No. 14-1243

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

KING DRUG COMPANY OF FLORENCE, INC.; LOUISIANA WHOLESALE DRUG CO., INC, , on behalf of itself and all others similarly situated,
Plaintiffs-Appellants,

v.

SMITHKLINE BEECHAM CORPORATION, D/B/A GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES LTD.; TEVA PHARMACEUTICALS, USA, INC.,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of New Jersey
Case No. 12-cv-995 (WHW)
Hon. William H. Walls, Presiding

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF BOTH PETITIONS FILED BY APPELLEES FOR PANEL REHEARING OR REHEARING *EN BANC*

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed.R.App.P. 26.1, the Washington Legal Foundation (WLF) states that it is a corporation organized under § 501(c)(3) of the Internal Revenue Code. WLF has no parent corporation, nor has it issued any stock owned by a publicly held company.

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IDENTITY AND INTERESTS OF *AMICUS CURIAE*

Washington Legal Foundation (WLF) is a public interest law firm and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, a limited and accountable government, and the rule of law. WLF has appeared before this and other courts in numerous cases involving the intersection of patent rights and anti-trust law. *See, e.g.*, *FTC v. Actavis*, 133 S. Ct. 2223 (2013); *In re K-Dur Antitrust Litigation*, 686 F.3d 2012 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013).

The panel's decision represents a major expansion of antitrust law and directly conflicts with the Supreme Court's decision in *Actavis*. WLF is concerned that the decision will make it virtually impossible for parties to settle drug patent disputes and will have serious negative effects on incentives for drug companies to develop and market innovative, life-saving products.

INTRODUCTION AND SUMMARY OF ARGUMENT

In establishing a patent system, Congress recognized the value of temporary restraints on trade for the purpose of providing financial incentives designed to spur innovation. While such restraints cut against the normal goals of antitrust

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[1] Pursuant to Fed.R.App.P. 29(c)(5), WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

law, Congress mandated that courts should strive to maintain a balance between patent law and antitrust law, and that antitrust law should not be applied in a manner that short changes the rights of patent holders. *Simpson v. Union Oil Co.*, 377 U.S. 13, 14 (1964).

In its *Actavis* decision, the Supreme Court sought to maintain that balance in the context of drug patent litigation settlements involving brand-name and generic drug companies. It sought to steer a middle ground between the "presumption of unreasonable restraint" approach adopted by this Court in *K-Dur*, under which settlements involving payments from a patentee to the alleged infringer were rebuttably presumed to violate antitrust laws, and the "scope of the patent" test adopted by other federal appeals courts, under which such "reverse payment" settlements were not subject to antitrust scrutiny so long as they did not extend beyond the exclusionary effects of the underlying patent. *Actavis*, 133 S. Ct. at 2237-38.

The Supreme Court held that when a generic drug company agrees, in connection with a patent litigation settlement, to postpone efforts to market a generic version of the patented drug, the agreement is subject to antitrust scrutiny under a traditional rule-of-reason analysis whenever the settlement also includes a "large" and "unexplained" payment from the brand-name drug company to the

generic company. *Id.* at 2237. On the other hand, it held that an agreement to postpone entry is *not* subject to antitrust scrutiny when the benefit bestowed on the generic company is the right to enter the brand-name company's market "prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Ibid.* The middle position adopted by *Actavis* strongly suggests, therefore, that the dividing line between patent litigation settlements that invite antitrust scrutiny and those that do not is the presence of a *payment* in exchange for the generic company's agreement to delay entry.

The panel rejected that approach; it held that the presence of *any* benefit (including benefits the generic enjoys by entering before the patent's scheduled expiration) flowing from a brand-name company to a generic company subjects a patent settlement to antitrust scrutiny. Slip op. 31-36. The panel's holding directly conflicts with *Actavis*. It abandons the required balance between antitrust law and patent law (whose very point is to reward innovators by permitting them to temporarily exclude competition) and instead subjects to full-scale antitrust scrutiny virtually any effort by a patent holder to protect its exclusivity rights.

Such scrutiny is particularly inappropriate in the context, as here, of a brand-name drug company granting an exclusive license to market generic versions of its products. The grant of an exclusive license, an action whose purpose is to restrict

competition as compared to a non-exclusive license, is explicitly sanctioned by federal patent law and has long been upheld by the Supreme Court as an integral part of a patent holder's right to employ (and thereby profit from) its patent. Yet, by subjecting to antitrust scrutiny the grant of an exclusive license from one of the Appellees (GSK) to the other (Teva), the panel has called into question the legality of this long-sanctioned method of utilizing one's patent. And it raises that legal question regardless whether the exclusive license is granted in connection with a litigation settlement, because the effect of *any* exclusive license is to reduce the level of competition below the level that might have existed had the license not been exclusive.

En banc review is warranted to re-examine the panel's dramatic expansion of antitrust law, an expansion that conflicts with *Actavis* and threatens to upset long-settled, investment-backed expectations of patent holders.

ARGUMENT

I. THE PANEL DECISION REPRESENTS AN UNWARRANTED EXPANSION OF THE LIMITED ANTITRUST SCRUTINY CONTEMPLATED BY *ACTAVIS*

A. *Actavis* Held That Federal Courts Reviewing Challenges to Patent Settlement Agreements Must Maintain a "Balance" Between Antitrust Law and Patent Law

In *Actavis*, the Supreme Court faced a Federal Trade Commission antitrust challenge to a patent-litigation settlement under which the patent holder, Solvay Pharmaceuticals, had agreed to make hundreds of millions of dollars in cash payments to several generic drug companies in return for those companies' agreement not to market generic versions of the patented drug for another nine years. The drug companies argued that the settlement should be immune from antitrust scrutiny because the settlement was within the scope of the patent; *i.e.*, the patent at issue was not scheduled to expire until 2021, while the agreement permitted the generic companies to begin marketing in August 2015—65 months sooner. The FTC argued, on the other hand, that the "large and unexplained" cash payments from Solvay indicated that Solvay was paying potential competitors not to enter the market, and therefore that the agreement should be *presumed* to constitute an illegal conspiracy in restraint of trade, subject to the defendants' right to attempt to demonstrate that the agreement actually promoted competition.

The Supreme Court rejected both arguments and instead adopted a compromise position that attempted to balance the competing demands of antitrust law and patent law. It concluded that litigation settlements in which the brand-name company transfers something of value to the generic company can "sometimes" be subject to antitrust scrutiny and can "sometimes" violate the antitrust laws. *Actavis*, 133 S. Ct. at 2227. The Court repeatedly stated that courts hearing antitrust challenges to patent settlement agreements must seek to "balance" the often-conflicting principles of antitrust and patent law. *See, e.g.*, *id.* at 2231 (describing its previous decision in *United States v. Line Material Co.*, 333 U.S. 287 (1948), as an effort to "strike [a] balance" between "the lawful restraint of trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act."); *ibid.* (stating that "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust immunity—that is conferred by a patent.").

The Court held that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects" and thus subject a patent settlement to antitrust scrutiny under a rule-of-reason analysis—particularly when "parties may well find ways to settle patent disputes without use of reverse

payments." *Id.* at 2237.[2] In contrast, the Court held that *no* antitrust scrutiny is warranted if the generic company drops its patent invalidity claim in return for a license to market its product in advance of the patent's expiration—even if, as will often be the case, the early-entry license is worth many millions of dollars to the generic company. *Ibid.* The Court did not define precisely what sorts value transfers it intended to include within the term "reverse payment." But one can reasonably infer that the Court intended to confine the term to transfers of cash (or cash equivalents) that were made in exchange for delay, not to apply the term to any contractual arrangement that confers value.

B. *King* Conflicts with *Actavis* Because It Makes No Effort to Balance the Goals of Antitrust and Patent Law and Instead Subjects Virtually All Settlement Agreements to Antitrust Scrutiny

The 2005 patent litigation settlement agreement entered into between GSK and Teva did not provide for any payment from GSK to Teva. Instead, in return

[2] The Court rejected the FTC's contention that "reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a "quick look" approach, rather than applying a "rule of reason." *Ibid.* The Court explained that a rule-of-reason approach is appropriate because "the likelihood of a reverse payment bringing about anticompetitive effects" depends heavily on the facts of each case. *Ibid.* The Court declined to specify what evidence would tend to show the absence of anticompetitive effects. Presumably, defendants would be entitled to attempt to demonstrate, among other things, that allowing a generic product to infringe a valid patent would be anti-competitive because it would diminish benefits to consumers from innovation.

for Teva's stipulation to dismissal of all claims and counterclaims (including Teva's counterclaim that GSK's patents on Lamictal were invalid), Appellants allege that GSK agreed: (1) to permit Teva to begin marketing chewable forms of the drug by June 1, 2005 (more than three years in advance of expiration of the patents); (2) to permit Teva to begin marketing tablet forms of the drug six months in advance of patent expiration; and (3) during the 180-day exclusivity period following the launch of Teva's tablet product (*i.e.*, the period during which other generic companies would be prohibited from competing with Teva), to grant Teva *exclusive* rights to market a generic version of Lamictal. *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 561-62 (D.N.J. 2014).

The panel recognized that *Actavis* expressly exempted from antitrust scrutiny the first two forms of consideration provided by GSK to Teva. It held, however, that the third form of consideration—GSK's agreement to grant Teva exclusive generic rights during the 180-day exclusivity period (the "No-AG Agreement")—should be subject to the same antitrust scrutiny that *Actavis* applied to reverse payments. Slip op. at 31. The panel held that *Actavis* applies not just to payments but also to *any* "unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition." *Id.* at 10. The

panel held that the No-AG Agreement had considerable value to Teva (even though it had value only when Teva entered the market and was to last for only 180 days) and thus was subject to antitrust scrutiny. *Id.* at 31-32.

The panel's expansion of antitrust scrutiny to cover any "reverse transfer[s] of considerable value" is, for the reasons stated above, at odds with *Actavis*'s directive that courts seek to "balance" the competing interests of antitrust and patent law. Instead of seeking such a balance, the panel has simply applied full-bore antitrust scrutiny to all patent litigation settlements. While the Supreme Court limited the scope of antitrust scrutiny to settlement agreements that include "reverse payments," the panel has substituted its own, far broader criterion: antitrust scrutiny is now deemed applicable whenever the brand-name company "transfers" anything of "considerable value" to the generic company.

More importantly, the panel cannot reconcile its adoption of a "considerable value" criterion with the explicit exemption from antitrust liability that *Actavis* provided to license agreements that allow "the generic manufacturer to enter the patentee's market prior to patent expiration." *Id.* at 2237. *Actavis* provided that exemption even though such early-entry licenses are often of considerable value to generic drug companies—indeed, in some cases they can be worth many millions of dollars. Accordingly, under the panel's "reverse payment of considerable

value" criterion, such early-entry licenses should be subject to antitrust scrutiny too. Yet we know from *Actavis* that such licenses are *not* subject to antitrust scrutiny—a clear indication that the panel has misconstrued *Actavis*.

Moreover, *Actavis* was decided based on an assumption that it would still be possible for litigants to settle pharmaceutical patent infringement litigation even without "reverse payment" settlements. *Ibid.* (stating that "parties may well find ways to settle patent disputes without use of reverse payments."). Yet, under the panel's expansive definition of what constitutes a "reverse payment," it is doubtful that a drug patent lawsuit would *ever* settle.

The impossibility of settlement under the panel's antitrust standards is the result of unique litigation dynamics created by the Hatch-Waxman Act, Pub. L. No. 98-417. Unlike the defendants in patent infringement litigation that arises in other contexts, a generic drug company that initiates infringement litigation (by filing a "Paragraph IV certification" with FDA and thereby essentially forcing a brand-name company to file an infringement lawsuit) cannot be held liable for damages because it has not marketed any infringing products.[3] Of course, no

[3] In contrast, patent infringement litigation arising in other contexts generally involves defendants who are alleged to be committing infringement acts. Such defendants face severe, potentially-bankrupting damage awards if the trial court sustains the infringement claim.

litigant will agree to a settlement unless he perceives that it is advantageous. Accordingly, if a patentee cannot transfer anything of "considerable value" to a generic drug company without facing antitrust scrutiny, and if there are no potential damages that a patentee could offer to forbear, there will never again be a settlement of any drug patent litigation because a patentee will never be able to offer lawful settlement terms that a generic drug company would find attractive.

As Judge Posner has cogently observed:

> [A]ny settlement agreement can be characterized as involving "compensation" to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden "reverse payment," we shall have no more patent settlements.

Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003). Thus, the panel's establishment of antitrust criteria that would halt all future drug patent litigation settlements conflicts with *Actavis*, given its stated intent to create a standard under which settlements could still flourish. As this Court has routinely noted, "Settlement agreements are to be encouraged because they promote the amicable resolution of disputes and lighten the increasing load of litigation faced by the federal courts." *Ehrheart v. Verizon Wireless*, 609 F.3d 590, 595 (3d Cir. 2010).

In sum, rehearing *en banc* is warranted because the panel decision conflicts

with *Actavis* and will lead to antitrust scrutiny of virtually all drug patent litigation settlements, and thus will end such settlements. That will, in turn, likely lead to a sharp reduction in challenges to drug patents; generic companies would, in all likelihood, be reluctant to initiate expensive lawsuits whose outcome is uncertain if they lacked any means of extricating themselves from the litigation short of trial. Such a reduction is precisely the opposite of Congress's goal when it adopted the Hatch-Waxman Act for the purpose of encouraging such challenges.

II. EXCLUSIVE LICENSES ARE A WELL-ACCEPTED MEANS BY WHICH PATENTEES MAY BENEFIT FROM THEIR PATENTS

The exacting antitrust scrutiny mandated by the panel is particularly inappropriate in the instant context of a brand-name drug company that grants an exclusive license to market generic versions of its products. The grant of an exclusive license, an action whose purpose is to restrict competition as compared to a non-exclusive license, is explicitly sanctioned by federal patent law, 35 U.S.C. § 261, and has long been upheld by the Supreme Court as an integral part of a patent holder's right to utilize its patent so as to maximize profits. *Actavis* indicated that the need to balance the goals of antitrust and patent law strongly counsels against applying antitrust scrutiny when settling parties can point to a patent statute that authorizes "either expressly or by fair implication" the patentee's

grant to third parties of the rights extended by the settlement. *Actavis*, 133 S. Ct. at 2233. GSK and Teva have pointed to just such a statute. The panel mandated antitrust scrutiny for "unusual" reverse payments, slip op. at 10; even if the grant of the No-AG Agreement (which is a form of exclusive license) could somehow be deemed a reverse "payment," it is far from "unusual" in the patent world.

An exclusive license's tendency to reduce competition is not a reason to question its validity under antitrust laws; indeed, reducing competition (as compared to competition present under a non-exclusive license) is precisely its purpose. "The essence of a patent grant is the right to exclude others from profiting by the patented invention." *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). As one leading commentator has noted, "[Licensing] agreements would generally be classified either as per se unlawful naked price fixing, or as per se unlawful naked horizontal market division" in the "absence of a patent." XII Herbert Hovenkamp *et al.*, ANTITRUST LAW ¶ 2040b (1999). Indeed, because the effect of *any* exclusive license is to reduce the level of competition below the level that might have existed in the absence of an exclusive license, the panel decision calls into question the legality of *all* exclusive licenses, regardless of whether they are part of a litigation settlement.

Finally, WLF notes that the value assigned by GSK and Teva to the No-AG

Agreement in February 2005 was likely considerably less than the large value assigned to it by the panel in 2015. At the time of the settlement, whether federal law permitted brand-name companies to market authorized generic versions of their own drugs during the 180-day exclusivity period was an unresolved (and hotly disputed) legal issue. No federal appeals court had addressed it. Indeed, at the same time that Teva was negotiating the No-AG Agreement with GSK in connection with its February 2005 litigation settlement, it was arguing strenuously in the D.C. Circuit that the Hatch-Waxman Act prohibited brand-name companies from marketing authorized generics during the 180-day exclusivity period. *See* Brief of Appellants in *Teva Pharm. Inds. Ltd. v. Crawford*, 2005 WL 429575 (D.C. Cir., filed February 18, 2005). Because Teva believed that the Hatch-Waxman Act already barred the marketing of authorized generics in order to prevent such marketing from significantly reducing the value of the financial inducements that Congress offered to generic companies willing to challenge drug patents, Teva—when it entered into the February 2005 litigation settlement—is unlikely to have assigned the No-AG Agreement a value anywhere near as large as the panel estimated. Slip op. at 32 & n.21.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court grant the petitions of GSK and Teva for panel rehearing or rehearing *en banc*.

Respectfully submitted,

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Dated: August 3, 2015

CERTIFICATE OF COMPLIANCE

I am an attorney for *amicus curiae* Washington Legal Foundation (WLF). Pursuant to Fed.R.App.P. 32(a)(7)(C), I hereby certify that the foregoing brief of WLF is in 14-point, proportionately spaced Times New Roman type. According to the word processing system used to prepare this brief (WordPerfect X5), the word count of the brief is 3,172, not including the corporate disclosure statement, table of contents, table of authorities, certificate of service, certificate of bar membership, and this certificate of compliance. The hard copy and the electronic copy of this brief are identical. The electronic copy has been scanned using a virus detection program (VIPRE Business, Version 5.0.4464) and no virus was detected.

Dated: August 3, 2015

/s/ Richard A. Samp
Richard A. Samp

CERTIFICATE OF BAR MEMBERSHIP

I hereby certify that I am a member of the bar of this Court.

/s/ Richard A. Samp
Richard A. Samp

CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of August, 2015, I electronically filed the brief of *amicus curiae* Washington Legal Foundation with the Clerk of the Court of the U.S. Court of Appeals for the Third Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Richard A. Samp
Richard A. Samp