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

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

In assessing whether patent claims are obvious, courts primarily consider technical evidence—what prior art taught and any reasons to combine or modify those teachings. As "secondary considerations," courts also assess market and motivational evidence. In particular, commercial success of an invention may suggest non-obviousness because market forces normally incentivize competitors to pursue obvious solutions. The same is true for long-felt but unsolved needs. But courts have long recognized that that logic may not always hold, and the inference of non-obviousness is accordingly weaker, when an existing patent blocked competitors from entering the market.

In this case, the district court found that numerous published studies had described methods of treatment that rendered obvious the drug dosing regimen patented by Acorda. Acorda presented some evidence of commercial success, long-felt but unsolved need, and failure of others, but the district court found that that evidence was weak, in part because a blocking patent had prevented others from pursuing the claimed invention. Weighing all the evidence, the district court found that the strong technical evidence overwhelmed Acorda's weak secondary considerations. The Federal Circuit affirmed the district court's factual findings as not clearly erroneous, expressly rejecting any categorical rules and making clear that the significance of blocking patents depends on the facts of each case.

The questions presented are (1) whether the Federal Circuit properly considers effects of blocking patents when assessing secondary considerations evidence, and (2) whether the district court committed clear error in making its factual findings in this case.

RULE 29.6 STATEMENT

Respondent Mylan Pharmaceuticals Inc. is wholly owned by Mylan Inc., which is indirectly wholly owned by Mylan N.V., a publicly held company.

Respondent Roxane Laboratories, Inc. is now known as Hikma Labs Inc. and is an indirect wholly owned subsidiary of Hikma Pharmaceuticals PLC.

The following entities are parent corporations or publicly held companies that own 10% or more of the stock of Respondent Teva Pharmaceuticals USA, Inc.: Teva Pharmaceuticals Holdings Coöperatieve U.A; IVAX LLC; Orvet UK; Teva Pharmaceuticals Europe B.V.; and Teva Pharmaceutical Industries, Ltd.

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TABLE OF ABBREVIATIONS

Acorda	petitioner Acorda Therapeutics, Inc.
FDA	Food and Drug Administration
MS	multiple sclerosis
Pet.	Acorda's petition for a writ of certiorari
Pet. App.	appendix to Acorda's petition
PTO	United States Patent and Trademark Office
respondents	respondents Roxane Laboratories, Inc., Mylan Pharmaceuticals Inc., and Teva Pharmaceuticals USA, Inc., collectively
4-AP	4-aminopyridine, also known as dalfampridine and fampridine

BRIEF FOR THE RESPONDENTS IN OPPOSITION

INTRODUCTION

According to Acorda's petition, the Federal Circuit's decision below adopted a categorical rule that commercial success, long-felt but unsolved need, failure of others, and other "secondary considerations" or "objective indicia" of non-obviousness must be discounted entirely whenever practicing a patent-in-suit would also infringe an earlier, "blocking" patent. The petition then argues that a writ of certiorari should be granted because such a bright-line rule conflicts with this Court's analysis of obviousness in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), and its reaffirmance of patent challengers' burden of proof in *Microsoft v. i4i Limited Partnership,* 564 U.S. 91 (2011).

As shown below, the premise is false, and the alleged conflicts are illusory. The Federal Circuit expressly rejected any such per se rule and instead held that the significance of a blocking patent and the persuasive value of secondary considerations evidence depend on the facts of each case. It simply found no error in this district court's determination that this patentee's equivocal evidence of secondary considerations did not overcome these defendants' powerful evidence that these patent claims were obvious in view of the prior art as a whole.

The Federal Circuit carefully considered each of the four factors identified in *Graham*, and it expressly recognized that respondents bore the burden of proving obviousness by clear and convincing

evidence, as held in *Microsoft v. i4i*. There is no conflict with any decision of this Court, and Acorda's real complaint is with the outcome of the Federal Circuit application of correct legal principles to the facts of this case. The petition for a writ of certiorari should therefore be denied.

STATEMENT

A. 4-AP and Elan's original patent on using sustained-release formulations of 4-AP to treat symptoms of MS

Multiple sclerosis (MS) is a neurological disease that damages the myelin insulation of human nerves. 4-aminopyridine, also known as "4-AP" and dalfampridine, is a potassium channel blocker that slows potassium flow during transmission of nerve impulses and helps restore conduction in nerves whose myelin insulation has been damaged. Pet. App. 5a. 4-AP was first identified in 1902 and has been studied as a treatment for MS and other neurological diseases since the 1970s. *Ibid.*

During the 1980s, researchers studied the efficacy of various dosing regimens on various symptoms of MS, including walking problems. Pet. App. 5a-13a. In 1990, Elan, a pharmaceutical company with expertise in sustained-release formulations, began working with some of those researchers. Pet. App. 13a. (Sustained-release formulations smooth release rates of active ingredients and make it easier for patients to adhere to their dosing regimens, which is important for diseases like MS that require long-term treatment.) In 1991, Elan applied for a patent on administering sustained-release

formulations of 4-AP once or twice daily for treating symptoms of MS or other neurological diseases. The claims covered both stable and titrated (escalating) doses. The Elan patent issued in 1996 and remained in force until 2018. Pet. App. 13a-14a.

Elan continued to study 4-AP, and in 1997 it published a paper that reported that 17.5 mg sustained-release doses of 4-AP twice a day improved the timed gait (walking speed) of some MS patients. The paper called for more trials and refinement of the dosing regimen. Pet. App. 15a-16a.

B. Acorda's exclusive license to the Elan patent and its follow-on patents on a more specific dosing regimen for improving MS patients' ability to walk

Around that time, Acorda expressed interest in studying sustained-release 4-AP as a treatment for patients with nerve problems. In 1997, Acorda obtained an exclusive license to Elan's patent in the field of treating spinal-cord injuries. In 1998, when Elan decided to discontinue its MS research program, Acorda took over that research and obtained an exclusive license to practice Elan's patent in the field of treating MS. Pet. App. 16a-17a.

Acorda's exclusive license to Elan's patent enabled Acorda to dominate research in that field in the ensuing years. Acorda-sponsored investigators conducted several studies and published results in 2002 and 2003. The studies involved administration of certain doses of sustained-release 4-AP twice daily, and the results indicated that those regimens improved the mobility of some MS patients. Pet. App. 17a-24a; Pet. App. 36a-38a.

In 2004, Acorda filed a patent application that ultimately led to the issuance of several patents between 2011 and 2014. The patent claims at issue in this case call for administering 10 mg of a sustained-release formulation of 4-AP to an MS patient twice a day for two weeks or more, resulting in 4-AP serum levels within certain ranges and improvement in walking. Pet. App. 26a-27a. As such, they are narrower than the claims in Elan's earlier patent but still covered by that patent.

C. The district court's rulings upholding the validity of the Elan patent but finding Acorda's follow-on claims invalid as obvious over intervening art

In 2010, Acorda received Food and Drug Administration (FDA) approval to market Ampyra®, Acorda's branded version of sustained-release 4-AP, for administration in doses of 10 mg twice a day to MS patients who have difficulty walking. In 2014, respondents Roxane, Mylan, and Teva applied for FDA approval to market generic versions of sustained-release 4-AP with similar indications. Acorda and the successor owner of the Elan patent, Alkermes, then sued respondents in the District of Delaware, alleging infringement of the Elan patent and the Acorda patents under the Hatch-Waxman Act, 35 U.S.C. § 271(e).

Respondents conceded that their proposed products would infringe but argued that the asserted claims were invalid. After a bench trial, the district court (Stark, J.) concluded that respondents had *not* proven by clear and convincing evidence that the original Elan patent was invalid,

but that respondents *had* proven by clear and convincing evidence that the asserted claims in the later Acorda patents were invalid under 35 U.S.C. § 103 because they were obvious over prior art. Pet. App. 86a-186a.

As to the Elan patent, the district court agreed with respondents that persons of ordinary skill in the art (POSAs) were motivated to pursue sustained-release formulations of 4-AP in 1991. Pet. App. 135a-142a. But it found that POSAs were not reasonably likely to succeed at that early date and therefore concluded that Elan's claims were not invalid for obviousness. Pet. App. 142a-152a. The district court also concluded that the specification of Elan's patent adequately described and enabled its claims under 35 U.S.C. § 112. Pet. App. 153a-155a.

But the district court agreed with respondents that Acorda's later patent claims were invalid for obviousness, primarily in view of studies published between 1991 and 2004. Based on both the prior-art publications themselves and expert testimony, the court found that it was obvious as of 2004 to administer stable doses of 10 mg of 4-AP twice-a-day with a reasonable expectation of success in improving MS patients' walking ability, and that the claimed serum-level limitations were inherent in administering such doses. Pet. App. 155a-174a.

Most of the parties' disputes, and most of the district court's opinion, focused on what prior art had taught to skilled artisans. Acorda also argued that secondary considerations (market and motivational factors) indicated that the claimed invention was not obvious, but the district court found

that that evidence was not strong enough to overcome respondents' overwhelming showing that the claimed dosing regimen was obvious in view of the prior art. Pet. App. 174a-186a.

Consistent with its analysis of the prior art, the district court rejected Acorda's assertion that the claimed results were unexpected. Pet. App. 181a-182a. The district court did find that Acorda's Ampyra product had enjoyed commercial success (albeit constrained by the small target population) and that such success had some nexus to the claimed invention even though it reflected both Elan's earlier invention and Acorda's contribution. Pet. App. 174a-180a. The district court concluded, however, that Ampyra's commercial success had little probative value to the obviousness inquiry in this case because Elan's patent had blocked everyone but Elan and Acorda from practicing the claimed invention and thus reduced others' incentives to pursue it. Pet. App. 180a.

The district court found no relevant failure of others because there was only minimal evidence that others had failed in trying to develop a therapy to improve walking in MS patients. One drug company, Sanofi-Aventis, had experimented with a different potassium channel blocker, but the court found its ultimate failure not very probative because the Elan patent had likely blocked Sanofi-Aventis from pursuing 4-AP. And Elan's own early failures in developing drugs to treat other effects of MS had not deterred Elan from performing other studies that established 4-AP's efficacy at improving walking. Pet. App. 183a. The district court further found that although Ampyra addressed a

long-felt, unsolved need for a method of improving walking in MS patients, that also had limited probative value because others could not practice the claimed invention without infringing Elan's patent. Pet. App. 184a (reasoning that due to the Elan patent, the need may have remained unmet despite the obvious solution).

Finally, the district court weighed all the evidence—both the technical evidence and the secondary considerations—and found that respondents had proven by clear and convincing evidence that Acorda's patent claims were obvious and therefore invalid. Pet. App. 184a, 186a (finding that the evidence of secondary considerations was not sufficient to overcome the clear motivation to combine the teachings of the prior art with a reasonable expectation of success).

D. The Federal Circuit's affirmance of the invalidity of the Acorda patents and its denial of rehearing en banc

On appeal, the Federal Circuit (in an opinion by Taranto, J., joined by Dyk, J.) affirmed the invalidity of the asserted claims of the Acorda patents and dismissed respondents' cross-appeal regarding the validity of the Elan patent as moot because that patent had expired during the appeal and Acorda had not claimed any damages. Pet. App. 1a-60a.

1. Like the district court's opinion, the Federal Circuit majority's opinion primarily considered, and rejected, Acorda's arguments that skilled artisans had no motivation to combine the teachings of the prior art to achieve the claimed invention or no

reasonable expectation of success in doing so. Pet. App. 31a-48a.

Acorda again asserted that Elan's 1997 study taught away from the claimed invention, but the majority found no clear error in the district court's contrary finding. Pet. App. 33a-36a. Citing both prior-art studies and expert testimony, the majority also rejected Acorda's argument that the prior art had taught to administer sustained-release 4-AP using only titrated dosing rather than stable dosing. Pet. App. 36a-38a. The majority concluded that prior art and expert testimony likewise supported the district court's finding that POSAs at the time of the alleged invention would have had a reasonable expectation of success in administering 10 mg of 4-AP twice daily to improve MS patients' walking ability. Pet. App. 38a-45a. The majority also affirmed the district court's finding that a prior-art study that described using the same 4-AP formulation to treat spinal cord injuries inherently disclosed the claim limitations requiring particular 4-AP serum levels. Pet. App. 45a-48a.

2. After analyzing whether the claims were obvious in view of the technical teachings of the prior art, the majority turned to the district court's analysis of secondary considerations—in particular, Acorda's evidence of commercial success, failure of others, and long-felt but unsolved need. Pet. App. 48a-59a.

Acorda accused the district court of having adopted a "categorical rule" that blocking patents necessarily negate all evidence of commercial success, failure of others, and long-felt but unmet need. But the majority disagreed, concluding that

the district court had properly evaluated the factual record before it and did not err in concluding that respondents had proven obviousness in view of all the evidence presented. Pet. App. 49a.

The majority first observed that a blocking patent "may deter non-owners and non-licensees from investing the resources needed to make, develop and market ... a later, 'blocked' invention, because of the risk of infringement liability and associated monetary or injunctive remedies." *Ibid.* After surveying Federal Circuit cases dating back to *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005) ("*Merck I*"), the majority observed that "as a theoretical matter, a blocking patent may or may not deter innovation in the blocked space by commercially motivated potential innovators other than the owners or licensees of the blocking patent." Pet. App. 51a-52a. The majority then listed various factors relevant to that issue, including the prospects for challenging the validity of the blocking patent, the cost of the research project, the risk of research failure, the possibility of discovering improvements not entirely covered by the blocking patent, the size of the market for such improvements, the costs of achieving such improvements and bringing them to market, the risk of losing the invention race to the blocking-patent owner or licensee, and the risk that the blocking-patent owner would refuse to license the improvement or demand such high royalties that the project made no economic sense. Pet. App. 52a-53a.

The majority thus concluded that "if all other variables are held constant, a blocking patent

diminishes possible rewards from a non-owner's or non-licensee's investment activity" in the blocked space, but whether the magnitude of that disincentive is enough to deter entry is a "fact-specific inquiry." Pet. App. 53a (citation omitted). The majority noted that this inquiry may be difficult as a practical matter, given limited direct evidence of deterrence, and that courts must bear in mind challengers' burden of persuasion on obviousness issues. *Ibid*.

On the facts, the majority concluded that the district court "did not err in viewing the Elan patent, among other evidence, as evidence that discounted the weight of Acorda's evidence of commercial success, failure of others, and long-felt but unmet need so that 'the evidence as a whole' in the case 'prove[d] clearly and convincingly that the Acorda Patents are invalid due to obviousness." Pet. App. 54a (quoting Pet. App. 186a).

In particular, as to commercial success, Acorda presented evidence that Ampyra had been modestly successful. The majority recounted that over the course of six years, Acorda made domestic sales of about $1.7 billion and domestic profits of nearly $1 billion, but those revenues accounted for just 2 to 3% of the sales revenue for the top ten MS drugs. The majority also noted that Ampyra is indicated only for improvement of walking and is not effective in all patients with walking problems. Indeed, Ampyra is prescribed for only 15 to 20% of MS patients with walking problems. Pet. App. 28a.

The majority proceeded to conclude that record evidence supported the district court's finding that the risk of infringement liability for marketing the

claimed invention in the United States would have disincentivized and deterred others from pursuing that approach even if it was obvious. Pet. App. 55a. In addition to the Elan patent itself, that evidence included unrebutted testimony from respondents' market expert; the fact that other groups had pursued research before Elan's patent issued in 1996, yet only Elan and Acorda pursued clinical trials involving sustained-release 4-AP after that date; the exclusivity of Elan's license to Acorda; and the lack of evidence that Elan or Acorda desired to license anyone else. Pet. App. 55a-56a. The majority recognized that Elan's U.S. patent did not block sales outside the U.S. and that 35 U.S.C. § 271(e)(1) provides a limited safe harbor for activities "solely for uses reasonably related to the development and submission of information" to FDA. But it concluded that neither factor made it unreasonable or clear error for the district court to find that Elan's blocking patent was a significant factor that reduced the strength of Acorda's evidence of commercial success. Pet. App. 56a-57a.

The majority likewise found no clear error in the district court's analysis of failure of others and long-felt but unsolved need. Acorda presented evidence that Sanofi-Aventis's experiments with a *different* potassium channel blocker had been unsuccessful, but that did not prove much because the Elan patent likely prevented Sanofi-Aventis from using 4-AP. Pet. App. 58a. The majority likewise concluded that the evidence of blocking was "pertinent" to, though "not dispositive" of, the factual question of long-felt but unmet need after issuance of Elan's patent in 1996. Pet. App. 59a.

3. Judge Newman dissented, asserting that the district court committed clear error in evaluating the facts. Most of her opinion was devoted to a lengthy discussion of the prior art. Pet. App. 62a-76a. Based on that evidence, she contended that the district court clearly erred in finding a motivation to combine the teachings of the prior art to produce the claimed invention with a reasonable expectation of success. Pet. App. 76a-82a. Based on her assessment of the facts, she also concluded that the failure of others, a long-felt need, and Ampyra's commercial success indicated non-obviousness. Pet. App. 83a-85a. Her opinion only briefly mentioned the blocking-patent issue on which Acorda's petition focuses. *See* Pet. App. 62a, 84a.

4. Acorda petitioned for rehearing en banc, but no circuit judge—including Judge Newman—voted to rehear the case. Pet. App. 187a-188a.

REASONS FOR DENYING THE PETITION

Fourteen years ago, another petitioner, supported by several of the same amici, argued that the Federal Circuit's recognition that blocking patents may reduce the significance of evidence of commercial success contradicted this Court's decision in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), unsettled the burdens of proof regarding obviousness, and undermined incentives to pursue improvement patents. *See* Petition, *Merck & Co. v. Teva Pharm. USA, Inc.*, No. 05-236 (U.S.) (filed Aug. 19, 2005). This Court denied certiorari. 546 U.S. 972 (2005). Just recently, this Court denied another petition that raised similar issues to Acorda's. *See Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 12-1289 (U.S.), *cert. denied*, Jun. 3, 2019.

Acorda's claims of conflicts with this Court's precedents fare no better, and the passage of time has both confirmed the wisdom of considering the blocking effects of issued patents and belied the notion that doing so will discourage research to improve on patented inventions. As shown below, the Federal Circuit's decision was legally sound and fact-bound, it does not conflict with any precedents of this Court, and Acorda's assertion that it will ring the death knell for improvement patents has no merit. The petition for a writ of certiorari should therefore be denied.

A. The Federal Circuit's longstanding consideration of blocking patents has a sound theoretical basis

Courts rely on a chain of inferences when evaluating commercial success and long-felt but unsolved need as part of an obviousness analysis. The fact that a patentee enjoyed great commercial success or that there was a long-felt but unsolved need for the claimed solution may suggest that there was a market incentive to develop the claimed invention. And the fact that competitors did not achieve the invention despite that incentive may suggest that the invention was not obvious.

This theory has been the premise of the secondary considerations analysis since *Graham*, this Court's seminal case on assessing obviousness under 35 U.S.C. § 103. In discussing the import of secondary considerations, the *Graham* Court relied on an insightful then-recent Note in the University of Pennsylvania Law Review. *See* 383 U.S. at 17-18, 36 (citing Richard L. Robbins, Note, *Subtests of*

"Nonobviousness": A Nontechnical Approach to Patent Validity, 112 U. Pa. L. Rev. 1169 (1964)). The Note laid out this economic explanation in detail. Existence of a long-felt need, it observed, "creates a demand for its correction, and it is reasonable to infer that [the need] would not persist were the solution 'obvious.'" 112 U. Pa. L. Rev. at 1172. "This is the rationale of longfelt demand and its justification as a test of nonobviousness." *Ibid.* The same logic extends to commercial success: "The possibility of market success attendant upon the solution of an existing problem may induce innovators to attempt a solution. If in fact a product attains a high degree of commercial success, there is a basis for inferring that such attempts have been made and have failed." *Id.* at 1175. And that in turn suggests non-obviousness.

In the years that followed, the lower courts followed this Court in adopting that logic. *See, e.g.*, *Higley v. Brenner*, 387 F.2d 855, 859 (D.C. Cir. 1967); *In re Fielder*, 471 F.2d 640, 644 (C.C.P.A. 1973); *Charvat v. Comm'r of Patents*, 503 F.2d 138, 141 (D.C. Cir. 1974).

As the Federal Circuit observed in *Merck I*, however, that chain of inferences fails when others are legally barred from commercially pursuing the claimed invention. In particular, when a blocking patent or lack of regulatory approval bars market entry, the inference of non-obviousness is weak. 395 F.3d at 1376-77. It follows that commercial success and long-felt need are not perfect shibboleths for distinguishing obvious from non-obvious inventions. They are indicia that *may* indicate non-obviousness, but they can also be spurious indi-

cators when the market- and incentive-based premises for relying on them do not apply.

The Federal Circuit has adhered to this insight since 2005, and correctly so. Commentators and the Federal Circuit have also recognized that the strength of secondary considerations evidence may vary for other reasons. Commercial success, for example, is a matter of degree, and the strength of the inference of non-obviousness depends on whether the success was due to the patented invention as opposed to unpatented features or other factors such as marketing prowess. *See, e.g.*, 112 U. Pa. L. Rev. at 1176. Likewise, "[t]he more pronounced and persistent the [market need], the stronger the inference of longfelt demand" and non-obviousness, but even then, the strength of the inference depends on factors such as the state of the art and the patentee's market power and ability to suppress the solution. *Id.* at 1173-74. Simply put, evidence of secondary considerations can be informative, but its nexus to the claimed invention must be scrutinized rather than accepted blindly.

Acorda suggests that the "entire premise ... that researchers will be dissuaded by the existence of a blocking patent ... is unmoored from the realities of scientific research." Pet. 19. But it is Acorda's argument that is unmoored from commercial reality. In some cases, academics or government agencies may pursue small-scale scientific research without regard for others' patent rights. But for-profit companies that develop commercial products routinely consider the patent landscape when engaging in expensive and protracted research, development, and marketing programs because

rational economic actors must consider risks as well as rewards.

This case is a good example. A prudent pharmaceutical company would not invest many millions of dollars and years of efforts investigating uses of 4-AP to treat symptoms of MS without considering whether another company's patent rights would prevent it from earning any return on that investment. Indeed, Acorda itself cleared Elan's blocking patent by taking an exclusive license before embarking on further research. Notably, the article on which Acorda relies for its suggestion that companies blithely ignore patents specifically carves out the pharmaceutical industry. Mark A. Lemley, *Ignoring Patents*, 2008 Mich. St. L. Rev. 19, 29 (2008) ("[T]he characteristics of the pharmaceutical industry are quite different than the component industries in which it is common to ignore patents.").

Acorda argues that "[e]xisting patents are particularly unlikely to stifle research in the pharmaceutical industry" because 35 U.S.C. § 271(e)(1) precludes liability for "uses reasonably related to the development and submission of information" to regulators such as the Food and Drug Administration (FDA). Pet. 20. But although § 271(e)(1) provides immunity for trial studies related to FDA approval, it provides no protection against liability for ordinary commercial sales after FDA approval. And those commercial sales are where drug companies earn the necessary return on their investment. Moreover, in Hatch-Waxman Act cases, generic manufacturers face a 30-month stay of final FDA approval while patent infringement issues

are litigated. 21 U.S.C. § 355(j)(5)(B)(iii). An altruistic professor or billionaire philanthropist might be content with conducting abstract scientific research, but drug companies need to sell products to survive and thus worry about blocking patents.[1]

B. Acorda mischaracterizes the Federal Circuit's decision in this case

Contrary to Acorda's suggestion, the Federal Circuit did not announce a new, rigid rule that commercial success, long-felt but unsolved need, and other secondary considerations have no force in an obviousness analysis whenever a dominant earlier patent covered the claimed invention. The Federal Circuit recognized that the significance of blocking patents is a fact-specific inquiry and simply found no clear error in this district court's factual findings and ultimate determination that respondents' strong evidence that Acorda's patent claims were obvious as a technical matter clearly outweighed Acorda's relatively weak evidence regarding secondary considerations. The Federal Circuit's discussion of Elan's blocking patent

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[1] Acorda also contends that U.S. patents do not cover activities overseas. That is an overstatement, *see, e.g.*, 35 U.S.C. § 271(f), but more importantly, the U.S. is a large market and often the most significant one. In this case, for example, Acorda's six-year net revenues from U.S. sales were $1.7 billion, while its revenues from licensing abroad were about $135 million—an order of magnitude less. Pet. App. 28a-29a. Moreover, U.S. patent rights restrict importation of products into the U.S. 35 U.S.C. § 271(a). In any event, patentees often hold corresponding foreign patent rights as well.

involved one subsidiary issue affecting one of multiple factors in the balancing test, and even as to that factor, the Federal Circuit expressly rejected any categorical rule in favor of a case-specific analysis. Even if the Federal Circuit's fact-bound, case-specific ruling were mistaken—and it was not—no further review is warranted.

1. The Federal Circuit's decision turned primarily on the district court's findings regarding the extensive prior art, and the petition does not challenge those findings

Under *Graham*, obviousness turns on four factors: (1) the scope and content of the prior art; (2) differences between the prior art and the patent claims at issue; (3) the level of ordinary skill in the art; and (4) secondary considerations such as commercial success, long-felt but unsolved needs, and failure of others. 383 U.S. at 17-18. The first three factors involve technical issues, and courts generally address them together. The fourth factor focuses on economic and motivational issues rather than technical issues. *Id.* at 36.

Although secondary considerations may add perspective and "lend a helping hand" to judges who lack technical expertise, they may or may not "tip the scales of patentability," depending on the facts of each case. *Ibid.* In *Graham* itself, for example, they did not save the patent claims at issue: this Court held the claims invalid for obviousness because there were only minor differences between the claimed invention and the prior art, despite evidence of commercial success, long-felt need, and

failure of others. *Id.* at 35-37. In *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969), this Court likewise held the claims invalid for obviousness despite alleged long-felt need and commercial success. *Id.* at 61-63; *see also Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282-83 (1976) (similar). And in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Court similarly held that no secondary factors "dislodge[d]" its determination that the claimed invention was obvious in view of the prior art. *Id.* at 426.

In this case, Acorda's petition focuses on one subsidiary issue (the role of Elan's blocking patent) that affected only a few subfactors (commercial success and to a lesser extent long-felt but unsolved need and failure others) of one of the four *Graham* factors (secondary considerations). The district court and Federal Circuit, by contrast, properly addressed obviousness holistically. As in *Graham*, *Anderson's-Black Rock*, *Sakraida*, and *KSR*, their primary conclusion was that extensive teachings from decades of prior research on using 4-AP to treat MS and other neurological diseases led skilled artisans to the claimed invention. As in those cases, they then considered Acorda's evidence of secondary considerations and found that evidence too weak to tip the scales and dislodge the conclusion that the claimed invention was obvious.

Acorda's petition does not seek review of the lower courts' analysis of the first three *Graham* factors. In passing, Acorda suggests that it "made an unexpected breakthrough" by using stable doses rather than escalating doses of 4-AP. Pet. 4. But the district court and the Federal Circuit

specifically rejected that argument and found that POSAs *were* motivated to pursue stable dosing and had a reasonable expectation of success in doing so. Pet. App. 36a-38a, 168a-171a. In any event, this highly factual issue does not warrant further review, and the technical merits must be taken as settled against Acorda.

Acorda's petition focuses on the fourth *Graham* factor (secondary considerations), but even there the facts are now largely settled against Acorda. The district court rejected Acorda's claim of unexpected results, Pet. App. 181a-182a, and Acorda did not appeal that finding, *see* Pet. App. 54a n.16, so its contrary suggestion, Pet. 4, has been waived. As to failure of others, the petition briefly refers to a mid-1990s study by Elan that failed to show benefits for indications other than walking. *Ibid.* But the district court found that that failure was not particularly probative of obviousness in 2004 because later prior-art studies showed promising results for walking, the indication at issue here, Pet. App. 183a. The Federal Circuit affirmed that finding. Pet. App. 58a-59a.

The blocking-patent issue did not affect any of these issues and findings. The lower courts cited the blocking effects of Elan's patent as mitigating counter-evidence on only three discrete points, and as to each Acorda's evidence was independently problematic.

As to commercial success, Ampyra's success has been modest. Its revenues and profitability pale in comparison to the top MS drugs, its only indication is for walking problems, and due to limited efficacy it is prescribed for less than 20% of MS patients

with walking problems. Pet. App. 28a-29a. Moreover, although the district court found some nexus between that success and Acorda's refinement of the dosing regimen, Elan developed the underlying sustained-release formulation of 4-AP.

As to long-felt but unsolved need, there were numerous other MS drugs, and the need to improve walking in MS patients remains largely unmet because Ampyra helps only a fraction of MS patients with walking problems. As to failure of others, the lower courts rejected Acorda's argument regarding failure of Elan. Beyond that, Acorda presented only "minimal" evidence, and that evidence said nothing about the obviousness of 4-AP dosing regimens because Sanofi-Aventis experimented with a different potassium channel blocker. Pet. App. 182a.

Simply put, respondents presented a strong and now unassailable technical obviousness case, while Acorda put on a weak secondary-considerations case even apart from the blocking effect of Elan's patent. Further review is unwarranted for that reason alone.

2. The Federal Circuit rejected a bright-line approach toward blocking patents in favor of a balanced, nuanced, fact-dependent analysis

Acorda portrays the Federal Circuit's decision as "effectively a categorical rule that the mere existence of a so-called 'blocking patent' overrides" all secondary-considerations evidence presented by the patentee. Pet. 18. But the Federal Circuit expressly rejected any such "categorical rule,"

Pet. App. 49a, and the multi-factor, fact-intensive, fact-specific standard it adopted is the antithesis of a *per se* rule, Pet. App. 49a-53a.

The Federal Circuit recognized that (a) the existence of a blocking patent "*may* deter non-owners and non-licensees from investing the resources needed to make, develop, and market ... a later, 'blocked' invention, because of the risk of infringement liability" and (b) that "*potential* deterrent effect is *relevant* to understanding why others had not made, developed that 'blocked' invention and, hence, to evaluating objective indicia of the obviousness of the later patent." Pet. App. 49a (emphasis added). The Federal Circuit did not say that the existence of an earlier, dominant patent *always* negates evidence of commercial success, long-felt but unmet need, etc. To the contrary, it reaffirmed its holding in *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 730-31 (Fed. Cir. 2017) ("*Merck II*), that a patentee's exclusive license to a blocking patent does "*not*, all by itself, justify discounting evidence of commercial success." Pet. App. 51a. The weight that blocking-patent evidences warrants is instead "'a fact-specific inquiry.'" *Ibid.* (quoting *Merck II*, 874 F.3d at 731).

More generally, the Federal Circuit recognized that "as a theoretical matter, a blocking patent *may or may not* deter innovation in the blocked space" by others. *Ibid.* (emphasis added). And it recited a long list of case-specific factors that may be relevant in assessing the import of an alleged blocking patent, including the availability of a license to the blocking patent, whether the blocking patent can be successfully challenged, the cost of

the research in the blocked space, the risk of research failure, the potential improvements resulting from the investment, the extent to which the blocking patent would cover those improvements, the market opportunity for the improvements, the costs of getting the improvement to market, the risks of losing the invention race, the likely response of the blocking patent owner, and other investment opportunities. Pet. App. 52a-53a.

Summing up, the Federal Circuit recognized that "*if all other variables are held constant*, a blocking patent diminishes the possible rewards from a non-owner's or non-licensee's investment" in research and development of products in the blocked space, and thus "a blocking patent therefore *can be* evidence that can discount the significance of evidence that nobody but the blocking patent's owners or licensees arrived at, developed, and marketed the [patented] invention." Pet. App. 53a (emphasis added). But it also agreed that "the *magnitude* of the diminution in incentive in any context—in particular, whether it was great enough to have actually deterred activity that otherwise would have occurred—is 'a fact-specific inquiry.'" *Ibid.* (emphasis added) (quoting *Merck II*, 874 F.3d at 731). Such a multi-factor, fact-specific balancing test is the opposite of a categorical rule.

3. The district court reasonably inferred blocking from the evidence presented, and the Federal Circuit properly affirmed that factual finding as not clearly erroneous

In reality, Acorda complains about the Federal Circuit's *application* of a longstanding, well-founded, balanced, and nuanced legal standard to the facts of this case, and the resulting unfavorable outcome for Acorda. That is not an issue worthy of this Court's review. *See* Sup. Ct. R. 10 ("A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law."). In any event, the Federal Circuit properly found no clear error in the district court's fact-findings and assessment of the evidentiary record in this case.

Contrary to Acorda's suggestion, the Federal Circuit did not ignore the legal standard it had just explained at length and did not simply affirm the district court based on the mere existence of Elan's blocking patent. For starters, respondents not only identified the Elan patent; they showed that it covered Acorda's claimed improvement, *see* Pet. App. 180 n.43, and presented "unrebutted testimony from an expert in economics and pharmaceuticals that the Elan patent acted as a blocking patent for entities other than Acorda (the exclusive licensee to the Elan patent) that wanted to pursue commercial opportunities like Ampyra," Pet. App. 55a. Furthermore, the record showed that multiple groups were pursuing 4-AP research before Elan's patent issued in 1996, yet only Elan and Acorda

pursued clinical research afterward. Pet. App. 56a. This circumstantial evidence suggested that the deterrence was real, not just theoretical. Moreover, as the Federal Circuit also noted, Acorda had an *exclusive* license to the Elan patent, and there was no evidence that Elan or Acorda was willing to relax that restriction by licensing others. *Id.*

Acorda complains that there was no evidence of "actual blocking," by which it apparently means direct evidence that particular companies wanted to enter the market and did not do so due to Elan's blocking patent. That argument has two flaws.

First, our legal system necessarily relies on indirect (circumstantial) evidence, inferences, and presumptions as well as direct evidence. That is particularly true of patent law: patentees, for example, need not extract confessions from defendants to establish the intent elements of inducement of infringement or willful infringement. Indeed, as discussed above, secondary considerations themselves are based on judicial presumptions and inferences rather than direct proof. *See, e.g.*, *Graham*, 383 U.S. at 35-36 (referring to secondary considerations as "legal inferences"); *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 495 (1876) (referring to commercial success as evidence supporting an "inference" of invention); 112 U. Pa. L. Rev. at 1172, 1175.

Second, by insisting on direct evidence of specific deterrence, Acorda is demanding a practical impossibility. Defendants in patent litigation do not have access to the files and employees of their competitors, and courts do not allow fishing expeditions via third-party subpoenas. Even if a

defendant managed to find a former employee who specifically recalled being deterred by a blocking patent years ago, Acorda would dismiss that as just a single example.

As a practical matter, Acorda seeks a bright-line rule of its own—that blocking patents have no significance whatsoever. As discussed above, such a rule cannot be right. In assessing secondary considerations evidence, courts must take care that the premises for crediting such evidence (e.g., the likelihood of market entry) hold true.

4. The Federal Circuit did not "drastically expand" its longstanding blocking-patent jurisprudence in this case

Recognizing that this Court has declined to take up the blocking-patent issue before, Acorda accuses the Federal Circuit of "drastically expanding" the doctrine in this case. Pet. 17. Not so.

Since *Merck I*, the Federal Circuit has consistently recognized that blocking patents may prevent market entry by others and weaken the inference of non-obviousness as a result. *See Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1383 (Fed. Cir. 2005); *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740-41 (Fed. Cir. 2013); Pet. App. 49a-51a. In *Merck II*, the Federal Circuit held that the mere existence of blocking patents does not necessarily eliminate the probative value of secondary-considerations evidence, 874 F.3d at 730-31, and the Federal Circuit reaffirmed that point here, Pet. App. 51a-53a.

Acorda complains that the Federal Circuit has extended its "blocking-patent doctrine" to long-felt but unsolved need and failure of others. But as discussed above, the rationales for considering commercial success and long-felt but unsolved need are similar: both rely on the theory that others would have adopted the claimed invention and entered the market if it had been obvious. *See* 112 U. Pa. L. Rev. at 1172, 1175. The Federal Circuit's previous cases addressed commercial success because that was the issue presented, but the concern (inapplicability of the underlying chain of inferences) applies equally to long-felt but unsolved need. Simply put, blocking patents affect the relevance of long-felt but unsolved need because they may deter or prevent competitors from solving the need even when the solution is obvious. The Federal Circuit accordingly recognized that the obstacle of Elan's blocking patent was "pertinent, in this case"—but "not dispositive"—regarding the significance of the alleged long-felt but unsolved need. Pet. App. 59a.

As to failure of others, the main issue was the nexus to the claimed invention. Sanofi-Aventis did not fail in experiments with 4-AP. It failed using a *different* potassium channel blocker, and the question was whether that failure indicated the nonobviousness of pursuing the claimed 4-AP regimen. In finding Acorda's evidence unpersuasive, the district court observed that Sanofi-Aventis likely did not use 4-AP due to Elan's patent, and the Federal Circuit found no clear error in that analysis. Pet. App. 58a. Even if that ruling was mistaken (it was not), it was a case-specific ruling regarding a subsidiary point, not a broad holding that blocking

patents negate all evidence of failure of others. Further review is unwarranted.

C. The Federal Circuit's decision does not conflict with any of this Court's decisions

Acorda argues that the Federal Circuit's decision conflicts with two decisions of this Court. There is no conflict whatsoever.

1. The Federal Circuit did not nullify or disregard secondary considerations, and its decision does not conflict with *Graham v. John Deere*

Acorda first argues that the Federal Circuit adopted a "categorical rule" regarding blocking patents and secondary considerations that is "squarely at odds with *Graham*." Pet. 18 (capitalization removed). That assertion is doubly flawed.

First, as discussed above, the Federal Circuit has squarely *rejected* any such categorical rule. Pet. App. 49a-53a. In *Merck II*, it held that the presence of a blocking patent is *not*, in Acorda's words (Pet. 18), "sufficient, standing alone, to justify discounting entirely ... evidence of ... commercial success." *See* Pet. App. 51a-52a (reaffirming *Merck II*). In this case, the Federal Circuit reaffirmed that point and ruled on case-specific evidentiary grounds:

> [T]he district court did not err in viewing the Elan patent, *among other evidence*, as evidence that discounted the weight of Acorda's evidence of commercial success, failure of others,

> and long-felt but unmet need so that "the evidence as a whole" in the case "prove[d] clearly and convincingly that the Acorda Patents are invalid due to obviousness."

Pet. App. 54a (emphasis added) (second alteration in original) (citation omitted); *see also* Pet. App. 55a-56a (discussing additional evidence of deterrence of entry).

Second, *Graham* is entirely consistent with the analysis and result here. *Graham* observed that "[s]uch secondary considerations as commercial success long felt but unsolved needs, failure of others, etc. *might* be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented" and "*may* have relevancy" "[a]s indicia of obviousness or nonobviousness." 383 U.S. at 17-18 (emphasis added); *see also id.* at 36 ("[s]uch inquiries *may* lend a helping hand to the judiciary") (emphasis added). This Court nowhere said or suggested that secondary considerations evidence must not be discounted even when such evidence is unpersuasive or undermined by additional evidence. Indeed, in *Graham* itself the Court held that "wide commercial success," "long-felt need in the industry," and repeated failure of a competitor to solve the problem did *not* "tip the scales [in favor] of patentability" given the close prior art. *Id.* at 35-36; *see also Anderson's-Black Rock*, 396 U.S. at 61-63; *Sakraida*, 425 U.S. at 282-83; *KSR*, 550 U.S. at 426 (all likewise holding that secondary considerations did not save the day for the patentee).

Graham at most suggests that secondary considerations should be considered in an obviousness analysis. But the Federal Circuit and the district court did consider Acorda's evidence. Both courts simply found that evidence not persuasive evidence of non-obviousness in this case.

Acorda further argues that the Federal Circuit violated *Graham* by transforming an objective analysis into a subjective one. Pet. 19. To begin with, however, *Graham* never distinguished between "subjective" and "objective" analyses. It distinguished between "technical" issues regarding prior art and "economic and motivational" inferences from secondary considerations. 383 U.S. at 35-36. As between technical issues and economic and motivational issues, the latter are certainly more subjective.

In any event, the Federal Circuit has not transformed secondary considerations into a subjective analysis. It has merely recognized that it is appropriate to consider whether the premises and presumptions that justify reliance on secondary considerations hold true in a particular case. The Federal Circuit also has not "blur[red] the line" between the first three *Graham* factors and secondary considerations, as Acorda charges. Pet. 19. Even if there were bright lines between the *Graham* factors (in actuality, the four factors are part of a common analysis), the Federal Circuit has not imported technical prior-art analysis into secondary considerations analysis. It has merely asked whether alleged secondary considerations make sense on their own terms.

Ultimately, Acorda is trying to have it both ways. It complains that the Federal Circuit's approach is too subjective because it assesses competitors' incentives. Yet it simultaneously complains that the Federal Circuit was too objective because it did not require direct evidence that specific companies were "actually blocked." In truth, neither complaint has merit.

2. The Federal Circuit recognized respondents' burden of persuasion, and its decision does not conflict with *Microsoft v. i4i*

Acorda further argues that the Federal Circuit imposed the burden of persuasion on it, contrary to *Microsoft Corp. v. i4i Limited Partnership*, 564 U.S. 91 (2011). Pet. 23-27. In fact, the Federal Circuit repeatedly recognized respondents' burden of proof and the standard of proof.

The Federal Circuit noted that the extent to which a blocking patent diminished others' incentives is a "fact-specific inquiry" that must be "conducted within the framework under which the *challengers* always retain the burden of persuasion on obviousness." Pet. App. 53a (emphasis added) (citation omitted). On the next page, it reiterated that "the 'ultimate burden of proving obviousness' at all times remained with the defendants" and simply held that the district court did not err in finding "that 'the evidence as a whole' in the case 'prove[d] clearly and convincingly that the Acorda Patents are invalid due to obviousness." Pet. App. 54a (alteration in original) (citation omitted).

Acorda's actual argument is not that the Federal Circuit reversed the burden of proof, but that the Federal Circuit should have required *direct evidence* that particular competitors were deterred rather than inferring such deterrence from circumstantial evidence including but not limited to Acorda's blocking patent. As discussed above, however, neither this Court's case law nor principles of evidence require direct evidence of blocking. Acorda's secondary considerations case itself relied on inferences of non-obviousness, respondents were entitled to rebut those inferences, and the district court was entitled to determine whose evidence and inferences were stronger.

Acorda also quibbles with the language the Federal Circuit used in affirming certain factual findings, but the Federal Circuit repeatedly recognized respondents' burden of proof, and Acorda's snippets do not show otherwise. As discussed above, respondents established the existence of Elan's blocking patent and relied on an expert in the economics of the pharmaceutical industry to explain its significance. Pet. App. 55a. The record also showed that multiple groups conducted research before Elan's patent issued, yet only Elan and its licensee, Acorda, did so afterward. Pet. App. 56a. The Federal Circuit also observed that there was no evidence that Elan sought to license its patent to others and, more generally, that Acorda did not present persuasive evidence rebutting the inference of blocking. Pet. App. 56a-57a. But that analysis did not flip the burden of proof; it simply affirmed that the district court reasonably weighed the evidence on this point. Likewise, although Acorda raised the Section 271(e)(1)

regulatory safe harbor and the possibility of practicing Elan's patent overseas, the district court was entitled to find that the blocking patent remained a significant impediment. The lower courts' reasonable and case-specific analysis of the facts does not warrant further review.[2]

D. The Federal Circuit's decision will neither deter innovation nor prevent true innovators from obtaining improvement patents

Finally, Acorda argues that it is "certain" that the Federal Circuit's approach to blocking patents will deter research into pharmaceutical improvements. Pet. 27-30. Ironically, despite demanding direct evidence throughout its petition, Acorda presents no evidence of such deterrence even though it contends the Federal Circuit has gone astray since *Merck I* in 2005. And Acorda's own amici below undercut that argument by pointing out that FDA approved twenty-three pharmaceutical improvements in 2016 alone. *See* Pet. App. 57a n.18.

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[2] Acorda suggests that district courts routinely rely on the mere existence of blocking patents to discount patentees' commercial success. Pet. 26 & n.5. But most of the cases it cites pre-dated the Federal Circuit's call for a totality-of-the-circumstances analysis in *Merck II* and this case. Acorda also neglects to mention that in *UCB, Inc. v. Accord Healthcare, Inc.*, 201 F. Supp. 3d 491, 539 (D. Del. 2016), *aff'd*, 890 F.3d 1313 (Fed. Cir. 2018), the same district judge found the patentee's commercial-success evidence persuasive, and its patent claims non-obvious, *despite* disincentives from blocking patents. Both lower courts understood that there is no *per se* rule.

As a practical matter, pharmaceutical companies—especially patentees—will continue to invest in research and development in an effort to achieve improvements to the extent they have a financial incentive to do so. Patents eventually expire, and competitors may offer non-infringing alternatives even before then. Improvement patents can help patentees retain their commercial advantage.

Furthermore, Acorda forgets that blocking patents are just one sub-factor in a multi-factor, fact-intensive obviousness analysis. When a challenger (or the examiner during patent prosecution) fails to present a strong technical case of obviousness over prior art, secondary considerations make no difference. Even in closer cases where secondary considerations come into play, blocking patents have no effect on some factors (e.g., unexpected results, copying, praise, acquiescence) and typically have little impact on others (e.g., failure of others). Acorda cries that the sky has fallen, but blocking patents have only a marginal and fact-dependent effect. As this case confirms, cases in which courts find blocking-patent evidence persuasive tend to be cases in which the patent claims are already dubious in view of the prior art and the secondary considerations touted by the patentee or patent applicant are suspect for other reasons.

In short, the Federal Circuit's treatment of blocking patents has not deterred improvement patents in the last fourteen years, and there is no reason to think it will do so in the future.

CONCLUSION

The petition for a writ of certiorari should be denied.

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