No.

IN THE
Supreme Court of the United States

ACORDA THERAPEUTICS, INC.,

Petitioner,

v.

ROXANE LABORATORIES, INC.,
MYLAN PHARMACEUTICALS, INC., AND
TEVA PHARMACEUTICALS USA, INC.,

Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Under 35 U.S.C. § 103, a patent "may not be obtained . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious . . . to a person having ordinary skill in the art." In *Graham v. John Deere Co.*, 383 U.S. 1 (1966), this Court explained that the obviousness inquiry should encompass objective "indicia" of nonobviousness such as "commercial success, long felt but unsolved needs, [and] failure of others," *id.* at 17–18. In the decision below, however, a divided panel of the Federal Circuit discounted what the district court deemed to be Acorda's "significant" and "convincing" evidence of nonobviousness because the claimed invention—the first drug for treating walking in patients with multiple sclerosis—built on a prior patent licensed to Acorda that supposedly "blocked" other companies from developing the claimed methods. According to the Federal Circuit, the defendants had met their burden of proving obviousness by clear and convincing evidence because Acorda had not "suppl[ied]" its own "evidence to make unreasonable" the district court's "implicit finding" that "securing freedom from blocking patents . . . is likely important to pharmaceutical research."

The question presented is whether objective indicia of nonobviousness may be partially or entirely discounted where the development of the invention was allegedly "blocked" by the existence of a prior patent, and, if so, whether an "implicit finding" that an invention was "blocked," without a finding of *actual* blocking, is sufficient to conclude that an infringer has met its burden of proof.

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

In addition to the parties named in the caption, Alkermes Pharma Ireland Limited was a plaintiff in the district court and a cross-appellee in the Federal Circuit.

Acorda Therapeutics, Inc. is a publicly held corporation. Ten percent or more of its stock is owned by Black Rock, Inc., a publicly held corporation.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Acorda Therapeutics, Inc. ("Acorda") respectfully submits this petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the court of appeals is published at 903 F.3d 1310. Pet. App. 1a–85a. The district court's opinion is unreported but is available at 2017 WL 1199767. Pet. App. 86a–186a. The court of appeals' order denying rehearing and rehearing en banc is unreported. *Id.* at 187a–188a.

JURISDICTION

The court of appeals entered its judgment on September 10, 2018, and denied a timely petition for rehearing or rehearing en banc on January 4, 2019. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Relevant provisions of Article I of the United States Constitution and the Patent Act are set forth in Appendix D to the petition. Pet. App. 189a–196a.

INTRODUCTION

The Federal Circuit has manufactured a rigid, legally flawed doctrine that impairs patent rights and deters innovation in direct contravention of the Patent Act and this Court's precedent. In the decision below, the Federal Circuit applied, and expanded, its so-called "blocking patent" doctrine to invalidate for obviousness Acorda's patents for Ampyra®, a breakthrough drug that represents the first treatment for improving walking in patients with multiple sclerosis

("MS"). In so ruling, the Federal Circuit entirely discounted what the district court found to be Acorda's "significant" and "convincing" evidence of nonobviousness, Pet. App. 184a—including the repeated failure of others to develop a similar drug to address this long-recognized need and Ampyra®'s commercial success—solely because Ampyra® built on a prior patent licensed to Acorda that supposedly "blocked" other companies from developing the claimed methods, *id.* at 54a–59a. The court of appeals gave dispositive weight to the existence of that "blocking patent" despite the absence of a finding that any pharmaceutical researcher was *actually* deterred by that patent from attempting to develop Acorda's MS treatment—and despite the availability of a statutory safe harbor that would have shielded researchers from infringement liability. In fact, the court of appeals did not require the defendants to produce any evidence of actual "blocking" and instead shifted the burden to Acorda to "supply evidence" sufficient to overcome the district court's "implicit finding" that "securing freedom from blocking patents . . . is likely important to pharmaceutical research." *Id.* at 57a.

The Federal Circuit's application of its blocking-patent doctrine to negate Acorda's evidence of nonobviousness is impossible to reconcile with this Court's decision in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), which makes clear that objective "indicia" of nonobviousness, such as commercial success, long-felt but unmet need, and the failure of others, are an essential component of the obviousness inquiry because they "'guard against slipping into the use of hindsight'" when evaluating whether an invention would have been obvious to a person of ordinary skill in the art. *Id.* at 18, 36 (citation omitted). By shifting the burden to Acorda to prove the validity of its patents,

the Federal Circuit also overrode this Court's decision in *Microsoft Corp. v. i4i Limited Partnership*, 564 U.S. 91 (2011), which held that, because patents are "presumed valid" under 35 U.S.C. § 282(a), a party challenging a patent as obvious bears the burden of proving invalidity by clear and convincing evidence. 564 U.S. at 101–02.

As Judge Newman recognized in her dissent, "[t]he consequences of this new legal theory are large," and "[t]he loser is the afflicted public." Pet. App. 62a. By dramatically lowering the bar for successful obviousness challenges, the blocking-patent doctrine will inevitably deter pharmaceutical companies from undertaking the costly, high-risk, and time-consuming research required to produce innovative drugs, like Ampyra®, that can immeasurably improve the quality of patients' lives. This Court should grant certiorari to reject the Federal Circuit's judicially created blocking-patent doctrine and, in so doing, restore the presumption of patent validity that Congress established and that this Court has repeatedly acted to safeguard.

STATEMENT

1. Multiple sclerosis is a chronic disease that causes nerves to lose their protective covering, known as myelin. This results in a range of debilitating symptoms, the most common of which is difficulty walking. Pet. App. 91a.

Determined to find a treatment for MS, Acorda took up research in 1998 that had been abandoned by Elan Corporation ("Elan") into 4-aminopyridine ("4-AP"), a substance first discovered in 1902 that was known to be a bird toxin and to be capable of triggering seizures in humans. Pet. App. 5a, 94a. 4-AP is a

potassium channel blocker, and in the 1980s, some researchers had hypothesized that it could help restore connections in nerves with damaged myelin insulation. *Id.* at 5a, 98a. Multiple researchers investigated the possibility of treating MS with 4-AP, but they produced unreliable and inconsistent results. *Id.* at 5a–17a, 62a–68a. Elan was one of the companies that conducted that research using a sustained-release formulation of 4-AP that it developed and patented. *Id.* at 13a–16a, 68a–70a. After its own research efforts had failed—which included running the then-largest human clinical trial on 4-AP—Elan granted Acorda an exclusive license to its patent. *Id.* at 17a, 98a.

At significant cost and substantial risk, Acorda, then a small team of dedicated doctors and scientists, began its own research into possible MS treatments using 4-AP, and it too was initially unsuccessful. Pet. App. 17a–24a, 71a–74a. Virtually all of the prior work was focused on incrementally titrating the dose of 4-AP to the highest level a patient could tolerate without experiencing a seizure or other adverse effects, and Acorda initially proceeded along that path. *Id.* at 12a–13a, 19a–21a, 37a, 66a, 73a–74a. In 2003, however, Acorda made an unexpected breakthrough that departed sharply from the prior approach of using escalating doses of 4-AP. After reanalyzing the results from its latest failed clinical trial, Acorda hypothesized that patients could likely be treated at much lower, stable—and safer—dosages than were previously assumed to be effective. Acorda's hypothesis was confirmed after it conducted additional studies that were successful in improving walking in MS patients. *Id.* at 25a–26a, 74a–75a. Acorda filed a patent application in 2004 and was ultimately granted four patents for various aspects of its invention: a twice-

daily low, fixed dose of sustained release 4-AP used to improve walking in MS patients. *Id.* at 3a–4a.

Acorda also undertook the process of obtaining approval from the Food and Drug Administration ("FDA") for this revolutionary treatment, known as Ampyra®. The FDA granted priority review to Acorda's New Drug Application—which reflected the drug's great promise in treating MS—and approved Ampyra® in 2010. Pet. App. 28a. Ampyra® remains the first and only FDA-approved drug for treating walking in MS patients. Despite a relatively small patient population, Ampyra® has been a tremendous commercial success, generating sales of $1.7 billion since 2010. *Id.* at 28a–29a.

2. Roxane Laboratories, Inc., Mylan Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc. (collectively, "defendants") sought to share in Acorda's success by introducing generic versions of Ampyra®. To that end, they filed Abbreviated New Drug Applications with the FDA under the procedures specified by the Hatch-Waxman Act. *See* 21 U.S.C. § 355(j). In response, Acorda, along with Alkermes Pharma Ireland Ltd., the successor to Elan, filed this patent-infringement suit in the U.S. District Court for the District of Delaware. Defendants stipulated to infringement but challenged Acorda's and Elan's patents as invalid for obviousness. Pet. App. 4a.

After a bench trial, the district court found that Acorda had produced "significant" and "convincing" evidence of nonobviousness, including the commercial success of Ampyra®, the failure of others (including Elan) to develop a safe and effective treatment to improve walking in MS patients, and a long-felt but unmet need for such a treatment, Pet. App. 175a–179a, 182a–184a—precisely the type of evidence identified

by this Court in *Graham* as objective "indicia" of "nonobviousness." 383 U.S. at 18. Nonetheless, the court entirely dismissed Acorda's evidence of nonobviousness based on the blocking-patent doctrine, Pet. App. 180a, 182a–184a, which the Federal Circuit had first articulated in *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005). There, the Federal Circuit discounted evidence of commercial success because the claimed invention built on a prior patent held by the same patentee. *Id.* at 1376–77. In the Federal Circuit's view, the possibility of liability for infringing a so-called "blocking patent" may have deterred researchers from developing the drug in question, despite the prospect of realizing commercial success from that new drug. *See id.*

According to the district court, *Merck* and later Federal Circuit decisions applying the same reasoning required it to ignore the evidence of Ampyra®'s commercial success because other researchers may have been "blocked" from developing the claimed methods of Acorda's patents by the Elan patent, which Acorda built upon in developing Ampyra®. Pet. App. 180a, 182a–184a. The district court identified no evidence and made no finding, however, that anyone *actually* refrained from researching and developing the claimed methods due to the risk of infringing the Elan patent. Nor did the district court make a finding that anyone other than Acorda had tried to license the Elan patent. And, even though the Federal Circuit had previously applied its blocking-patent doctrine only to discount evidence of commercial success, the district court also discounted Acorda's evidence of the failure of others and long-felt but unmet need based on the purported (but unproven) "blocking" effect of the Elan patent. *Id.*

After rejecting Acorda's evidence of nonobviousness, the court concluded that defendants had met their burden of proving obviousness by clear and convincing evidence and declared the four Acorda patents to be invalid. Pet. App. 184a–186a.[1]

3. A divided panel of the Federal Circuit affirmed. Pet. App. 60a.

According to the panel majority, "the district court did not err in viewing the Elan patent . . . as evidence that discounted the weight of Acorda's evidence of commercial success, failure of others, and long-felt but unmet need." Pet. App. 54a. With respect to commercial success, the panel majority acknowledged that "the Elan patent would not preclude practice of the Elan invention outside the United States," but dismissed that possible research avenue because "it is not shown to be weighty in this case by any concrete evidence about the particular inventions at issue." *Id.* at 55a–56a.

The panel majority likewise recognized that "potential innovators would not have been blocked from practicing the Elan patent in the ways covered by the safe harbor provision of 35 U.S.C. § 271(e)(1), which declares specified activities to be non-infringing if undertaken 'solely for uses reasonably related to the development and submission of information' to the FDA." Pet. App. 56a (quoting § 271(e)(1)). The panel majority nevertheless upheld the district court's decision to discount the commercial success of Ampyra®

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[1] The district court rejected defendants' obviousness challenge to the Elan patent. Pet. App. 186a. Defendants cross-appealed that issue to the Federal Circuit, which dismissed the cross-appeal as moot because the Elan patent expired in July 2018. Pet. App. 60a.

in the face of the research safe harbor because "Acorda did not supply evidence to make unreasonable the *implicit* finding that securing freedom from blocking patents in advance is likely important to pharmaceutical research investments." Pet. App. 56a–57a (emphasis added). The panel majority then offered up its own extra-record secondary authorities to substantiate its conclusion that there is "nothing inherently unreasonable about the implicit finding to that effect." *Id.* at 57a n.17. Like the district court, however, the panel majority identified no record evidence that anyone had actually been deterred by the Elan patent from researching MS treatments using 4-AP. *Id.* at 55a–57a.

The panel majority reached the same conclusions with respect to the other objective indicia of nonobviousness. Although "the district court found that Sanofi-Aventis experimented with another potassium-channel blocker and was unsuccessful," the panel majority afforded no weight to that failure. Pet. App. 58a. It instead endorsed the district court's unsubstantiated speculation that "'Sanofi-Aventis likely did not use 4-AP because' of the blocking effect of the Elan patent." *Id.* The panel majority similarly concluded that there was "no clear error" in the district court's decision to "discount[ ]" evidence of "long-felt but unmet need . . . in light of the evidence of blocking by the Elan patent." *Id.* at 59a.

Judge Newman dissented because, in her view, it was "apparent that there is not clear and convincing evidence of obviousness." Pet. App. 62a. In particular, she criticized the panel majority for "discounting the undisputed evidence of commercial success, long-felt need, [and] failure of others." *Id.* at 83a. Judge Newman emphasized that the "Acorda product met a

long-felt need, for which the failure of others, despite decades of experimenting with the neurological properties of 4-AP, is evidence of the unobviousness of the Acorda achievement." *Id.* According to Judge Newman, the panel majority had "misappl[ied] the concept of 'blocking patent'" because "a prior patent would not have categorically precluded others from further developing the technology" in light of "the statutory safe harbor of § 271(e)(1), the knowledge provided in the patents, and the right to conduct research on patented subject matter." Pet. App. 84a. "The consequences of this new legal theory," Judge Newman cautioned, "are large," and "[t]he loser is the afflicted public." *Id.* at 62a. "Had the court's approach to the law of obviousness been in effect when Acorda took up the study of 4-aminopyridine after decades of failures by others," Judge Newman continued, "it is questionable whether this new treatment for multiple sclerosis would have been discovered." *Id.*

The Federal Circuit thereafter denied Acorda's petition for rehearing or rehearing en banc. Pet. App. 187a–188a.

REASONS FOR GRANTING THE PETITION

The Federal Circuit's invocation and expansion of its judicially manufactured blocking-patent doctrine to negate Acorda's "significant," "convincing," and unrefuted evidence of nonobviousness is plainly irreconcilable with this Court's decision in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), which established that an inquiry into commercial success, failure of others, and long-felt but unmet need is an important protection against hindsight bias in the obviousness analysis. *Id.* at 36. As Judge Newman recognized in her dissent—and as Federal Circuit judges have empha-

sized in prior dissents highlighting the blocking-patent doctrine's deficiencies—the elimination of that essential safeguard makes it far more likely that courts will submit to the "temptation" of invalidating patents that are obvious only when viewed through the lens of the patents' own teachings. *Id.*

The Federal Circuit's application of its blocking-patent doctrine in this case was particularly problematic because the court of appeals identified no evidence that anyone was *actually* deterred by the Elan patent from researching low-dose uses of 4-AP—and instead shifted the burden of proof to Acorda to "supply evidence" to negate the district court's "implicit finding" of blocking. Pet. App. 57a. In so doing, the Federal Circuit upended the clear-and-convincing-evidence burden of proof for invalidity challenges that this Court recognized in *Microsoft Corp. v. i4i Limited Partnership*, 564 U.S. 91, 101–02 (2011), and obliterated the presumption of validity that Congress codified in the Patent Act, 35 U.S.C. § 282(a).

By confounding the obviousness inquiry and inverting the burden of proof, the Federal Circuit's blocking-patent doctrine imperils the validity of numerous other patents that, like Acorda's patents on Ampyra®, build upon the prior art to develop innovative solutions to long-recognized problems. Indeed, the district court's implicit finding of blocking could be made in any case where a pharmaceutical company improved upon a preexisting patent that it held or practiced via license to develop a new, lifesaving treatment. This Court should grant certiorari and reject the blocking-patent doctrine before its severe curtailment of intellectual-property rights deters companies

from undertaking the huge risks and expense required to develop cutting-edge pharmaceutical treatments.

I. THE DECISION BELOW CONFLICTS WITH THIS COURT'S DECISION IN *GRAHAM V. JOHN DEERE CO.* BY NEGATING THE OBJECTIVE INDICIA OF NONOBVIOUSNESS.

The objective indicia of nonobviousness "'may often be the most probative and cogent evidence in the record'" regarding a patent's validity. Pet. App. 83a (Newman, J., dissenting) (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983)). Yet the Federal Circuit's blocking-patent doctrine eliminates consideration of this evidence—which plays a vital role as a check against hindsight bias—where a patentee improves upon the teachings of a prior patent that it held or practiced via license. That outcome is impossible to square with this Court's decision in *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

A. The Objective Indicia Are An Essential Element Of The Obviousness Inquiry.

To be patentable, a "claimed invention" must not "have been obvious . . . to a person having ordinary skill in the art." 35 U.S.C. § 103. This statutory requirement, enacted by Congress in 1952, reflected a "codification of judicial precedents" defining patentability. *Graham*, 383 U.S. at 17. Drawing on this prior case law, this Court in *Graham* outlined a four-part test to evaluate obviousness under Section 103. Courts must consider: (1) "the scope and content of the prior art," (2) "differences between the prior art and the claims at issue," (3) "the level of ordinary skill in the pertinent art," and (4) objective "indicia," or "secondary considerations," of nonobviousness, such

as "commercial success, long felt but unsolved needs, [and] failure of others." *Id.* at 17–18.

As this Court emphasized, the objective indicia of nonobviousness are a particularly important component of the obviousness analysis because they "focus attention on economic and motivational rather than technical issues and are, therefore, more susceptible of judicial treatment." *Graham*, 383 U.S. at 36 (citing *Reiner v. I. Leon Co.*, 285 F.2d 501, 504 (2d Cir. 1960)). The objective indicia "lend a helping hand to the judiciary," which is generally "ill-fitted to discharge the technological duties cast upon it by patent legislation." *Id*. At least as importantly, they also perform an essential function as a "'guard against slipping into use of hindsight,'" equipping courts "to resist the temptation to read into the prior art the teachings of the invention in issue." *Id.* (quoting *Monroe Auto Equip. Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (6th Cir. 1964)).

Although the objective indicia of nonobviousness were formalized in *Graham* as the fourth element of the obviousness inquiry, they have jurisprudential roots that long predate that decision. Five decades before *Graham*, this Court recognized that commercial success is "of itself . . . persuasive evidence of that invention which it is the purpose of the patent laws to reward and protect." *Minerals Separation v. Hyde*, 242 U.S. 261, 270 (1916); *see also Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 495 (1876) (describing commercial success as evidence supporting an "inference" that the improvement "was, in truth, invention"). And, in a decision invoked by this Court in *Graham*, Judge Learned Hand highlighted evidentiary "sign posts" that aided judges in the obviousness inquiry, including: "how long did the need exist; how

many tried to find the way; how long did the surrounding and accessory arts disclose the means; [and] how immediately was the invention recognized as an answer by those who used the new variant?" *Reiner*, 285 F.2d at 504.

As technology has become increasingly complex in the years since *Graham*, the objective indicia have assumed even greater importance, and this Court has reaffirmed their essential role in the obviousness inquiry. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007) ("While the sequence . . . might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls."); *see also Roanwell Corp. v. Plantronics, Inc.*, 429 U.S. 1004, 1009 (1976) (White, J., dissenting from denial of certiorari) ("In *Graham v. John Deere Co.* . . . we reaffirmed and refined the basic test of patentability and firmly established the role of 'secondary' factors in the procedure for determining when the standard of nonobviousness is met . . . .").

B. Initially, The Courts Of Appeals Correctly Applied *Graham*.

In the initial aftermath of *Graham*, the regional circuits faithfully applied the objective indicia as an integral component of the obviousness analysis.

The Ninth Circuit, for example, vacated a district court's obviousness determination where it failed to make findings on the "secondary indicia of nonobviousness." *Palmer v. Orthokinetics, Inc.*, 611 F.2d 316, 325 (9th Cir. 1980). Similarly, the Tenth Circuit described the "secondary considerations" as "mandated by *Graham*," *Milgo Elec. Corp. v. United Bus. Commc'ns, Inc.*, 623 F.2d 645, 655 (10th Cir. 1980), and the Second Circuit emphasized that "[i]n referring

to such factors as 'secondary considerations' the Court surely did not intend to depreciate their importance," *Timely Prods. Corp. v. Arron*, 523 F.2d 288, 294 (2d Cir. 1975).[2]

After its creation in 1982, the Federal Circuit followed suit, at least initially. The court explained that the objective indicia of nonobviousness "serve as insurance against the insidious attraction of the siren hindsight," *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983), and that they "may often establish that an invention appearing to have been obvious in light of the prior art was not," *Stratoflex*, 713 F.2d at 1538. Thus, like its predecessor, the Court of Customs and Patent Appeals, the Federal Circuit made clear that, where present, evidence of the objective indicia "must *always*" be considered. *In re Sernaker*, 702 F.2d 989, 996 (Fed. Cir. 1983) (emphasis added); *see also In re Mageli*, 470 F.2d 1380, 1383 (C.C.P.A. 1973) ("[E]vidence bearing on the facts [such as evidence of objective indicia] is never of 'no moment,' [and] is always to be considered"). Indeed, the Federal Circuit repeatedly emphasized that "[s]econdary considerations may be the most pertinent, probative, and revealing evidence

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[2] *See also Kori Corp. v. Wilco Marsh Buggies & Draglines, Inc.*, 708 F.2d 151, 156 (5th Cir. 1983) (concluding that the "district court's finding of nonobviousness is further supported by such secondary considerations as commercial success, copying, and previous need and failure"); *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 680 F.2d 483, 496 (7th Cir. 1982) (outlining and considering "[s]econdary tests" of "nonobviousness"); *Parker Sweeper Co. v. E.T. Rugg Co.*, 474 F.2d 950, 952 (6th Cir. 1973) ("The secondary considerations referred to in *Deere* reinforce the nonobviousness of plaintiff's patent.").

available to the decision maker in reaching a conclusion on the obviousness/nonobviousness issue." *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 (Fed. Cir. 1985).[3]

C. The Blocking-Patent Doctrine Is Now Firmly Entrenched In The Federal Circuit.

In 2005, the Federal Circuit departed sharply from the course charted by this Court when it fashioned its novel blocking-patent doctrine.

In *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005), a divided panel discounted the district court's finding of commercial success, and rejected its determination of nonobviousness, with respect to Merck's method of treating osteoporosis with the drug Fosamax. *Id.* at 1376–77. The panel majority assumed that "market entry by others was precluded" because Merck held an earlier patent involving the same drug as well as an "exclusive statutory right, in conjunction with FDA marketing approvals, to offer Fosamax at any dosage for the next five years." *Id.* The panel majority therefore concluded that "[f]inancial success [wa]s not significantly probative" on the question of obviousness "because others were legally-barred from commercially testing the . . . ideas." *Id.* at 1377.

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[3] *See also Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000); *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed. Cir. 1997); *Lamb-Weston, Inc. v. McCain Foods, Ltd.*, 78 F.3d 540, 548 (Fed. Cir. 1996); *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1573 (Fed. Cir. 1992); *Simmons Fastener Corp. v. Ill. Tool Works, Inc.*, 739 F.2d 1573, 1575 (Fed. Cir. 1984).

The Federal Circuit denied rehearing en banc over the dissent of three judges who objected that the panel's "unsound" rule "holds in effect that commercial success for an improvement is irrelevant." *Merck & Co. v. Teva Pharm. USA, Inc.*, 405 F.3d 1338, 1339 (Fed. Cir. 2005) (Lourie, J., dissenting). "Success is success," the dissenting judges emphasized. *Id.* "It is not negatived by any inability of others to test various formulations because of the existence of another patent." *Id.*

The Federal Circuit nevertheless reaffirmed its newly discovered blocking-patent doctrine in *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371 (Fed. Cir. 2005), where it directed the district court to "reconsider the significance of the commercial success of the patented formulation in light of" *Merck*, *id.* at 1379, and in *Galderma Laboratories, L.P. v. Tolmar, Inc.*, 737 F.3d 731 (Fed. Cir. 2013), where, over a dissent, the court deemed evidence of commercial success "of minimal probative value" because of "blocking patents," *id.* at 740–41 (internal quotation marks omitted). In neither case did the Federal Circuit discuss or require evidence of actual blocking; instead, following *Merck*, it appeared to assume that the mere existence of a "blocking patent" held by the patentee was sufficient to override actual evidence of commercial success. *See Syntex*, 407 F.3d at 1383; *Galderma*, 732 F.3d at 740; *see also Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 733 (Fed. Cir. 2017) (Newman, J., dissenting) (criticizing the Federal Circuit for continuing to disregard the legal significance of the objective indicia, which "play a critical role in the obviousness analysis").

In the decision below, the Federal Circuit went even further, drastically expanding the blocking-patent doctrine to negate not only evidence of commercial success but also evidence of the failure of others and long-felt but unmet need. Although the panel majority purported to eschew a "categorical rule that a blocking patent defeats . . . objective indicia," Pet. App. 49a, and initially outlined "a number of variables" that should be considered in the analysis, Pet. App. 52a–53a, it entirely ignored those variables in its application of the doctrine and required no evidence that the Elan patent *actually* blocked other companies from engaging in MS research using 4-AP.

Instead, the Federal Circuit relied on what it characterized as the district court's "implicit finding that securing freedom from blocking patents in advance is likely important to pharmaceutical research investments." Pet. App. 57a. That purported finding—unexpressed by the district court and unsupported by any record evidence that other researchers were actually deterred by the Elan patent—will necessarily be present in every case in which the patent at issue builds upon a patent held by, or licensed to, the patentee. Indeed, this is not even a case like *Merck* where the holder of the "blocking patent" already enjoyed a multiyear-period of regulatory exclusivity to market its drug. *See* 395 F.3d at 1377. It is therefore impossible to cabin the Federal Circuit's expansive application of the blocking-patent doctrine to the particular facts of this case. The Federal Circuit's opinion eliminates any conceivable doubt that the

blocking-patent doctrine is now, in practice, indistinguishable from a *per se* rule.[4]

D. The Blocking-Patent Doctrine Is Squarely At Odds With *Graham*.

The Federal Circuit's adoption of what is effectively a categorical rule that the mere existence of a so-called "blocking patent" overrides even "significant" and "convincing" evidence supporting the objective indicia of nonobviousness is incompatible with *Graham*, which makes clear that the objective indicia constitute an integral component of the obviousness inquiry and serve as essential safeguards "against slipping into use of hindsight." 383 U.S. at 36 (internal quotation marks omitted).

According to the Federal Circuit, Acorda's license to practice the Elan patent and its use of that patent in developing Ampyra® were sufficient, standing alone, to justify discounting entirely the evidence of Ampyra®'s commercial success, the failure of others to develop an MS treatment using 4-AP, and the long-recognized need for such a treatment—even though neither the district court nor the Federal Circuit

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[4] The Federal Circuit cited testimony "from an expert . . . that the Elan patent acted as a blocking patent for entities other than Acorda," Pet. App. 55a (citing J.A. 965–66), but the expert simply relied on the existence of the Elan patent and Acorda's accompanying license to assume that there was "blocking." He expressly disclaimed a finding that there were in fact other researchers who wanted to pursue similar opportunities using 4-AP and who were deterred from doing so. *See* J.A. 965–66 ("In effect, other entities that might want to pursue commercial opportunity like Ampyra, *even if they would—again, I don't find that, but if they would*, they would not have access to it because Acorda has that exclusive license.") (emphasis added).

found that another researcher would actually have attempted to develop Acorda's claimed methods if the Elan patent had not been in force. The Court rejected that type of "narrow, rigid" approach to obviousness in *KSR* as "inconsistent with § 103 and [this Court's] precedents." *KSR Int'l Co.*, 550 U.S. at 427–28.

The blocking-patent doctrine also transforms what *Graham* intended to be an *objective* analysis into a *subjective* examination of the reasons why other researchers did not attempt to develop the claimed invention. 383 U.S. at 17–18, 36. According to the Federal Circuit, courts must consider, among other factors, whether a "potential innovator might or might not think it could successfully challenge the blocking patent" and whether "such a potential innovator might or might not be willing to research in the blocked space without a license . . . and wait until it has already developed and patented its aimed-at improvement to negotiate for a cross-license with the blocking patent's owner." Pet. App. 52a. Courts undertake exactly that type of hypothetical inquiry with respect to the other obviousness factors when attempting to divine the understanding and motivations of a person of ordinary skill in the art. *See KSR Int'l Co.*, 550 U.S. at 417–18. The blocking-patent doctrine would blur the line between the first three obviousness factors and the objective indicia of nonobviousness and, in so doing, eviscerate the role of the objective indicia as a factually grounded check against hindsight bias.

Furthermore, the entire premise of the Federal Circuit's blocking-patent doctrine—that researchers will be dissuaded by the existence of a blocking patent, Pet. App. 49a—is unmoored from the realities of scientific research. The doctrine ignores the fact that

companies and individuals frequently engage in research without regard to existing patents. *See*, *e.g.*, Mark A. Lemley, *Ignoring Patents*, 2008 Mich. St. L. Rev. 19, 21 (2008). Existing patents are particularly unlikely to stifle research in the pharmaceutical industry because researchers are protected by the safe-harbor provision of 35 U.S.C. § 271(e)(1), which permits "the use of patented compounds in preclinical studies . . . 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). And because United States patents do not extend overseas, researchers that remain concerned about potential infringement liability are free to undertake research outside the United States without risk of infringement—an eminently realistic option for sophisticated, multinational pharmaceutical companies.

The Federal Circuit's categorical approach to the blocking-patent doctrine—which requires no examination of whether the patent in question was an actual obstacle to research—likewise ignores the ability of researchers to request a license from the holder of the "blocking patent," as Acorda did here. And it disregards the possibility that innovations that emerge from research in the supposedly "blocked space" can be licensed to the holder of the "blocking patent" to facilitate a sharing of profits. *See* Pet. App. 52a, 55a–57a (noting these possibilities but failing to analyze them on the facts of this case).

Thus, the "implicit finding that securing freedom from blocking patents in advance is likely important to pharmaceutical research investments"—the lynchpin of the Federal Circuit's decision to negate Acorda's

objective evidence of nonobviousness—is untethered from both the record in this case and the realities of pharmaceutical research more broadly. *See* John P. Walsh et al., *Working Through the Patent Problem*, 299 Science 1021, 1021 (2003) ("Our interviews reveal that university and industrial researchers have adopted 'working solutions' that allow their research to proceed," including "licensing, inventing around patents, going offshore, . . . court challenges, and simply using the technology without a license (*i.e.*, infringement).").

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The Federal Circuit's blocking-patent doctrine fatally undermines this Court's decision in *Graham* to identify a set of easily administrable, objective factors to ensure that the obviousness inquiry is not tainted by hindsight bias and judicial unfamiliarity with complex technology. According to the Federal Circuit, those protections automatically evaporate whenever the party pressing an invalidity challenge can identify a "blocking patent" that supposedly impaired others from developing the allegedly obvious invention. This Court should grant certiorari to reject the Federal Circuit's fundamentally flawed blocking-patent doctrine and to restore the essential role of the objective indicia in the obviousness analysis.

II. THE DECISION BELOW CONFLICTS WITH THIS COURT'S DECISION IN *MICROSOFT CORP. V. I4I LIMITED PARTNERSHIP* BY INVERTING THE BURDEN OF PROOF.

Certiorari is also warranted because the Federal Circuit's categorical approach to the blocking-patent doctrine—which requires no proof of actual "blocking" and requires the patent holder to prove that blocking

did *not* occur—conflicts with this Court's decision in *Microsoft Corp. v. i4i Limited Partnership*, 564 U.S. 91 (2011).

A. Clear And Convincing Evidence Is Required To Overcome The Presumption Of Validity.

Patents are "presumed valid." 35 U.S.C. § 282(a). As this Court explained in *i4i*, "a defendant seeking to overcome this presumption must persuade the fact-finder of its invalidity defense by clear and convincing evidence." 564 U.S. at 97; *see also Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1929 (2015) ("Congress . . . ha[s] chosen" a "high bar" for proving invalidity: the "clear and convincing evidence standard.").

"While the ultimate question of patent validity is one of law," the underlying factors to be considered, including the objective indicia of nonobviousness, are questions of fact. *Graham*, 383 U.S. at 17. Thus, although the patent holder typically makes an initial production of evidence exhibiting objective indicia of nonobviousness, at all times the burden of proving obviousness remains with the infringer asserting an invalidity defense. *See In re Cyclobenzaprine*, 676 F.3d 1063, 1078 & n.5 (Fed. Cir. 2012) (rejecting district court's imposition of burden-shifting framework for inquiry into objective indicia). Where a patent holder has come forward with evidence of commercial success or other objective indicia of nonobviousness, the infringer therefore must overcome that showing by clear and convincing evidence. *See i4i*, 564 U.S. at 100 ("by its express terms, § 282 . . . provides that a challenger must overcome th[e] presumption [of patent validity] to prevail on an invalidity defense").

B. The Federal Circuit Improperly Shifted The Burden Of Proof To Acorda.

1. Far from requiring defendants to prove obviousness by clear and convincing evidence, the Federal Circuit discounted Acorda's "significant" and "convincing" evidence of nonobviousness based on the district court's "*implicit* finding that securing freedom from blocking patents in advance is likely important to pharmaceutical research." Pet. App. 57a (emphasis added). To shore up this finding—which, of course, was never actually made by the district court—the Federal Circuit identified its own academic authorities, effectively assuming for itself the evidentiary burden that squarely rested on defendants. Pet. App. 57a n.17.

Neither the Federal Circuit nor the district court identified any evidence in the record or made any finding that other companies were *actually* deterred by the Elan patent from researching the use of 4-AP to improve walking in MS patients. Instead, the Federal Circuit improperly faulted *Acorda* for failing to "supply evidence to make unreasonable the implicit finding" of "blocking" made by the district court. Pet. App. 57a.

This inversion of the burden of proof permeates the Federal Circuit's discussion of the objective indicia. For example, although the Federal Circuit cited expert testimony that no entities other than Acorda held a license to the Elan patent, Pet. App. 55a, neither the Federal Circuit nor the district court identified evidence or made a finding that other researchers were precluded from seeking a license from Elan (as Acorda did), or prevented from obtaining a sublicense from Acorda. The Federal Circuit instead shifted the

burden to Acorda, relying on the *absence* of evidence that Elan or Acorda had affirmatively "sought to license the Elan patent" to other entities. Pet. App. 56a.

Similarly, neither court identified any evidence or made any finding that other entities were precluded from undertaking research into 4-AP pursuant to the safe-harbor provision of Section 271(e)(1) or prevented from conducting research overseas. Instead, once again, the Federal Circuit shifted the burden to Acorda, concluding that the "observation" that "U.S. patents do not block sales outside the United States" was "not shown to be weighty in this case by any concrete evidence about the particular inventions at issue." Pet. App. 56a.

The Federal Circuit's treatment of Acorda's evidence of failure of others was equally problematic. The Federal Circuit held that it was appropriate for the district court to discount that evidence because it was "'*likely*'" that "'Sanofi-Aventis . . . did not use 4-AP because' of the blocking effect of the Elan patent." Pet. App. 58a (emphasis added). But that finding was grounded entirely on speculation, not evidence that Sanofi-Aventis in fact failed in its research because it considered itself "blocked" by the Elan patent from using 4-AP. Pet. App. 58a; *see also* Pet. App. 57a (appropriate to discount commercial success because "securing freedom from blocking patents in advance is *likely* important to pharmaceutical research") (emphasis added). Mere speculation about "likely" blocking is not clear and convincing evidence of actual blocking and falls well short of the "high bar" set by Congress. *Commil USA*, 135 S. Ct. at 1929; *see also California ex rel. Cooper v. Mitchell Bros.' Santa Ana Theater*, 454 U.S. 90, 93 n.6 (1981) ("'clear and convincing' . . .

require[s] a plaintiff to prove his case to a higher probability than is required by the preponderance-of-the-evidence standard").

By applying the blocking-patent doctrine to negate Acorda's strong evidence of nonobviousness—without any evidence of actual blocking—the Federal Circuit improperly relieved defendants of their burden to prove obviousness by clear and convincing evidence, in direct contravention of *i4i* and Congress's decision to establish the statutory presumption of validity in Section 282. An "implicit finding that securing freedom from blocking patents" is theoretically "important to pharmaceutical research investments" says nothing about whether the Elan patent was actually "important" in this case to companies considering whether to undertake "pharmaceutical research" into 4-AP. Pet. App. 57a. Allowing the bare existence of a "blocking patent" to overcome evidence of the objective indicia of nonobviousness—while requiring Acorda to prove that "blocking" did *not* occur—is a blatant inversion of the clear-and-convincing-evidence standard. *See i4i*, 564 U.S. at 97. Under the Federal Circuit's upside-down approach, patentees bear the potentially insurmountable burden of demonstrating the *absence* of "blocking" years after the relevant research window.

2. This is not the first time the Federal Circuit has cast aside the presumption of validity where the infringer was able to identify a purported "blocking patent." It has made similar errors in prior cases. In *Galderma*, for example, the Federal Circuit concluded that prior patents "blocked the market entry" based on the mere fact of their existence without citing any supporting evidence. 737 F.3d at 740–41. In dissent, Judge Newman criticized the majority for "distort[ing]

the burdens of proof and production, ignor[ing] the applicable standard of proof and rely[ing] on their own factual determinations and creative theories of law" to "eradicate the patent." *Id.* at 741 (Newman, J., dissenting). Much like this case, the "majority never require[d] . . . [the defendant to] meet its burden of persuasion," and it "mention[ed] but [did] not apply the presumption of validity." *Id.* at 749.

Following the Federal Circuit's lead, a number of district courts have also relied on the mere existence of a "blocking patent" to discount commercial success without requiring any evidence that others were actually dissuaded from pursuing research. *See*, *e.g.*, *BTG Int'l Ltd. v. Amneal Pharm. LLC*, 352 F. Supp. 3d 352, 387 (D.N.J. 2018).[5]

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This Court should grant review to reaffirm the presumption of validity and the applicability of the clear-and-convincing-evidence standard to the obviousness inquiry, which prevent an infringer from relying on the mere existence of a "blocking patent" to

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[5] *See also Allergan, Inc. v. Teva Pharm. USA, Inc.*, 2017 WL 4803941, at *49 (E.D. Tex. 2017), *aff'd*, 742 Fed. App'x 511 (Fed. Cir. 2018); *Warner Chilcott Co. v. Teva Pharm. USA, Inc.*, 37 F. Supp. 3d 731, 739 (D. Del.), *aff'd*, 594 F. App'x 630 (Fed. Cir. 2014); *Senju Pharm. Co. v. Apotex Inc.*, 717 F. Supp. 2d 404, 426 (D. Del. 2010), *aff'd*, 485 F. App'x 433 (Fed. Cir. 2012); *Proctor & Gamble Co. v. Teva Pharm. USA, Inc.*, 536 F. Supp. 2d 476, 496 (D. Del. 2008), *aff'd*, 566 F.3d 989 (Fed. Cir. 2009); *Sanofi-Synthelabo v. Apotex Inc.*, 492 F. Supp. 2d 353, 392 (S.D.N.Y. 2007), *aff'd*, 550 F.3d 1075 (Fed. Cir. 2008); *Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, No. 2:05CV421, 2006 WL 2008962, at *44 (E.D. Va. July 17, 2006), *rev'd on other grounds by* 499 F.3d 1293 (Fed. Cir. 2007).

negate objective indicia of nonobviousness. In so doing, the Court should make clear that, if the existence of a "blocking patent" is a permissible component of the obviousness inquiry, an infringer can use that patent to negate the objective indicia of nonobviousness only if it can produce clear and convincing evidence that other companies were *actually* blocked from researching and developing the claimed methods. The Federal Circuit's contrary presumption is irreconcilable with 35 U.S.C. § 282 and this Court's precedent.

III. THE BLOCKING-PATENT DOCTRINE DISCOURAGES LIFESAVING INNOVATION.

The blocking-patent doctrine poses a serious threat to pharmaceutical innovation and is certain to deter the development of new treatments for debilitating diseases that have long confounded researchers.

As this Court has emphasized, a patent is "a reward, an inducement, to bring forth new knowledge," *Graham*, 383 U.S. at 9, that is intended "[t]o promote the Progress of Science and useful Arts," U.S. Const., art. I, § 8, cl. 8. The original Patent Act "embodied Jefferson's philosophy that 'ingenuity should receive a liberal encouragement'"; that "same broad language" still appears in the current version of the statute. *Diamond v. Chakrabarty*, 447 U.S. 303, 308–09 (1980) (quoting 5 *Writings of Thomas Jefferson* 75–76 (Washington ed. 1871)).

But rather than promoting innovation, the Federal Circuit's blocking-patent doctrine inhibits it. The doctrine dramatically diminishes the intellectual-property protections afforded by improvement patents—in which a patent holder or licensee builds upon and improves a prior invention—by enabling in-

fringers to invoke a presumption that other researchers would have developed the invention if they had not been "blocked" by the patent that the invention improved. As confirmed by the Federal Circuit's reliance on an "implicit finding" of "blocking" in this case, that presumption requires no evidence of actual "blocking" and can be invoked in any case where the defendant allegedly infringed a patent that improved upon a preexisting patent held by or licensed to the plaintiff. The blocking-patent doctrine thus throws open the door to the frequent invalidation of legitimate improvement patents by effectively eviscerating the objective indicia of nonobviousness and relieving infringers of their burden of proving obviousness by clear and convincing evidence.

The practical consequences of the Federal Circuit's rewriting of the obviousness standard are serious, immediate, and far-reaching. If companies like Acorda know that successful innovations that improve on prior inventions are less likely to withstand an obviousness challenge, they may choose to forgo their innovative enterprises. This is not mere speculation. As researchers have demonstrated, "there is a causal relationship between the strength of patent rights and innovation." Stephen Haber, *Patents and the Wealth of Nations*, 23 Geo. Mason L. Rev. 811, 829–30 (2016) (surveying historical and statistical evidence).

These concerns are particularly acute in the pharmaceutical setting, where improvement patents are common, *see*, *e.g.*, Albert I. Wertheimer & Thomas M. Santella, *Pharmacoevolution: The Advantages of Incremental Innovation*, Int'l Pol'y Network (2005), and where the development of new drugs often requires tremendous expenditures on research, *see* Fed. Trade Comm'n, *To Promote Innovation: The Proper Balance*

of Competition and Patent Law and Policy ch. 3, at 5 (Oct. 2003) (explaining that new drug discoveries "typically require significant amounts of pioneering research, and both fixed costs and risks of failing to develop a marketable product, consequently, are very high"). In fact, given the extensive clinical trials and regulatory approvals required under federal law, it frequently takes ten years or more to bring a new drug to market. *Id.* It took Acorda twelve years to research, develop, and secure approval of Ampyra®.

Patents are crucial to ensuring that companies will be able to recoup some of these innovation costs. *See*, *e.g.*, Fed. Trade Comm'n, *supra*, ch. 3, at 4 (discussing testimony that "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 R&D efforts"). Indeed, because patents facilitate the recovery of research-and-development costs, increased patent protection has been found to accelerate the launch of new drugs in countries around the world. *See* Iain M. Cockburn et al., *Patents and the Global Diffusion of New Drugs*, 106 Am. Econ. Rev. 136 (2016).

Diminished patent protection, in contrast, is likely to produce the opposite outcome. As Judge Newman warned, it is the "afflicted public" that will be harmed if the Federal Circuit's blocking-patent doctrine is permitted to invalidate patents on drugs that innovative companies have often spent years and hundreds of millions of dollars to develop. Pet. App. 62a (Newman, J., dissenting).

This case is a powerful example of the pernicious consequences of limiting the legal protections for im-

provement patents through application of the blocking-patent doctrine. At great financial risk, Acorda spent many years, considerable human capital, and vast sums of money on the research that culminated in its discovery of the breakthrough drug Ampyra®. Rather than being rewarded for its innovative efforts, however, Acorda has now been stripped of its patent protection, despite substantial and uncontroverted evidence that it discovered a drug that had eluded the efforts of others who had tried for years to develop a treatment to improve walking in individuals struggling with the debilitating symptoms of MS.

This Court should grant review and reject the blocking-patent doctrine before other innovative companies are deterred in their development of lifesaving drugs by the Federal Circuit's failure to follow this Court's patent precedent and the presumption of validity established by Congress.

CONCLUSION

The Federal Circuit's blocking-patent doctrine contravenes this Court's precedent, erodes the policies underlying the Patent Act, and threatens to deprive doctors and patients of innovative, lifesaving treatments. The Court should grant the petition for a writ of certiorari and reject this innovation-stifling, health-imperiling judicial construct.

Respectfully submitted.

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