No. 18-1280

IN THE
Supreme Court of the United States

ACORDA THERAPEUTICS, INC.,
Petitioner,

v.

ROXANE LABORATORIES, INC., ET AL.,
Respondents.

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

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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MAY 8, 2019

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INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents leading biopharmaceutical research companies devoted to the research and development of medicines.[2] Those efforts produce the cutting-edge treatments that save, extend, and improve the quality of the lives of countless individuals around the world every day. Over the past decade, hundreds of new medicines have been approved by the Food and Drug Administration ("FDA"). In view of the risky biopharmaceutical research and development process, which has a significant failure rate, and the substantial requirements of the FDA to demonstrate safety and efficacy of new products, those results are not obtained cheaply. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $71.4 billion in 2017 alone.

PhRMA members depend heavily on a robust system of patent rights and a fair system for adjudicating their validity. PhRMA aims to advance public policies that foster innovation in pharmaceuticals, including by ensuring adequate patent protection to enable and

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[1] Pursuant to Rule 37.6, *amicus curiae* affirms that no counsel for a party authored this brief in whole or in part, and that no person other than *amicus curiae* or its counsel made any monetary contributions intended to fund the preparation or submission of this brief. The parties were timely notified of the intent to file this brief and consented to its filing.

[2] A complete list of PhRMA members is available at http://www.phrma.org/about/members (last visited May 7, 2019). Members include Teva US Specialty Medicines, a corporate affiliate of Respondent.

incentivize its members' substantial investments in research and development. To those ends, PhRMA seeks to prevent unlawful barriers from arising that undermine intellectual property protections, including as *amicus curiae* before this Court.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Federal Circuit has disregarded industry realities and this Court's precedent by creating its blocking-patent doctrine. The result is a rigid, *per se* rule that is contrary to the Patent Act and will likely stifle pharmaceutical development.

The embrace of form over function is not a first for the Federal Circuit. Rather, the blocking-patent doctrine is the latest in a line of mechanical rules that have been devised by the Circuit and then subsequently rejected by this Court. *See infra* section I. Those earlier erroneous constructions—including one that also arose in the context of obviousness, *see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007)—were invalidated as contrary to settled precedent and the Patent Act's scope and purpose. The blocking-patent doctrine should meet a similar fate.

The Federal Circuit's doctrine is not just wrong—it is also harmful. The protections that Congress has afforded patents help to fuel pharmaceutical development, which is costly, has long time horizons, and is characterized by a high degree of scientific and regulatory risk. The blocking-patent doctrine created by the Federal Circuit, however, weakens protections for an entire class of patents that improve on existing technology. *See infra* section II.A. That is no small

matter in the pharmaceutical industry, where empirical studies indicate that incremental advances in technology account for significant medical progress. *See infra* section II.B. Indeed, because seemingly "small differences may have large consequences or benefits" for the development of new medicines for patients, *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 749–750 (Fed. Cir. 2013) (Newman, J., dissenting), the blocking-patent doctrine will impose particular harm to pharmaceutical innovation.

The need for review by this Court is especially strong in this case because the Federal Circuit's blocking-patent doctrine is based on a flawed premise regarding research and development. Existing patents do not categorically "block" others from developing patented technology. Rather, research and development may proceed under a statutory safe harbor, or overseas, or through cooperative licensing arrangements such as those present here. The blocking-patent doctrine ignores the potential for such collaborative innovation and actively discourages it. *See infra* section II.C. For these reasons and those set forth below, review is warranted.

ARGUMENT

I. The Federal Circuit's Blocking-Patent Doctrine Is Another Rigid, *Per Se* Rule That Should Be Invalidated Because It Is At Odds With This Court's Patent Law Precedent

In adopting the blocking-patent doctrine, the Federal Circuit created a rigid, *per se* rule without anchor in the Patent Act or relevant precedent.

When Congress enacted the requirement in 1952 that a claimed invention must not "have been obvious . . . to a person having ordinary skill in the art," 35 U.S.C. § 103, it codified a century of judicial precedent defining obviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). That settled law contains guideposts that aid generalist judges and "guard against slipping into the use of hindsight." *Id.* at 35–36 (citation omitted). As explained in *Graham*, the objective "considerations" of "commercial success, long felt but unsolved needs, [and] failure of others" are essential "to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Id.* at 17–18. And the Court has made clear that *Graham*'s "factors continue to define the inquiry that controls." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007).

Yet the Federal Circuit has displaced this precedent and the Patent Act with its own contrived rule that requires trial courts to set aside and ignore the very objective considerations this Court has recognized since *Graham*. The decision below held that an "implicit finding that securing freedom from blocking

patents in advance is likely important to pharmaceutical research investments," Pet. App. 57a, could override even "significant" and "convincing" evidence of nonobviousness, Pet. App. 184a, even without *any* evidence of actual blocking. In other words, the Federal Circuit's opinion confirms that its blocking-patent doctrine—errant from the start—has hardened into a rigid, *per se* rule that disregards *Graham* and objective evidence of nonobviousness. Pet. App. 184a.

The blocking-patent doctrine is the latest in a succession of rigid, *per se* rules that have been fashioned by the Federal Circuit, and it should be similarly rejected by this Court as contrary to settled precedent and contrary to the Patent Act's scope and purpose.

In *KSR International Co. v. Teleflex Inc.*, for example, a different Federal Circuit obviousness rule was at issue. There, the Circuit had "employed an approach referred to . . . as the 'teaching, suggestion, or motivation' test," according to which a patent claim was obvious only if "'some motivation or suggestion to combine the prior art teachings' c[ould] be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art." *KSR*, 550 U.S. at 407 (quoting *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1323–1324 (Fed. Cir. 1999)). This Court rejected that "rigid approach." *KSR*, 550 U.S. at 415. The Federal Circuit had "addressed the question of obviousness in a manner contrary to § 103 [of the Patent Act] and [Supreme Court] precedents," *id.* at 407, which required "an expansive and flexible approach," *id.* at 415. In particular, this Court held that the Circuit's restrictive test was inconsistent with *Graham*'s

"broad inquiry," which encompassed "any secondary considerations that would prove instructive." *Id.*

Bilski v. Kappos, 561 U.S. 593 (2010), rejected another mechanical patentability test for similar reasons. Under the Federal Circuit's formulation, an invention was a patent-eligible "process" under § 101 of the Patent Act only if it satisfied the so-called "machine-or-transformation" test. *Id.* at 602. That judicially created rule was invalid, the Court held, because it "impose[d] . . . limitations that [we]re inconsistent with the text and the statute's purpose and design." *Id.* at 603; *see also id.* at 605 (noting that a "categorical rule denying patent protection" may "frustrate the purposes of the patent law" (citation omitted)).

KSR and *Bilski* illustrate a broader pattern wherein the Court has repeatedly struck down Federal Circuit *per se* rules because they contravene the Patent Act and established precedent, and the Court should grant review and do the same in the instant case. *See, e.g.*, *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 550, 553–554 (2014) (rejecting "mechanical" test for awarding attorney fees as "unduly rigid" in favor of approach that considers "the totality of the circumstances"); *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 625, 628 (2008) (rejecting determination that the doctrine of patent exhaustion categorically does not apply to method claims); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2007) (rejecting rule that a patent licensee in good standing cannot satisfy Article III's case-or-controversy requirement if bringing a declaratory

judgment action challenging the validity, enforceability, or scope of the patent); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006) (rejecting "categorical grant" of a permanent injunction based on rule denying such relief only "in rare instances," and directing that traditional four-factor framework applied); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 737 (2002) (rejecting *per se* rule that prosecution history estoppel poses complete bar to claims of equivalence, in favor of flexible-bar rule).

II. The Federal Circuit's Blocking-Patent Doctrine Stifles Pharmaceutical Innovation And Investment

A. The Blocking-Patent Doctrine Weakens Patent Rights That Fuel Pharmaceutical Innovation

The blocking-patent doctrine short-circuits the settled law regarding challenges to patent validity. In doing so, it discourages pharmaceutical innovation.

The economic incentive to innovate is essential in the pharmaceutical industry, where the development of new products carries tremendous expense. On average, developing a new medicine and obtaining regulatory approval takes ten to fifteen years and costs an estimated $2.6 billion, not including post-approval R&D costs.[3] Acorda, for instance, secured

[3] PhRMA, *Biopharmaceuticals in Perspective*, at 29 (Summer 2018), *available at* http://phrma-docs.phrma.org/files/dmfile/ChartPack2018_PDF_6.28.18_final.pdf; *see also* Joseph A.

approval of Ampyra® after twelve years of research and development. The pharmaceutical industry spends more on domestic R&D than any other sector, accounting for one of every six R&D dollars spent by U.S. businesses.[4]

Pharmaceutical innovation is also risky. Pharmaceutical companies may test vast numbers of compounds to identify a potential drug.[5] Fewer than 12% of drugs that reach a Phase I clinical trial are ultimately approved by the FDA.[6] The development of new medicines "typically require[s] significant amounts of pioneering research," and "both fixed costs and risks of failing to develop a marketable product . . . are very high."[7]

Because pharmaceutical development is a high-cost, high-risk business, "patent protection is indispensable in promoting pharmaceutical innovation" because it "enable[s] pharmaceutical firms to cover their fixed costs and regain the capital they invest in

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DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 26 (2016).

[4] PhRMA, *Biopharmaceuticals in Perspective*, *supra*, at 126.

[5] Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1582 (2003).

[6] PhRMA, *Biopharmaceuticals in Perspective*, *supra*, at 29.

[7] Fed. Trade Comm'n (FTC), *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, ch. 3, at 5 (Oct. 2003), *available at* https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf.

R&D efforts."[8] In other words, when it comes to pharmaceuticals, patents are essential to the cycle of invention.

For these reasons, "there is a causal relationship between the strength of patent rights and innovation."[9] Empirical evidence has demonstrated that upholding the patent protections created by Congress (even as limited both in time and scope) increases R&D investment in pharmaceuticals,[10] and accelerates development of drugs around the world.[11] By contrast, undermining such protections chills innovation.[12]

The blocking-patent doctrine—which arms infringers and handicaps patentees when litigating the validity of improvement patents—significantly undermines patent protections. As a result, the doctrine

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[8] FTC, *To Promote Innovation*, *supra*, ch. 3, at 4; *see also id.*, ch. 2, at 1 ("Pharmaceutical companies . . . rely on patents to prevent free riding, recoup their R&D investments, and learn about new technological breakthroughs . . . .").

[9] Stephen Haber, *Patents and the Wealth of Nations*, 23 Geo. Mason L. Rev. 811, 829 (2016).

[10] *See, e.g.*, Maureen K. Ohlhausen, *Patent Rights in a Climate of Intellectual Property Rights Skepticism*, 30 Harv. J. L. & Tech. 103, 127–131 (2016).

[11] *See, e.g.*, Iain M. Cockburn et al., *Patents and the Global Diffusion of New Drugs*, 106 Am. Econ. Rev. 136, 138–139 (2016).

[12] *See* Congressional Budget Office, *Pharmaceutical R&D and the Evolving Market for Prescription Drugs*, at 6 (Oct. 26, 2009), *available at* https://www.cbo.gov/system/files/2018-08/41373-2009-10-26-drugs.pdf ("[P]olicies that would lower expectations about revenues would discourage R&D investment . . . .").

will likely stifle pharmaceutical investment and ultimately harm the "afflicted public." Pet. App. 62a (Newman, J., dissenting).

B. Incremental Pharmaceutical Innovation Suffers Particular Harm From The Blocking-Patent Doctrine

By systematically discounting objective evidence of nonobviousness for improvement patents, the blocking-patent doctrine discourages pharmaceutical companies from building on their own previously patented work and the previously patented work of others. Such incremental innovation, however, is responsible for great advances in the safety and efficacy of pharmaceuticals. The blocking-patent doctrine is therefore likely to cause significant damage to the development of new drugs.

Nearly all inventions may be considered improvements on prior inventions. *See, e.g.*, *KSR*, 550 U.S. at 418–419 ("[I]nventions in most, if not all, instances rely upon building blocks long since uncovered . . . ."); *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1338 (Fed. Cir. 2015) ("In practice, 'all inventions are for improvements . . . .'" (citation omitted)).

Pharmaceutical innovation through incremental improvements on existing technology—including novel delivery systems, new forms of an active compound, alternative indications for existing drugs, new methods of using or making existing compounds, and novel combinations of active ingredients—is important.

Indeed, incremental advancements "are paramount to overall increases in the quality of health care" and "often represent advances in safety and efficacy."[13] In other words, in the field of pharmaceuticals, "small differences may have large consequences or benefits." *Galderma*, 737 F.3d at 749–750 (Newman, J., dissenting).

For example, "advances in delivery systems and dosage forms," including "transdermal delivery, delayed-onset, [and] extended release oral formulations," can "provide molecules with staying power, prolonging their therapeutic effect."[14] Furthermore, with a greater variety of drug options, physicians can "calibrate their prescribing patterns to address the needs of specific patients," who may react differently to different drugs.[15]

Ongoing research can also "generate very significant advances in treatment . . . for an indication quite

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[13] Albert I. Wertheimer & Thomas M. Santella, Int'l Pol'y Network, *Pharmacoevolution: The Advantages of Incremental Innovation*, at 3 (2005), *available at* https://www.who.int/intellectualproperty/submissions/Pharmacoevolution.pdf?ua=1.

[14] Wertheimer & Santella, *supra*, at 8.

[15] *Id.* at 6; *see also* Kristina M. Lybecker, *Incremental Innovation in the Pharmaceutical Industry*, *in* Steven Globerman & Kristina M. Lybecker, Fraser Inst., *The Benefits of Incremental Innovation: Focus on the Pharmaceutical Industry*, at 26–27 (June 2014), *available at* https://www.fraserinstitute.org/sites/default/files/benefits-of-incremental-innovation.pdf (describing how incremental innovation expands treatment options).

unrelated to the initial major breakthrough."[16] Such examples abound. For instance, a drug originally approved to treat a rare, hypersecretory condition known as Zollinger-Ellison syndrome was later developed and approved for the treatment of gastroesophageal reflux disease, a common form of heartburn.[17] And a drug initially approved to treat colorectal cancer has since been proven effective in treating certain lung cancers and breast cancer, and the drug "is being investigated in some 20 clinical trials against different cancers or stages of cancer."[18]

Incremental innovations have improved treatments for AIDS, bacterial infections, cancer, cardiovascular disease, congestive heart failure, diabetes, hepatitis C, malaria, and stroke, among many other conditions.[19]

Because the blocking-patent doctrine punishes patents that improve on existing technology—a significant form of innovation in the pharmaceutical industry—the rule has an especially pernicious effect on the development of new drugs. Under the Federal Circuit's rigid rule, a company must consider eschewing incremental research in favor of speculative, but more patentable, work. An innovator may fear that patents claiming improvements resulting from such

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[16] Ernst R. Berndt et al., *The Impact of Incremental Innovation in Biopharmaceuticals: Drug Utilisation in Original and Supplemental Indications*, 24 Suppl. 2 Pharmacoeconomics 69, 71 (2006).

[17] *Id.* at 71.

[18] Lybecker, *supra*, at 47.

[19] *Id.* at 46–48.

research will be judged by the Circuit's harsh validity standard: one in which objective indicia can be discounted or disregarded *per se* without supporting record evidence.

The blocking-patent doctrine thus "foreclose[s] patentability to a vast body of improvement patents," *Galderma*, 737 F.3d at 742 (Newman, J., dissenting), aggravating the risk that promising lines of research may be abandoned before their full potential is realized. "The losers are those afflicted with disease." *Id.*

C. The Blocking-Patent Doctrine Discourages Fruitful Research Partnerships

Pharmaceutical companies often innovate together through licensing and collaboration agreements. The blocking-patent doctrine discourages such partnerships.

In the pharmaceutical industry, it is common for one innovator or development partner to discover a way to turn an existing compound into an effective pharmaceutical where others have failed, and for multiple companies to collaborate with each other and with public-sector researchers in producing better medicines.[20] The law has evolved to encourage such

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[20] *See, e.g.*, Deloitte, *Partnering For Progress: How Collaborations Are Fueling Biomedical Advances* (2017), *available at* https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-partnering-for-progress-how-collaborations-are-fueling-biomedical-advances-abridged-version.pdf; Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 Tenn. L. Rev. 75, 81 (1994) (explaining that blocking patents "balance[]

joint activity. *See, e.g.*, Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Pub. L. 108-453, 118 Stat. 3596 (2004). The first-ever once-a-day AIDS treatment, for example, combined three existing drugs produced by two different pharmaceutical companies into a single pill, resulting in "a marked improvement over the original AIDS treatments developed in the 1990s."[21]

Such collaborative arrangements reveal a false premise underlying the blocking-patent doctrine. Preexisting patents do not "block" research and development for the subject matter they protect. Indeed, in the pharmaceutical industry, prior patents cannot "block" research because the safe harbor provision of 35 U.S.C. § 271(e)(1) permits the use of patented compounds for research "as long as there is a reasonable basis for believing that the experiments will produce 'the types of information that are relevant to [a new drug application].'" *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 208 (2005). Furthermore, researchers may request a license from the holder of the relevant "blocking patent," as Acorda did here. And because United States patents do not apply overseas, concerns about potential infringement liability may not apply abroad. All the above are avenues of research available for pharmaceutical development, despite the existence of a so-called "blocking" patent.

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incentives for pioneers with incentives for independent inventors to push pioneering technology forward").

[21] Joshua Cohen & Kenneth Kaitin, *Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice*, 15 Am. J. Therapeutics 89, 90 (2008).

The instant case illustrates how collaborative innovation in the pharmaceutical industry can, and should, work. Acorda licensed the Elan Patent and picked up where others left off, investing considerable sums in the clinical implementation of a 4-AP formulation. Acorda was not deterred by Elan's invention, but instead licensed it and built on it.

Due to the Federal Circuit's rigid blocking-patent doctrine, however, rather than being rewarded for its innovative and collaborative efforts—which have disclosed to the world especially beneficial methods of using 4-AP—Acorda has been stripped of its patent protection. Other pharmaceutical companies will expect to be similarly penalized for their collaborative efforts to invent.

CONCLUSION

For the reasons set forth above and in the petition, the Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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MAY 8, 2019