No. 18-1280

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

REPLY BRIEF FOR PETITIONER

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RULE 29.6 STATEMENT

The corporate-disclosure statement included in the petition for a writ of certiorari remains accurate.

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REPLY BRIEF FOR PETITIONER

The Federal Circuit's judicially manufactured blocking-patent doctrine undercuts this Court's decisions in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), and *Microsoft Corp. v. i4i Limited Partnership*, 564 U.S. 91 (2011), by effectively nullifying the objective indicia of nonobviousness and inverting the burden of proof whenever the patent at issue improved upon an earlier patent held by, or licensed to, the patent holder. In so doing, the blocking-patent doctrine "stifles pharmaceutical innovation" and "discourages pharmaceutical companies from building on their own previously patented work." PhRMA Br. 7, 10, 13 (capitalization altered).

Respondents agree that the blocking-patent doctrine is frequently applied by lower courts, that it has become entrenched in the Federal Circuit's jurisprudence, and that the decision below extended that doctrine to negate evidence of failure of others and long-felt but unmet need. Opp. 12, 13, 27. Respondents nevertheless contend that review is not warranted—primarily because the Federal Circuit's decision is supposedly "fact-bound" and turns on "a long list of case-specific factors" "recited" by the court. *Id.* at 13, 22. But the court of appeals' "recit[ation]" of those factors was meaningless because it did not actually *apply* any of them when deciding to disregard the objective indicia of nonobviousness based on the purported "blocking" effect of the Elan patent. Instead, relying on its own compilation of secondary sources and an "implicit finding" by the district court that the mere existence of a blocking patent likely deters other companies' research—two features of the opinion left studiously unacknowledged by respondents—the Federal Circuit wholly discounted Acorda's "significant" and

"convincing" objective evidence, Pet. App. 184a, including the substantial commercial success of Ampyra® and the repeated failure of others to develop a treatment to improve walking in MS patients, *id.* at 57a. The Federal Circuit disregarded those objective indicia of nonobviousness without requiring respondents, who bore the burden of proving obviousness by clear and convincing evidence, to demonstrate that anyone was *actually* deterred by the Elan patent from researching the use of 4-AP to treat MS patients.

Accordingly, in sum and substance, the decision below is indistinguishable from a categorical pronouncement that the mere existence of a "blocking patent" suffices to override the objective indicia of nonobviousness and shift the burden of proof to the patent holder to demonstrate that other researchers were *not* deterred by that patent. Because that inflexible approach is incompatible with this Court's precedent and poses an "existential threat to innovation in the pharmaceutical industry," Allergan Br. 4, this Court should grant review and reject the Federal Circuit's fundamentally flawed and inherently unworkable blocking-patent doctrine.

I. THE DECISION BELOW CONFLICTS WITH *GRAHAM V. JOHN DEERE CO.*

Respondents do not dispute that the objective indicia of nonobviousness provide a vital check against "'hindsight'" bias and are "more susceptible of judicial treatment" than "technical issues." *Graham*, 383 U.S. at 36. Nor do they dispute that the Court gave no hint in *Graham* that the existence of a so-called "blocking patent" can supersede this integral component of the four-part obviousness inquiry.

Respondents instead seek support for the blocking-patent doctrine in "commercial reality." Opp. 15. But respondents offer no real-world substantiation that "blocking patents" in fact deter research—a proposition that is especially doubtful in light of the safe-harbor provision of 35 U.S.C. § 271(e)(1), the options to conduct research overseas or obtain a license (as Acorda did here), and studies suggesting that researchers routinely steer around or ignore patents. Pet. 19–21; *see also* BPLA Br. 5 ("there are a number of instances where the existence of a purported blocking patent would not have the sweeping 'deterrent effect' that the court ascribed to the Elan patent"). At a minimum, these "realit[ies]" of pharmaceutical development underscore that the objective indicia of nonobviousness should not be negated by the existence of a "blocking patent" in the absence of a finding that the patent *actually* deterred research and development. Neither the district court nor the Federal Circuit made any such finding below. *See* Pet. 18–19.

Respondents seek to diminish the significance of the Section 271(e)(1) safe harbor by emphasizing that it does not apply to "commercial sales after FDA approval." Opp. 16. But a researcher who improved upon an existing patent under the safe harbor would be well-positioned to secure a license from the patent holder, who would stand to share in the researcher's profits without having incurred any of the researcher's costs or risks. *See* Allergan Br. 16; BIO Br. 12–13.

Respondents also contend that the academic studies documenting researchers' willingness to proceed in the face of existing patents do not extend to the pharmaceutical industry, Opp. 16, but respondents ignore work cited by Acorda that specifically examined

"pharmaceutical firms" confronting prior patents and found they "have adopted 'working solutions' that allow their research to proceed." John P. Walsh et al., *Working Through the Patent Problem*, 299 Science 1021, 1021 (2003); *see also* Pet. 21. In any event, the Federal Circuit has never held that the blocking-patent doctrine is limited to the pharmaceutical industry. Its reasoning would apply with equal force to any setting in which researchers improve upon existing patents to develop new inventions. *See* IPO Br. 4.

Nor is respondents' supposedly "strong and now unassailable technical obviousness case" under the first three *Graham* factors a basis for denying review. Opp. 21. As Judge Newman's detailed dissent makes clear, respondents' characterization of the "str[ength]" of their evidence is a substantial overstatement. *See* Pet. App. 61a–85a. And while Acorda is not asking this Court to review the Federal Circuit's application of the first three elements of the *Graham* standard, the law is clear that even strong evidence under the first three factors can be overridden by objective indicia of nonobviousness because those indicia "may often be the most probative and cogent evidence in the record" on the obviousness question. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). Thus, when appropriate weight is given to the "significant" and "convincing" evidence of commercial success, failure of others, and long-felt but unmet need identified by the district court, Pet. App. 184a, the likely outcome is a determination that respondents failed to meet their heavy burden of proving obviousness by clear and convincing evidence. *See also id.* at 186a (district court acknowledging that "there is evidence on both sides of the parties' dispute, and this was an eminently 'triable case'").

Respondents further contend that the blocking-patent doctrine is a "fact-specific inquiry" that does not "*always* negate[ ] [objective indicia] evidence." Opp. 17, 22. In reality, the Federal Circuit's application of the doctrine to invalidate Acorda's patents was the exact opposite of a "fact-dependent" analysis, *id.* at 21. To be sure, as Acorda acknowledged in its petition, the panel majority purported to reject a "'categorical rule'" that a "blocking patent" invariably negates objective indicia of nonobviousness and outlined a "'number of variables'" that could theoretically be relevant to ascertaining the impact of a "blocking patent." Pet. 17 (quoting Pet. App. 49a, 52a). But the Federal Circuit did not apply those factors in concluding that it was appropriate for the district court to "discount[ ] the weight of Acorda's evidence of commercial success, failure of others, and long-felt but unmet need" in light of the purported "blocking" effect of the Elan patent. Pet. App. 54a. There was no discussion, for example, of "the costliness of [a] project" to research the use of 4-AP to treat walking in MS patients, "the risk of research failure," or "the nature of improvements that might arise from the project." *Id.* at 52a.

Rather than examining what impact, if any, the Elan patent might actually have had on other researchers, the Federal Circuit endorsed what it described as the district court's "implicit"—and altogether generalized—"finding" that "securing freedom from blocking patents in advance is likely important to pharmaceutical research investments," and cited two extra-record articles to bolster that supposed "finding." Pet. App. 57a & n.17. The Federal Circuit could conjure the same "implicit finding" in any case where an infringer is challenging the validity of a patent that improved upon an earlier patent held by, or

licensed to, the patent holder. That is functionally indistinguishable from a *per se* rule.[1]

The irrelevance of case-specific facts to the Federal Circuit's application of the blocking-patent doctrine is confirmed by several earlier decisions in which the court similarly applied the doctrine to discount the objective indicia of nonobviousness without examining the record to determine whether, on the facts of those specific cases, anyone had actually been deterred from research by the "blocking patent." *See Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1366–67 (Fed. Cir. 2005); *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740–41 (Fed. Cir. 2013). Like the decision below, those decisions elicited dissents that criticized the court's "unsound" evisceration of the objective indicia of nonobviousness. *Merck & Co. v. Teva Pharm. USA, Inc.*, 405 F.3d 1338, 1339 (Fed. Cir. 2005) (Lourie, J., dissenting from denial of rehearing en banc); *see also Galderma Labs.*, 737 F.3d at 747 (Newman, J., dissenting).

Despite the Federal Circuit's settled approach, respondents contend that the court's opinion in *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724 (Fed. Cir. 2017) ("*Merck II*"), transformed the blocking-patent doctrine into a "'fact-specific inquiry.'" Opp. 22. But the Court need look no further than the Federal Circuit's subsequent decision in this case—

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[1] Moreover, the Federal Circuit's "variables"—which are intended to assess whether "a potential innovator might or might not be willing to research in the blocked space without a license to a blocking patent," Pet. App. 52a—would be insufficient to remedy the deficiencies in the blocking-patent doctrine because they impermissibly inject subjective elements into the *objective* inquiry mandated in *Graham*, *see* Pet. 19.

which did not apply any supposedly case-specific "variables" or consider other record evidence before discounting Acorda's objective indicia of nonobviousness—to conclude that *Merck II* had no impact on the Federal Circuit's categorical-in-all-but-name-only approach to the blocking-patent doctrine. The decision below rests on the reaffirmance, and extension, of a rule of law, not on one-off factual analysis.

Opinions that the Federal Circuit has issued in the wake of the decision below confirm this conclusion. In *BTG International Ltd. v. Amneal Pharmaceuticals LLC*, 923 F.3d 1063 (Fed. Cir. 2019), the Federal Circuit paid lip service to the notion that the existence of a blocking patent should not "necessarily" negate the objective indicia of nonobviousness, but, as in the decision below, proceeded to offer *no* analysis of whether the blocking patent had actually deterred research. *Id.* at 1076. In fact, far from establishing actual blocking, the record showed that the holder of the alleged "blocking patent" had "met with three drug companies . . . in an effort to partner and license" its patent. *BTG Int'l Ltd. v. Amneal Pharm. LLC*, 352 F. Supp. 3d 352, 387 (D.N.J. 2018). The Federal Circuit nevertheless held that the unproven "blocking" effect of that patent was sufficient to discount the objective indicia of nonobviousness. *BTG Int'l*, 923 F.3d at 1076; *see also Allergan, Inc. v. Teva Pharm. USA, Inc.*, 742 F. App'x 511 (Fed. Cir. 2018) (affirming rejection of evidence of commercial success and long-felt but unmet need based on the blocking-patent doctrine).[2]

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[2] Respondents (at 12–13) suggest that this Court's denial of certiorari in *Allergan* supports the denial of review here. *See Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 18-1289, 2019 WL 1558485 (U.S. June 3, 2019). But in contrast with the lengthy

Similarly, district courts have not understood *Merck II* as endorsing the type of "totality-of-the-circumstances analysis" that respondents seek to ascribe to that opinion. Opp. 33 n.2. In the aftermath of *Merck II*, district courts have continued to discount the objective indicia of nonobviousness based on the mere existence of a "blocking patent." *See*, *e.g.*, *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 343 F. Supp. 3d 823, 857–58 (N.D. Ill. 2018) ("[G]iven the existence of the [blocking patent], evidence of long-felt need does not support a finding of non-obviousness."); *Hospira, Inc. v. Amneal Pharm., LLC*, 285 F. Supp. 3d 776, 796–97 (D. Del. 2018) ("evidence of commercial success" had "little probative value" because of the "legal" existence of a blocking patent).

As these decisions underscore, there is nothing "fact-bound" about the Federal Circuit's nullification of the objective indicia of nonobviousness in this case.

II. THE DECISION BELOW CONFLICTS WITH *MICROSOFT CORP. V. I4I LIMITED PARTNERSHIP*.

The decision below is also impossible to reconcile with *i4i*. The Federal Circuit shifted the burden to Acorda to demonstrate that the Elan patent did *not* block other companies from researching the use of 4-AP to treat walking in MS patients—in direct conflict with this Court's holding that an infringer bears the burden of proving obviousness through clear and convincing evidence. *See* 564 U.S. at 97; *see also* Pet. 23–25.

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opinion and dissent in this case, the Federal Circuit resolved *Allergan* in a one-line summary affirmance that did not include any legal analysis or a single case citation.

Respondents emphasize (at 31) that the Federal Circuit initially recited the correct standard, stating that the burden of proving obviousness is on the infringer. Pet. App. 53a. But, as with the Federal Circuit's failure to apply its case-specific "variables," the Federal Circuit's analysis faltered when it came time to apply that burden of proof to the facts of this case. Opp. 31. Indeed, nowhere do respondents mention, let alone attempt to defend, the Federal Circuit's holdings that "Acorda did not supply evidence to make unreasonable the implicit finding" of "blocking" made by the district court, Pet. App. 57a, and failed to "show[ ]" that the ability of other companies to conduct research overseas was "weighty in this case" based on "concrete evidence about the particular inventions at issue," *id.* at 56a. While the Federal Circuit may have articulated the correct burden of proof at the outset of its analysis, these conclusions leave no doubt that, when it came to examining the objective indicia of nonobviousness, the court shifted the burden to Acorda to disprove a presumption of actual blocking—a virtually impossible evidentiary burden that would have required Acorda to establish that the decision of *every other* pharmaceutical company and academic researcher not to undertake research into 4-AP was unrelated to the existence of the Elan patent.

Indeed, respondents do not dispute that the Federal Circuit discounted Acorda's objective evidence without requiring respondents to demonstrate that other companies were actually blocked in their research of 4-AP by the Elan patent. Respondents instead point to "'unrebutted testimony from an expert in economics and pharmaceuticals'" and to evidence suggesting that companies other than Elan and Acorda did not pursue 4-AP research after issuance of the Elan patent. Opp. 24. But an appellate court's

recitation of testimony and evidence that *could* support a particular conclusion is no substitute for an actual finding of fact—and the parties agree that no finding of actual blocking was made by either court in this case. Moreover, the expert on whom respondents rely specifically *disclaimed* any finding of actual blocking by the Elan patent. *See* Pet. 18 n.4.

Respondents also accuse Acorda of "demanding a practical impossibility" by "insisting on direct evidence" of actual blocking. Opp. 25. But Acorda has never suggested that direct evidence—as opposed to circumstantial evidence—is required to prove actual blocking. As in a range of other settings, courts are free to consider both direct and circumstantial evidence to determine whether a preexisting patent "blocked" research by other companies that would have pursued the research undertaken by the patent holder. *See*, *e.g.*, *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1219 (Fed. Cir. 2006) (infringement can be proved "by either direct or circumstantial evidence"). What courts are not free to do, however, is override the presumption of patent validity, 35 U.S.C. § 282(a), and this Court's controlling precedent, by requiring patent holders to shoulder the burden of proving nonobviousness whenever an infringer can identify an alleged "blocking patent."

III. REVIEW IS NECESSARY TO PREVENT THE BLOCKING-PATENT DOCTRINE FROM STIFLING THE DEVELOPMENT OF LIFESAVING TREATMENTS.

As the five *amicus curiae* briefs urging review make clear, the "blocking-patent doctrine weakens patent rights that fuel pharmaceutical innovation." PhRMA Br. 7 (capitalization altered). The "development of improvements . . . to existing drug therapies

is critically important to the creation of safe and effective drugs, patient care, and patient quality of life." BPLA Br. 11. Yet, the blocking-patent doctrine generates "significant uncertainty and risk for companies that might pursue improvements" because it creates the possibility that innovators will be unable to rely on the objective indicia of nonobviousness to defeat an invalidity challenge in light of the purported "blocking" effect of the earlier, improved-upon patent. *Id.*

While respondents emphasize that the "FDA approved twenty-three pharmaceutical improvements in 2016 alone," Opp. 33, that merely underscores the magnitude of the stakes presented by this case. If the Federal Circuit's expansion of the blocking-patent doctrine—and facilitation of obviousness challenges to future improvement patents—deters only a fraction of research projects seeking to improve upon existing pharmaceutical patents, the result will still be that, each year, multiple drugs that would otherwise have been introduced to market—improving, or even saving, the lives of countless patients—will remain undiscovered and unavailable. That is an intolerable outcome for pharmaceutical innovation and, most importantly, for the public health.

CONCLUSION

According to the Federal Circuit, there is only one fact that matters when determining whether to give weight to the objective indicia of nonobviousness: the existence *vel non* of a "blocking patent." If the infringer can identify a "blocking patent," then even compelling objective indicia receive no weight unless the patent holder is able to prove the absence of blocking. That is in substance, if not in name, a categorical rule, and it is flatly inconsistent with this Court's precedent.

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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