No. 15-1055

IN THE

Supreme Court of the United States

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

Petitioners,

v.

KING DRUG COMPANY OF FLORENCE, INC.; LOUISIANA WHOLESALE DRUG CO., INC., ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,

Respondents.

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

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF THE *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association of the country's leading research-based pharmaceutical and biotechnology companies.[1] PhRMA's mission is to advocate public policies encouraging the discovery of life-saving and life-enhancing new medicines. PhRMA's member companies are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives, and have led the way in the search for new cures. Member companies have invested over $450 billion in research and development into medical innovations since 2005, and approximately $51.2 billion in 2014 alone.[2]

To continue their extraordinary investments in research and development necessary to offer new life-saving and life-enhancing treatments, PhRMA members must be able to maintain strong intellectual property protection and achieve some level of certainty and risk minimization with respect to that

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[1] Pursuant to Supreme Court Rule 37.6, *amicus* affirms that no counsel for a party authored the brief in whole or in part, that no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief, and that no person other than the *amicus* or its counsel made such a monetary contribution. Counsel for all parties received notice at least 10 days before the due date of *amicus*'s intention to file this brief. The parties' consents to the filing of this brief are on file with the Clerk's office.

[2] *See* PhRMA, *2015 Profile: Biopharmaceutical Research Industry*, ii, *available at* http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf ("Key Facts 2015") (last visited Mar. 31, 2016).

innovation, including by entering into licensing arrangements pursuant to patent litigation settlements. The Third Circuit's decision—that an innovator's grant of an exclusive license to a generic as part of a settlement agreement can open the door to treble-damages liability under the antitrust laws—jeopardizes the ability of PhRMA members to protect and enforce their intellectual property rights. PhRMA therefore has a strong stake in the outcome of this dispute.

INTRODUCTION AND SUMMARY OF ARGUMENT

This Court has long held that a patentee has the lawful right to exclude competitors and grant an exclusive license to practice its patent without running afoul of the antitrust laws. *See, e.g.*, *United States v. Gen. Elec. Co.*, 272 U.S. 476, 489 (1926). Despite this well-established rule, the Third Circuit held that an exclusive license is subject to antitrust scrutiny when it is negotiated to settle patent litigation between a pioneer pharmaceutical company and a generic manufacturer.

The Third Circuit purported to base its decision on *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), but the court of appeals badly misconstrued this Court's decision. In *Actavis*, the Court clearly distinguished between settlements involving "traditional settlement considerations" explicitly authorized by the patent laws (which are not subject to antitrust scrutiny), and settlements involving "large and unjustified reverse payment[s]" (which may be subject to antitrust scrutiny). *Id.* at 2236–37. The Third

Circuit upset this carefully considered distinction by holding that a licensing provision in a settlement agreement is subject to antitrust scrutiny—even though the Patent Act expressly authorizes licensing agreements.

The Court should grant the petition and reaffirm the important principle that settling patent disputes through "traditional," "familiar," or "commonplace" means—including the grant of an exclusive license—does not expose the settling parties to an antitrust lawsuit along with the attendant cost of burdensome discovery and the *in terrorem* effect of joint and several treble-damages liability. *Id.* at 2233. The ability of parties to settle Hatch-Waxman Act patent litigation will be imperiled if pioneer pharmaceutical companies cannot resolve such disputes with exclusive licenses in the same way that all other patentees are allowed to do. And jeopardizing innovators' ability to protect and enforce their intellectual property rights in this manner risks chilling life-saving innovation in the pharmaceutical industry.

ARGUMENT

I. THE THIRD CIRCUIT'S DECISION IS INCONSISTENT WITH THE PATENT LAWS AND *ACTAVIS*.

A. The Patent Laws Authorize Patentees To Grant Exclusive Licenses.

Patents are embedded deeply in the foundation of this country: "Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inven-

tors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. The Patent Act reinforces the importance of encouraging and protecting patent rights: "Every patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making, using, offering for sale, or selling the invention." 35 U.S.C. § 154(a)(1); *see also Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) ("A patentee has the exclusive right to manufacture, use, and sell his invention.").

The heart of the Patent Act is the grant of exclusivity. As this Court has recognized, "the essence of a patent grant is the right to exclude others from profiting by the patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). Patentees also have the concomitant right to grant licenses to their inventions as a lawful extension of the right of exclusivity. *Gen. Elec.*, 272 U.S. at 489 ("patentee may grant a license . . . upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure"); *United States v. Line Materials Co.*, 333 U.S. 287, 312 (1948) ("patent statutes give an exclusive right to the patentee to make, use, and vend and to assign any interest in this monopoly to others"); *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 949 (Fed Cir. 1993) ("grant of an exclusive license is a lawful incident of the right to exclude provided by the Patent Act"), *abrogated on other grounds by Wilton v. Seven Falls Co.*, 515 U.S. 277 (1995).

The patent laws thus imbue a patentee with flexibility in structuring licensing arrangements, including granting licenses that are limited in nature. For example, patentees have the right to select their licensees and to decide whether to license the patent on an exclusive or non-exclusive basis without converting those decisions into anticompetitive restraints of trade. *Genentech*, 998 F.2d at 949. Patentees may grant licenses that are restricted to certain classes of customers. *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175 (1938) (approving license that restricted the licensee's sales to non-commercial use). Patentees may grant licenses that contain restrictions on fields of use. *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1338 (Fed. Cir. 2006) ("Field of use licensing restrictions . . . are also within the scope of the patent grant.") (citing *Gen. Talking Pictures*, 305 U.S. at 127)). And, patentees may grant licenses restricted by geographic territory. *See* 35 U.S.C. § 261 (patentee "may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States").

Rather than licensing their patents, patentees may "refuse[] to license or use any rights to the patent." 35 U.S.C. § 271(d)(4); *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir. 1981) (refusal to license a patent "is expressly permitted by the patent laws").

It is well-established that the antitrust laws do not alter these fundamental rights. *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) (patent laws

"are in pari materia with the antitrust laws and modify them pro tanto"); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456 (1940) (patentee "may grant licenses . . . restricted in point of space or time, or with any other restriction upon the exercise of the granted privilege, . . . [but] he may not enlarge his monopoly and thus acquire some other which the statute and the patent together did not give"); *see also Kimble v. Marvel Enter.*, 135 S. Ct. 2401, 2413 (2015) ("The patent laws—unlike the Sherman Act—do not aim to maximize competition (to a large extent, the opposite).").

B. The Third Circuit Misconstrued *Actavis* in Holding That Patent Settlements Involving Exclusive Licenses Are Subject to Antitrust Scrutiny.

The Supreme Court in *Actavis* was careful not to disturb the balance between lawful patent rights and the protections of the antitrust laws. Nothing in *Actavis* suggests that the Supreme Court intended to restrict the ability of a patentee to enter into an exclusive or non-exclusive licensor-licensee relationship with whomever the patentee sees fit. Instead, *Actavis* drew a contrast between "traditional," "familiar," or "commonplace" settlement forms that are explicitly authorized by the patent laws, 133 S. Ct. at 2233, and the conduct at issue in *Actavis*—an alleged unexplained, large, reverse cash payment to the patent challenger provided as part of a settlement that ended the patent challenge. *See id.*

Of course, as noted in *Actavis*, patentees' rights are not unlimited. *See United States v. Singer Mfg.*

Co., 374 U.S. 174, 196-97 (1963) ("By aggregating patents in one control, the holder of the patents cannot escape the prohibitions of the Sherman Act."); *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 380 (1952) (arrangement "between patent holders to pool their patents and fix prices on the products for themselves and their licensees" violated the Sherman Act); *Line Materials*, 333 U.S. at 314-15 ("when patentees join in an agreement as here to maintain prices on their several products, that agreement . . . is unlawful per se under the Sherman Act"). The guiding principle is that a patentee may not obtain "protection from competition which the patent law unaided by restrictive agreements does not afford." *United States v. Masonite Corp.*, 316 U.S. 265, 279 (1942).

Here, GSK entered into a licensor-licensee relationship with Teva whereby GSK granted Teva the patent licenses necessary to market generic versions of Lamictal prior to the expiration of GSK's patent and pediatric exclusivity period.[3] Under the terms of the licenses, GSK agreed not to market an "authorized generic" version of Lamictal in the generic distribution channel. In other words, the settlement included a well-established term in a licensor-licensee relationship—the licensor (GSK) agreed not to compete with its licensee. That GSK did not cede the entire market to Teva (as it is permitted to do under the Patent Act), and instead reserved the right to sell its patented product in any manner it desired,

[3] "Pediatric exclusivity" is a six-month period of statutory exclusivity (that extends other forms of exclusivity) granted to drug manufacturers who conduct pediatric clinical studies on their products as requested by FDA.

does not convert the license into an anticompetitive restraint of trade. Nothing in this license enlarged GSK's patent monopoly. *See Ethyl Gasoline*, 309 U.S. at 456 (patentee "may grant licenses . . . restricted in point of space or time"); *Gen. Talking Pictures*, 304 U.S. at 175 (patentee may restrict licensee's sales for class of use). And despite Plaintiffs' characterizations, the alleged "no-AG" agreement is nothing more than an exclusive license whereby the licensor agreed not to compete (albeit in a limited way) with its licensee. Certainly, the arrangement is nothing like the cases noted in *Actavis* involving patent-related agreements found to have violated the antitrust laws. *See Actavis*, 133 St. Ct. at 2231-32 (citing *Singer*, *New Wrinkle*, and *Line Materials*).

For this reason, the Third Circuit misapprehends the import of a patentee's promise to extend an exclusive license. The court reasoned that a promise not to launch an authorized generic should be subject to antitrust scrutiny because it is "a promise not to compete" that may induce the generic to drop its suit. *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.* ("*Lamictal*"), 791 F.3d 388, 407 (3d Cir. 2015). But the court's reasoning may be read to prove too much. A negative commitment in connection with a license, whether express or implied, could be viewed as an inducement for the generic to drop its suit and thus a limitation on competition. A commitment not to exact royalties, for example, could be called an anticompetitive inducement. Indeed, a type of settlement explicitly blessed by the Supreme Court—*i.e.*, one "allowing the generic manufacturer to enter the patentee's market prior to the

patent's expiration, without the patentee paying the challenger," *Actavis*, 133 S. Ct. at 2237—could be cast as a commitment not to exact royalties. There is nothing in the Third Circuit's reasoning that would prevent courts from limiting *Lamictal* to the exclusive license context. If permitted to stand, the Third Circuit's decision might be relied on (albeit incorrectly) by courts, the FTC, and would-be antitrust plaintiffs to question the legality of many licensing arrangements entered by parties settling Hatch-Waxman patent disputes—that, surely, was not this Court's intent when it drew such a careful line in *Actavis* between traditional settlement forms explicitly authorized by the patent laws and "large and unjustified" reverse payments which may sometimes run afoul of the antitrust laws.

The exclusive license at issue here is protected under the patent laws "expressly" and "by fair implication." *Actavis*, 133 S. Ct. at 2233. Announcing such a bright-line rule is necessary to protect the legitimate rights of patentees. A contrary holding would subject parties holding valid patents to an "elaborate inquiry" under the Sherman Act's rule of reason analysis, which "produces notoriously high litigation costs and unpredictable results." *Kimble v. Marvel Enter.*, 135 S. Ct. at 2411 (internal quotation omitted).

II. THE QUESTION PRESENTED IS EXCEPTIONALLY IMPORTANT.

The Third Circuit's decision warrants review because it has great importance for all patentees. The question presented is particularly important to

pharmaceutical companies for at least two reasons. *First*, the decision will discourage settlement of patent litigation. Innovator companies often grant an exclusive license to a generic company to settle patent litigation. That practice will likely end if, as the Third Circuit held, such a settlement will lead to antitrust litigation. *Second*, the Third Circuit's decision could be read in ways that would chill innovation by discouraging exclusive licensing agreements generally in the pharmaceutical industry. Pioneer pharmaceutical companies rely on the patents laws to recoup the considerable investments necessary to produce innovative new therapies. Exclusive licensing agreements play an important role in this process.

A. The Third Circuit's Decision Discourages Settlement of Patent Litigation.

This Court has long recognized the benefit of encouraging settlements. *See, e.g.*, *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994) ("public policy wisely encourages settlements"). The Court reaffirmed this view in *Actavis*, acknowledging the "value" and "desirability" of settlements. 133 S. Ct. at 2234, 2237. Yet the Third Circuit's decision will discourage settlements by making innovator companies less willing to offer an exclusive license as part of the settlement agreement.

The Hatch-Waxman Act creates powerful incentives for generics to file lawsuits challenging the patents held by innovator companies. Generic companies may initiate a patent challenge without incurring any liability by filing a Paragraph IV certi-

fication, which constitutes an act of patent infringement. 35 U.S.C. § 271(e)(2)(A). Lawsuits initiated in this manner differ from other patent infringement actions because the generic challenger is not required to bring products to market as a prerequisite to bringing the suit, which means that the litigation takes place before the patentee has suffered monetary damages. 35 U.S.C. § 271(e)(1). As further incentive to challenge existing patents, the Hatch-Waxman Act grants 180 days of exclusivity to the first generic company to challenge an innovator's patents and win FDA approval for its product. 21 U.S.C. § 355(j)(5)(B)(iv).[4]

These powerful incentives to challenge patents lead to a predictable result: generic manufacturers will challenge patents of innovator companies even when a challenge has little merit. Indeed, as the FTC has acknowledged, "for a drug with [annual] brand sales of $130 million, a generic that does not anticipate [authorized generic] competition will expect a patent challenge to be profitable if it has at least a *4 percent chance of winning . . .*."[5] As a re-

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[4] Incentives to challenge patents are not limited to the first generic filer; widely prescribed medications often attract multiple generic challengers. *See* Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 Santa Clara Computer & High Tech. L.J. 489, 520–21 & n.177 (2007); Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 367, at 377 & n.59 (2010). And the experience of innovators litigating is that subsequent filers will continue to litigate even after the first-filer holding exclusivity has settled.

[5] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, at iii n.7 (2011) (emphasis added), *available at*
(continued...)

sult, patent challenges are occurring earlier in the life cycle of a patented drug and more often. Henry Grabowski, G. Long & R. Mortimer, *Recent Trends in Brand-Name and Generic Drug Competition*, 17 J. of Med. Econ. 207, 212–13 (2014).

With the proliferation of Hatch-Waxman litigation, litigants often look for ways to resolve these expensive, protracted lawsuits. Settlements are an attractive option because they resolve disputes with far less risk, time, and expense than litigation. Settlements also reduce the burden on scarce judicial resources, and provide certainty for all parties, allowing companies to focus on business interests rather than litigating disputes. Given these significant benefits, the vast majority of patent disputes settle. Indeed, over 90 percent of patent suits filed in 2008 and 2009 settled before courts had ruled on their merits.[6] Patent settlements also are common in the pharmaceutical industry.[7]

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https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf (last visited Mar. 31, 2016).

[6] John R. Allison et al., *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1780 (2014).

[7] Bret Dickey & Jonathan Orszag, *The Benefits of Patent Settlements: New Survey Evidence on Factors Affecting Generic Drug Investment*, at 8 (2013), available at http://www.gphaonline.org/media/cms/Dickey_Orszag_Benefits_of_Patent_Settlements_2012-07-21_FINAL.pdf (64 percent of patent suits between branded and generic pharmaceutical companies settle) (last visited Mar. 31, 2016).

Granting an exclusive license to a generic manufacturer—like GSK did here—is a common way to settle patent suits in the pharmaceutical industry. Between 2004 and 2010, approximately 25 percent of settlements of Hatch-Waxman patent suits between brand firms and the first generic patent challenger involved exclusive licenses.[8] And between October 1, 2010 and September 30, 2014, 38 of the settlements of Hatch-Waxman patent litigation that pharmaceutical companies reported to the FTC involved exclusive licenses.[9]

The Third Circuit's decision is likely to change this practice. As discussed above, generic manufacturers have strong incentives to challenge patents

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[8] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, *supra* note 5, at 140.

[9] FTC, *Overview of Agreements Filed in FY 2011*, 1, *available at* https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/1110mmaagree-2.pdf (last visited Mar. 31, 2016) (ten); FTC, *Overview of Agreements Filed in FY 2012*, 1, *available at* https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf (last visited Mar. 31, 2016) (nineteen); FTC, *Overview of Agreements Filed in FY 2013*, 1, *available at* https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/141222mmafy13rpt-1.pdf (last visited Mar. 31, 2016) (four); FTC, *Overview of Agreements Filed in FY 2014*, 1-2, *available at* https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf (last visited Mar. 31, 2016) (five).

with little merit. Consequently, innovator companies often settle cases to avoid the burden of litigation, even though they fully expect to prevail on the merits. But the incentive to offer an exclusive license to settle patent litigation would disappear if the Third Circuit's decision stands. That is because settling the patent suit would expose the company to an antitrust suit that may be even more burdensome.

Hatch-Waxman patent cases will become considerably more difficult to settle if innovator companies can no longer offer an exclusive license. Settlement negotiations are more likely to be successful when the parties have several issues on which they can seek compromise.[10] Settling a Hatch-Waxman case is already more difficult than other patent cases because the patentee typically has not yet suffered any damages, and thus the parties cannot negotiate on the amount that the infringing party should pay as damages to the patentee.[11] When the parties cannot

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[10] Negotiation experts have recognized that a "negotiation is more likely to be successful when there are several issues to be resolved ('integrative bargaining') rather than just one, because it is easier in the former case to strike a deal that will make both parties feel they are getting more from peace than from war." Br. Mediation & Negotiation Professionals Amici Curiae Supp. Resp't, *Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 838156, at *6–7 (Feb. 28, 2013) (internal citations omitted).

[11] *See* Gerald Sobel, *Consideration of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Act Settlements*, 20 Fed. Cir. B.J. 47, 51 (2010) ("Unlike the usual patent case, there are ordinarily no damages claims against the generic because Hatch-Waxman forces the litigation to occur in the period prior to marketing by the generic. As a result, no sales or profits are lost by the patentee to the generic. While patent infringement suits are often settled by compromise of a damages (continued...)

reach agreement based on the generic product's entry date alone, the ability to negotiate regarding exclusivity may facilitate resolution of Hatch-Waxman litigation.[12] Because the Third Circuit's decision discourages negotiating exclusive licenses, Hatch-Waxman patent cases will be much less likely to settle if this decision stands.

B. The Third Circuit's Decision Will Chill Innovation in the Pharmaceutical Industry.

The Third Circuit's decision is sufficiently important to warrant further review based solely on the negative effect that it will have on settling patent cases. But the potential of wasting judicial resources by impeding settlements is only the beginning of the problems created by the court of appeals' decision. As noted above, there is nothing in the Third Circuit's reasoning that would limit courts to applying the decision only to the facts of a so-called no-AG commitment. The decision thus could have the effect of discouraging innovator companies from entering into exclusive licensing agreements at all, chilling innovation in the pharmaceutical industry.

Pharmaceutical innovations are at the center of many of the most significant advances in personal and public health. New and innovative therapies

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claim, that vehicle is typically not available in Hatch-Waxman cases.").

[12] *See* Dickey, *supra* note 4, at 391–97; 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, 618–19, 628–31 (2005).

have saved millions of lives and added trillions of dollars to national wealth.[13] But developing these new therapies comes at considerable cost. Obtaining FDA approval for a new drug, on average, takes at least 10 years and costs $2.6 billion.[14]

Patent protection is critical to pharmaceutical innovation, given the immense investments in money and time required to discover and obtain regulatory approval for new drugs, on the one hand, and the comparative ease of copying after an innovator has made those investments, on the other.[15] "Without a

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[13] PhRMA, *2015 Profile: Biopharmaceutical Research Industry*, *supra* note 2, at 5-6 (discussing lives saved for HIV/AIDS and cancer as a result of new medicines); Kevin M. Murphy & Robert H. Topel, *The Value of Health and Longevity*, 114 J. Pol. Econ. 871, 872 (2006) ("From 1970 to 2000, gains in life expectancy added about $3.2 trillion per year to national wealth . . . ."), *available at* https://www.dartmouth.edu/~jskinner/documents/MurphyTopelJPE.pdf (last visited Mar. 31, 2016).

[14] *See* PhRMA, *Chart Pack: Biopharmaceuticals in Perspective* 29 (Spring 2015), *available at* http://www.phrma.org/sites/default/files/pdf/chartpack-2015.pdf ("PhRMA 2015 Chart Pack") (last visited Mar. 31, 2016); Tufts Center for the Study of Drug Development, *Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion* (Nov. 18, 2014), *available at* http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study (last visited Mar. 31, 2016).

[15] *See, e.g.*, Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1616–17 (2003) ("ratio of inventor cost to imitator cost, therefore, is quite large in the absence of effective patent protection. As a result, it is likely that innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection."); *see also* Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. Int'l Econ. L. 849, 851 (2002) ("Absent (continued...)

well-structured system of patent protection, neither the research pharmaceutical industry nor the generic industry would be able to grow and prosper, as the rate of new product introductions and patent expirations would decline significantly." Grabowski, *supra* note 15, at 853. One study concluded that, without patent protection, 65 percent of pharmaceutical products would never have been brought to market. Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 Mgmt. Sci. 173, 175 (1986). Ultimately, there is no dispute that pharmaceutical products bring numerous measurable and immeasurable medical and financial benefits to patients.

The ability to grant an exclusive licenses is an important piece of the innovation puzzle in the pharmaceutical industry and the life sciences sector more generally.[16] Exclusive licenses foster collaboration, paving the way for important medical advances and groundbreaking discoveries.[17] They also allow pharmaceutical companies with greater research-and-development and/or marketing resources to transform discoveries into life-saving or life-enhancing drugs. Such collaboration would be re-

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patent protection, . . . imitators could free ride on the innovator's FDA approval and duplicate the compound for a small fraction of the originator's costs.").

[16] *See, e.g.*, Thomas R. Varner, *An Economic Perspective on Patent Licensing Structure and Provisions*, 46 Bus. Econ 229, 237 (2011) (84 percent of patent licenses in the life sciences industries are exclusive).

[17] *See, e.g.*, Viktor Braun, *Licenses as Critical Sources of Innovation*, 44 les Nouvelles 9, 13 (2009) (describing exclusive licenses as "useful collaborative tools" for improving both drugs and medical devices).

duced if patentees are permitted to grant only non-exclusive licenses. Just as a patentee may be unwilling to invest in developing and marketing a new drug without strong patent protection, so too is it unlikely that a licensee would invest in collaborating to develop and market the new medicine if it would not have exclusive rights to a successful collaboration.[18]

There are many instances in which innovative new therapies resulted from collaborations based on exclusive licenses. For example, after researchers at Yale University found the drug stavudine to be an effective antiretroviral treatment for HIV, the university granted an exclusive license to Bristol-Myers Squibb ("BMS") to develop and market the drug.[19] BMS brought the drug to market, and it became the most frequently prescribed antiretroviral in the world in 1998.[20] Similarly, GSK developed Ziagen, another antiretroviral drug for HIV, after the University of Minnesota granted it an exclusive license in connection with the settlement of a patent dispute.[21]

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[18] *See* Lita Nelsen, *The Role of University Technology Transfer Operations in Assuring Access to Medicines and Vaccines in Developing Countries*, 3 Yale J. of Health Pol'y, L. & Ethics 301, 302 (2003).

[19] Universities Allied for Essential Medicines, *Stavudine and Yale* (2010), *available at* http://uaem.org/cms/assets/uploads/2013/03/Universities-Allied-for-Essential-Medicines-Stavudine-and-Yale-2009-12-24.pdf (last visited Mar. 31, 2016).

[20] *Id.*

[21] Risa L. Lieberwitz, *Confronting the Privatization and Commercialization of Academic Research: An Analysis of Social Implications at the Local, National, and Global Levels*, 12 Ind. J. of Global Legal Stud. 109, 133-34 (2005).

Collaboration through exclusive licenses also makes it easier for innovators to combine multiple cutting-edge pharmaceutical technologies. For instance, Alza and Pfizer entered into an exclusive licensing agreement in 1989 that merged Alza's new laser technology—which enabled better targeted release of medicines—with Pfizer's cardiovascular drug Procardia. *See* Braun, *supra*, at 10–11. This combination reduced the dosing schedule for Procardia from twice a day to once a day. *Id.* at 11.

Finally, exclusive licenses promote collaboration between the government and private industry. For example, the FDA advertises opportunities for "[c]ollaborative research and development work" through exclusive licensing agreements with "commercial partners interested in developing and marketing technologies that FDA scientists have created."[22]

As these examples demonstrate, exclusive licenses are common in the pharmaceutical industry for a good reason. They facilitate the collaboration necessary to create, manufacture, and sell innovative new products that save lives. The Third Circuit's decision should not be allowed to stand if it could be read to impinge on these important functions of exclusive

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[22] FDA, *Licensing and Collaboration Opportunities* (Nov. 9, 2015), *available at* http://www.fda.gov/ScienceResearch/CollaborativeOpportunities/Inventions/default.htm (last visited Mar. 31, 2016); *see also* 37 C.F.R. §404.7(a)(1)(B) (recognizing that an exclusive license on a government patent can be "a reasonable and necessary incentive to call forth the investment capital and expenditures needed to bring the invention to practical application").

licenses in the pharmaceutical industry. Moreover, the Third Circuit was wrong to hold that a pharmaceutical company may be subjected to an antitrust suit simply because the exclusive license it entered into was negotiated as a part of a settlement between an innovator and a generic pharmaceutical company. The Court should grant the petition for certiorari and reaffirm *Actavis*'s holding that a patentee faces antitrust liability for settling a patent case only if the case is settled on terms not authorized by the patent laws.

CONCLUSION

The petition for a writ of certiorari should be granted and the judgment of the court of appeals should be reversed.

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