating Is Unprecedented and Incorrect

a. No court before *K-Dur* had imposed liability on settling parties under a theory based in whole or in part on the failure of the litigation to continue to judgment. The Third Circuit's approach – forcing parties to "test[]" patents through litigation and therefore presuming that payments resulting in a delayed entry by generics are "*prima facie* evidence of an unreasonable restraint of trade, Pet. App. 32a – does exactly that.[3] But no principle of antitrust law has ever imposed liability on settling parties simply for failing to continue the fight. The Third Circuit apparently believes that the litigation in *K-Dur* would necessarily have been won by the generic challenger.

But other courts have recognized the uncertainty inherent in attempting to predict the outcome of a case that did not get tried due to settlement. Those courts emphasized that any standard lesser than the "objectively baseless" test, such as having an antitrust jury choose a winner of the settled patent case, "is unduly speculative." *Cipro I*, 261 F. Supp. 2d at 200-01 (citing *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990)); *see Tamoxifen*, 466 F.3d

[3] The *K-Dur* rule is erroneous in cases like *K-Dur* where infringement is contested. But the rule is even more problematic in cases such as *Cipro* in which the generic challenger concedes infringement.

at 203 ("[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.") (quotation omitted).

The Eleventh Circuit made the point in rejecting the FTC's argument that the patent should be deemed to have no exclusionary power at all if "it is more likely than not that the patent would not have blocked generic entry." *Watson*, 677 F.3d 1298 at 1312-13:

> The FTC's position equates a likely result (failure of an infringement claim) with an actual result, but it is simply not true that an infringement claim that is "likely" to fail actually will fail.
>
> Predicting the future is precarious at best; retroactively predicting from a past perspective a future that never occurred is even more perilous. And it is too perilous an enterprise to serve as a basis for antitrust liability and treble damages.

All federal appellate courts but the Third Circuit have thus concluded that only a showing of objective baselessness will meet the antitrust plaintiff's burden without undue speculation.

b. There is an equally fundamental flaw in any attempt to base a theory of harm on the anticipated or "expected" outcome of patent litigation. This one-sided theory presumes, incorrectly, that consumers benefit only when the generic challenger *wins* a patent case. The theory ignores the competitive benefit that all consumers receive when a patent is enforced. As the FTC's current General Counsel

previously pointed out, "what is neglected is that, if the settlement prevents infringing entry, such prevention in itself is a *pro-competitive* effect." 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, 622 (2006) (original emphasis).

c. There are additional flaws in the *K-Dur* court's insistence on continuing the litigation while ignoring the patent merits. First, the court's rule has the effect of reading out of the patent statute the statutory presumption of validity. *See, e.g.*, *Cardinal Chem.*, 508 U.S. at 93 n.15 ("Under 35 U.S.C. § 282, all patents are presumed valid."); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J.). The *K-Dur* court appeared to recognize that the presumption must apply where patent validity is at issue, but insisted that the presumption is rebuttable. Pet. App. 25-26a. The court then went on, however, to adopt a rule that renders the patent "merits" irrelevant to liability – so the antitrust plaintiff is not required to supply *any* rebuttal. Indeed, the defendant cannot even provide evidence that the patent is in fact valid. The presumption of validity under *K-Dur* thus becomes changed essentially to an unrebuttable presumption of invalidity. Under *K-Dur*, the antitrust court in the Third Circuit must treat the patent as invalid. If applied in a case such as *Cipro*, where only validity is at issue, the Third Circuit's rule would eviscerate the presumption of validity.

The Third Circuit's rule undermining the presumption of validity is directly at odds with the Federal Circuit's holding in *Cipro III* that a patent is

presumed valid for purposes of antitrust analysis of reverse payment settlements. The Federal Circuit stated:

> Pursuant to statute, a patent is presumed to be valid, 35 U.S.C. § 282, and patent law bestows the patent holder with 'the right to exclude others from profiting by the patented invention.' A settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled – a monopoly over the manufacture and distribution of the patented invention.

Cipro III, 544 F.3d at 1337 (citation omitted).

Second, the *K-Dur* rule impermissibly shifts the burden from the plaintiff who has to show the challenged action has had an actual adverse effect on competition, *Times-Picayune Publ'g Co. v. United States*, 345 U.S. 594, 622 (1953), to defendants who now have to disprove antitrust liability. This is contrary to the general rule that "[a]bsent some reason to believe that Congress intended otherwise, … we will conclude that the burden of persuasion lies where it usually falls, upon the party seeking relief." *Gross v. FBL Fin. Servs., Inc.*, 557 U.S. 167, 177 (2009) (citation omitted).

II. THE DELETERIOUS CONSEQUENCES OF THE THIRD CIRCUIT'S RULE STRONGLY SUPPORT THIS COURT'S REVIEW

A. The Scope Of The Patent Rule Fosters Innovation

It is well-known that "[d]evelopment of new uses for existing chemicals .... is extraordinarily expensive.

It may take years of unsuccessful testing before a chemical having a desired property is identified, and it may take several years of further testing before a proper and safe method for using that chemical is developed." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 221-22 (1980). More so for chemicals for human use: "To be deemed 'safe and effective' and thereby obtain FDA approval, a new drug must undergo an extensive application and approval process.... The test is rigorous, requiring expensive and time-consuming clinical trials estimated by some to cost more than $800 million per drug." *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 388-89 (5th Cir. 2008) (quotations and footnotes omitted).

The scope of the patent rule correctly balances the policies of fostering innovation and creation of new life-saving drugs, such as Cipro, with the short-term goal of lowered generics prices. As the Eleventh Circuit in *Watson* explained, given the costs of developing new drugs, "[n]o rational actor would take that kind of a risk over that period of time without the prospect of a big reward." 677 F.3d at 1300. The reward is the patent monopoly "over the sale of the new drug for the life of the patent" allowing the innovator to charge higher prices than it "could if competitors were allowed to sell bioequivalent or 'generic' versions of the drug." *Id.* This allows "recoup[ment of] its investment and gain[ing] a profit." *Id.*

Indeed, the exercise of the patentee's right to exclude "serves a very positive function in our system of competition, *i.e.*, the encouragement of investment based risk." *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 876 (Fed. Cir. 1985) (quotation marks and

citation omitted); *see also Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006). Specifically, "[t]he Hatch-Waxman Act … extended the patent term for pharmaceutical products to account for the costs and delays of the FDA approval process, and its legislative history[] make this link especially clear for patented drugs." *Biotech. Indus. Org. v. District of Columbia*, 505 F.3d 1343, 1346 (Fed. Cir. 2007) (Gajarsa, J., concurring on rehearing denial) (discussing H.R. Rep. No. 98-857, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650 ("[Innovator] profits act as incentives for innovative activities.")).

Conversely, focusing solely on lowered prices of the generic drugs "ignores the first principle that enforcing valid patents makes a major contribution to consumer welfare by providing the incentive for innovation. We ignore that incentive at our peril." Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 618.

Although the court in *K-Dur* paid lip service to the patent protection policy Hatch-Waxman embodies, Pet. App. 30a, it then declared that "*[t]he* goal of the Hatch-Waxman Act is to increase the availability of low cost generic drugs," *id.* (emphasis added). Consequently, the court simply discarded the scope of the patent rule, calling it a "bad policy from the perspective of the consumer." Pet. App. 31a. A worse policy is to ignore the incalculable benefits of new, life-saving drugs made possible by the incentives for innovation. Without those drugs being created in the first place, there will be no prices to lower.

B. The *K-Dur* Rule Would Also Undermine The Universal Policy In Favor of Litigation Settlements

This Court has been emphatic that settlements are favored. *See, e.g.*, *Marek v. Chesny*, 473 U.S. 1, 10 (1985) (explaining in the context of civil rights litigation: "Rule 68's policy of encouraging settlements is neutral, favoring neither plaintiffs nor defendants; it expresses a clear policy of favoring settlement of all lawsuits"). And no less so in patent disputes: "[w]here there are legitimately conflicting [patent] claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [antitrust laws]." *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931), *cited in, e.g.*, *Cipro III*, 544 F.3d at 1333 *and Tamoxifen*, 466 F.3d at 201; *see also Bement,* 186 U.S. at 91-93 (upholding settlement agreements within the patent's scope).

As courts have likewise recognized in Hatch-Waxman cases, settlement is a critical means by which the benefits of patent rights are realized: "There is simply no legal basis for restricting the rights of patentees to choose their enforcement vehicle (*i.e.*, settlement versus litigation)." *Cipro-II*, 363 F. Supp. 2d at 531-32; *Cipro-III*, 544 F.3d at 1337.

C. The Third Circuit's Rationale For Rejecting The Presumption Of Validity Relies On Fundamentally Flawed Studies

1. *K-Dur* cites a study purportedly showing that "in Hatch-Waxman challenges made under paragraph IV, the generic challenger prevailed seventy-three percent of the time." Pet. App. 26a

(citing FTC, *Generic Drug Entry Prior to Patent Expiration* (2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf ("2002 Study")). Yet, the study actually shows a success rate for generic first-filers in all cases of just 29%. 2002 Study at 14-16 (22 victories in 75 challenges). To produce a 73% "success" rate, the FTC reduced the number of total drug products considered, eliminating cases still pending, cases that settled, cases in which the generic withdrew its ANDA, and – critically here – cases in which the same drug patent was litigated more than once. *Id.* at 19. Thus, Bayer's three separate Cipro victories counted as only one win for a patent holder. Subsequent studies have found that the actual generic success rate is less than 50%.[4]

2. *K-Dur* cites another study regarding the social costs of settlements, whose very title reflects its bias: FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010), *available at* www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf ("2010 Study"). Pet. App. 14a. Commentators have shown that the study is flawed and its central conclusion on consumer benefits "is not reliable."[5] For example, it compares the entry dates for different settlements without controlling for salient

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[4] Adam Greene & D. Dewey Steadman, *Pharmaceuticals, Analyzing Litigation Success Rates,* RBC Capital Markets 1 (2010) (overall generic success rate of 48% was significantly lower in courts and before judges who saw the greatest volume of cases), *available at* http://amlawdaily.typepad.com/pharmareport.pdf.

[5] Bret Dickey et al., *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on 'Reverse Payment' Settlements* at 2 (2010), *available at* http://newsroom.law360.com/articlefiles/186893-Analysis.pdf.

differences, including "the average patent life remaining" at the time of settlement.[6] Even with its flaws, the FTC Study concedes that the consumer "loss" it derives could fall from $3.5 to "$0.6 billion" (*i.e.*, over 82%) if some of its (undisclosed) "assumptions," were "varied." 2010 Study at 10.

These flawed premises of the Third Circuit's rationale only underscore the need for this Court's review.

CONCLUSION

The Court should grant the petitions for certiorari.

Respectfully submitted,

PHILLIP A. PROGER
KEVIN D. MCDONALD
LAWRENCE D. ROSENBERG
VICTORIA DORFMAN
MARK R. LENTZ
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001
(202) 879-3939

PETER B. BENSINGER, JR.
Counsel of Record
MICHAEL J. VALAIK
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 West Hubbard St.
Suite 300
Chicago, IL 60654
(312) 494-4400
Peter.bensinger@bartlit-beck.com

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Counsel for Amici Bayer AG & Bayer Corp.

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[6] *Id.* at 3 ("Such differences would render invalid the comparison of entry delay between [cash payment and other] settlements.").