No. 24-1132

In the Supreme Court of the United States

PURDUE PHARMA L.P.,
PURDUE PHARMACEUTICALS L.P.,
RHODES TECHNOLOGIES,
Petitioners,

v.

ACCORD HEALTHCARE, INC.,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR PETITIONERS

DANIEL G. BROWN
LATHAM & WATKINS LLP
1271 Avenue of the Americas
New York, NY 10020
(212) 906-1200

GREGORY G. GARRE
Counsel of Record
MARGARET A. UPSHAW
ALEXANDER G. SIEMERS
TIMOTHY J. BORGERSON
LATHAM & WATKINS LLP
555 11th Street, NW
Suite 1000
Washington, DC 20004
(202) 637-2207
gregory.garre@lw.com

Counsel for Petitioners

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INTRODUCTION

This Court should grant review and reject the Federal Circuit's unduly rigid approach to the objective indicia of non-obviousness. As a leading patent scholar recently explained in expressing his "strong[]" agreement with Purdue's petition, the Federal Circuit's "overly rigid" approach "contradicts [this Court's] longstanding precedent requiring a flexible and expansive analysis of the obviousness factors."[1] Accord does not meaningfully dispute the legal significance of the objective indicia to the obviousness analysis. It agrees that this Court's precedents mandate a "flexible and expansive" approach. BIO10. And, although Accord denies that the Federal Circuit has employed unduly rigid rules, its response confirms the opposite is true.

Accord contests the Federal Circuit's trend toward rigid rules by ignoring nearly all of the law cited in Purdue's petition and instead pointing to cases that Purdue already identified as falling on the *other side* of an entrenched divide in the Federal Circuit. That response does nothing to address the many cases, including this one, in which the Federal Circuit has aggressively applied rigid rules to dismiss compelling objective indicia of non-obviousness out of hand. And it underscores the discord and inconsistency in the Federal Circuit. This Court's intervention is sorely needed to ensure that courts afford the objective indicia their proper role in the obviousness analysis.

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[1] Dennis Crouch, *The Federal Circuit's Rigid Approach to Secondary Considerations*, Patently-O (May 5, 2025), https://patentlyo.com/patent/2025/05/circuits-secondary-considerations.html (login required) ("Crouch").

Tellingly, when it comes to defending the Federal Circuit's decision in *this* case, Accord resorts to the same cramped and rigid rules it claims the Federal Circuit has not adopted. Accord contends the panel correctly rejected Purdue's evidence of commercial success, long-felt need, and other indicia because Purdue failed to tie that evidence directly to the specific *curing process* claimed in the patents. But that mode of analysis defies common sense. Medical providers and patients value the invention *as a whole*—a commercially viable, abuse-deterrent, extended-release oxycodone pain medication.

That only Purdue's novel process succeeded after years of experimentation, hundreds of millions of dollars in funding, and the failures of others, in producing such a product—thereby averting the risk that competitors would displace OxyContin from the market—is overwhelming evidence of nexus. But on the panel and Accord's view, that evidence receives virtually no weight in the analysis. Such a cramped and rigid approach to the objective indicia is irreconcilable with this Court's precedents. And it will lead to the routine invalidation of novel and transformative patents, diminishing the incentives for innovation the patent system is designed to protect. The petition should be granted.

ARGUMENT

I. THE FEDERAL CIRCUIT'S RIGID APPROACH TO THE OBJECTIVE INDICIA CONFLICTS WITH THIS COURT'S PRECEDENTS

A. The Federal Circuit Routinely Negates The Objective Indicia Through Rigid Requirements

This Court long ago instructed lower courts to consider objective indicia of non-obviousness as a common-sense check on hindsight bias. *See* Pet.14-17. And it has rejected "narrow" and "rigid" rules that "deny factfinders recourse to common-sense." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421, 427-28 (2007). But the Federal Circuit has increasingly taken the opposite tack—adopting a cramped and rigid approach to the objective indicia that renders them meaningless in many cases. *See* Pet.21-28. That trend has elicited strong dissents from multiple members of the Federal Circuit bench, *id.* at 26-27, but it persists nonetheless—as this case amply demonstrates.

Accord makes a half-hearted attempt to deny the trend, BIO9-13, but nothing it says should give this Court comfort that the Federal Circuit is faithfully and consistently applying this Court's precedent.

1. Accord begins by broadly asserting (at 2) that the Federal Circuit does *not* require a direct connection to a particular claim limitation—all but conceding that such a stringent rule would conflict with this Court's precedent. Yet Accord ignores nearly all of the cases Purdue cited in its petition that employ such a rule.

The Federal Circuit has expressly held that a patentee must show that "the driving force" behind "product sales was a direct result of the unique characteristics of the claimed inventions." *WesternGeco LLC v. ION Geophysical Corp.*, 889 F.3d 1308, 1330-31 (Fed. Cir. 2018). And it has repeatedly applied that rule to demand proof that commercial success was "directly attributable" to a specific claim limitation. *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012); *see* Pet.22-25 (discussing cases).

In *Wm. Wrigley*, for example, the Federal Circuit found no nexus because the patentee had not shown that the success of its "cooling" chewing gum was due to using one coolant instead of another—*i.e.*, that the success "was directly attributable to combining WS-23, rather than WS-3, with menthol." 683 F.3d at 1364. That type of rigid "nexus" requirement is antithetical to the flexible, common-sense consideration this Court's precedents require, and the Federal Circuit has deployed it time and again to dismiss compelling evidence of non-obviousness.

In response, Accord defends (at 9) the analysis in a single case, *Cubist Pharms., Inc. v. Hospira, Inc.*, 805 F.3d 1112 (Fed. Cir. 2015). Even if Accord were right about *Cubist,* it would not disprove the broader trend Purdue identifies. But Accord is wrong. Accord contends that *Cubist* properly discounted objective evidence of non-obviousness because the patented dosing regime for a medication was used only in certain cases. But in discounting commercial success, long-felt need, and unexpected results, even though the patents were a critical advance for treating "serious infections," the decision effectively precludes patentees from relying on the objective indicia

whenever patents apply only to a subset of a drug's overall market, or improve upon a drug whose overall success is arguably "attributable to [the drug] itself." *Id.* at 1126.

Indeed, Accord attempts to leverage that rigid rule here, arguing repeatedly that Purdue's novel abuse-deterrent formulation of OxyContin was commercially successful because of "demand for oxycodone itself." BIO3-4, 6; *see infra* at 8-10. As Purdue explained, such a rule renders the objective indicia virtually irrelevant in any case involving a pharmaceutical improvement patent—not to mention in any case involving a patent that, as here, prevented the collapse of sales altogether. Pet.22-23. Accord has no answer to that problematic result, much less to the many other cases that confirm the Federal Circuit's unduly rigid approach to the objective indicia.

2. Accord instead cites *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1330 (Fed. Cir. 2016), and cases following that decision, in an attempt to claim the Federal Circuit has rejected a "rigid test." *See* BIO2, 12 & n.3.[2] But, as Purdue explained, *WBIP* exemplifies the *divide* in the Federal Circuit between those judges decrying an overly rigid analysis and those routinely applying such an analysis. *See* Pet.25-28. For patentees, the fact that the odd panel will get the law right is cold comfort. Inventors need

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[2] *See Medtronic, Inc. v. Teleflex Innovations S.A.R.L.*, 70 F.4th 1331, 1337 (Fed. Cir. 2023); *Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1211 (Fed. Cir. 2023); *Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, 4 F.4th 1370, 1378 (Fed. Cir. 2021); *LiquidPower Specialty Prods. Inc. v. Hughes*, 749 F. App'x 965, 968 (Fed. Cir. 2018).

certainty and predictability, not luck of the draw. Few inventors are likely to invest considerable time and resources into developing a new patent if its validity depends on drawing the right panel. And tellingly, Accord's defense of the holding in *this* case is a far cry from *WBIP*'s more flexible analysis—confirming that the decision below falls firmly on the problematic side of the line. *See infra* at 7-12. Only this Court can clarify the appropriate analysis and ensure application of a uniform standard across cases.

Apple Inc. v. Samsung Electronics Co., 839 F.3d 1034 (Fed. Cir. 2016) (en banc), confirms as much. Although the majority in *Apple* deferred to the jury's determination that there was "a nexus between the [challenged] slide to unlock feature and the iPhone's commercial success," *id.* at 1056, it did not overrule the unduly rigid "nexus" requirement applied in other cases, nor did it provide any meaningful clarity on how to evaluate nexus. *See id.* at 1082 (Dyk, J., dissenting). Indeed, decisions post-dating *Apple* continue to apply the flawed nexus standard.[3] And the Court's multiple separate writings in *Apple* on the objective indicia reveal the depth of the divide in the Federal Circuit. Accord attempts to cast this disagreement as factual, rather than legal, but the opinions speak for themselves. For example, Judge Dyk articulated a stringent form of the nexus rule,

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[3] *See, e.g.*, *Yita LLC v. MacNeil IP LLC*, 69 F.4th 1356, 1364-65 (Fed. Cir. 2023) (distinguishing *WBIP* and applying stringent standard to reverse nexus finding); *Centripetal Networks, Inc. v. Cisco Sys., Inc.*, 847 F. App'x 881, 888-89 (Fed. Cir. 2021) (no nexus where evidence did not directly "tie the benefits" of product "to the claim limitations"); *Sanofi-Aventis Deutschland GMBH v. Mylan Pharms. Inc.*, 791 F. App'x 916, 927 (Fed. Cir. 2019); *WesternGeco LLC*, 889 F.3d at 1330-31.

requiring a "demonstrated nexus . . . to what is new in comparison to the prior art," while accusing the majority of implicitly changing the "framework" for analyzing secondary considerations. *Id.* (dissenting). And Judge Prost articulated a similarly stringent rule. *Id.* at 1068-69 (dissenting). Far from quibbling about facts, these separate writings reflect an entrenched legal dispute over how to properly analyze the objective indicia. That "important" issue warrants this Court's review. *Id.* at 1089 (Reyna, J., dissenting).[4]

Accord also tries to spin (at 10) the Federal Circuit's fractured opinions as "evidence of a flexible and expansive test." But, again, the problem here is inconsistent *legal* standards, not differing factual assessments. Under *KSR*, courts must apply a *uniformly flexible* legal standard. The Federal Circuit does not. Instead, in this and many other cases, it applies a cramped, rigid standard that contravenes this Court's precedents and undermines the role of the objective indicia in the obviousness analysis.

B. The Decision Below Exemplifies The Federal Circuit's Unduly Rigid Approach

This case epitomizes the Federal Circuit's rigid approach and provides an ideal vehicle for review of the question presented. After years of research by highly talented scientists and the investment of hundreds of millions of dollars, Purdue created the

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[4] Accord claims (at 11) that the question of "how much weight to accord secondary considerations," 839 F.3d at 1089 (Reyna, J., dissenting), is "unrelated to nexus." But the Federal Circuit's rigid rules, including nexus, directly impact the weight the objective indicia receive in the obviousness analysis, as *Apple* itself demonstrates.

first opioid pain medication ever to receive FDA approval for abuse-deterrent labeling. In doing so, Purdue both addressed a widespread, severe public-health need and avoided the existential threat that OxyContin would be withdrawn from the market if Purdue failed to develop an abuse-deterrent oxycodone formulation. *See* Federal Circuit Appendix ("Appx") 6854. Yet the Federal Circuit afforded Purdue's evidence of objective indicia no weight by summarily deeming it insufficiently connected to a specific claim limitation. Pet.App.24a-26a.

Accord's defense of that decision merely underscores the flaws in the panel's analysis.

1. Although Accord again asserts (at 2) that the Federal Circuit did *not* require a direct connection to a particular claim limitation, Accord repeatedly embraces that exact requirement to defend the panel's decision. *See* BIO1, 3, 4-5, 6-7. In Accord's view, because a prior art reference, Bartholomaus, taught a (non-scalable) abuse-deterrent formulation, Purdue could not rely on abuse deterrence in any way to establish a nexus to its objective indicia. *See id.* at 3-4.[5] Instead, Accord contends, Purdue was required to show that commercial success, long-felt need, skepticism, and failure of others were all specifically due to the claimed "process difference" from the prior

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[5] Accord suggests (at 4) that Purdue gleaned its invention from Grunenthal, but Purdue began experimenting with PEO-based formulations *before* its scientist visited Grunenthal, Appx5337-5338, 5344-5347; that visit revealed "[n]o details of [Grunenthal's] manufacturing process or equipment," Appx8885; and Purdue's scalable invention was starkly different than Bartholomaus's small-scale curing in a bespoke contraption.

art—*i.e.*, Purdue's novel process of curing tablets without compression.

That rigid rule makes no sense. Purdue's invention must be considered "as a whole." 35 U.S.C. § 103; *WBIP*, 829 F.3d at 1331-32 (requiring connection to single claim limitation "runs counter to the statutory instruction" to evaluate invention "*as a whole*"). And the novelty of Purdue's patents stems from the unique combination of limitations that produced a commercially viable, scalable, *and* abuse-deterrent oxycodone formulation. By the same token, those patents drove Purdue's commercial success and filled a long-felt need not because medical providers and patients inherently value or need a specific curing process, but because that novel process produced and brought to market a desperately needed *product*. Under a common-sense analysis of the objective indicia, that weighs heavily against obviousness. Yet the Federal Circuit's "rigid rule" prevented "recourse to common sense." *KSR*, 550 U.S. at 419, 421.

For the same reason, Accord cannot avoid its expert's concession that Purdue's invention "definitely" solved a "long felt, but unmet need in the art" for an abuse-deterrent oxycodone formulation, Appx5704-5705 (Appel 671:22-672:2), by suggesting that Bartholomaus somehow filled that need instead. As the Federal Circuit recognized, Accord's motivation-to-combine argument turned on the notion that Bartholomaus was not "suitable for large-scale production," such that there was a strong motivation to modify it to achieve a commercially viable abuse-deterrent product. Pet.App.8a-9a (citation omitted). Bartholomaus thus could not fill the real-world need for an abuse-deterrent oxycodone pain medication. That a court could credit Accord's

motivation-to-combine theory in finding obviousness, but then deem the same facts *irrelevant* in assessing the objective indicia of *non*-obviousness highlights how severely the Federal Circuit's rigid approach has skewed the analysis. *See* Pet.25.

Such an analysis swallows the objective indicia whole, eliminating a critical "check against hindsight bias" in analyzing motivation to combine and reasonable expectation of success. Crouch, *supra*.

2. Accord also offers a handful of factor-specific responses, but none demonstrates the type of expansive and flexible analysis this Court's precedents require.

As to commercial success, Accord parrots the district court's statement that OxyContin sales did not *increase*. BIO3. But like the courts below, Accord ignores that the invention averted the impending *collapse* of those sales—as FDA's withdrawal of original OxyContin from the market confirms. Pet.30. Nor does Accord acknowledge that its own witness testified that "[t]here's no doubt" that OxyContin's sales would have been lower without its abuse-deterrent features. Appx5693 (Hoffman 660:19-22). Yet the Federal Circuit dismissed this powerful evidence of *non*-obviousness as merely a "[b]ald assertion[] of commercial success unconnected to the patented features," Pet.App.24a (first alteration in original), highlighting the impact of its rigid "nexus" rule.

As to skepticism, Accord resists the notion that the panel found skepticism irrelevant because abuse-deterrence is not "expressly claimed in the asserted patents." BIO6 (quoting Pet.32). But that's precisely what the panel said. Quoting *Accord's own brief*, the

panel stated that the "asserted patents 'contain[] no limitations requiring any level of abuse deterrence.'" Pet.App.25a (alteration in original) (quoting Federal Circuit Appellee's Br. 39). It thus concluded that FDA's undisputed skepticism about approving abuse-deterrent labeling simply did not count. *Id.* Again, that rigid analysis does not comport with this Court's precedents, and it had the perverse result of requiring courts to ignore abuse deterrence for "the first extended-release opioid to receive abuse-deterrent labeling." *Id.* (citation omitted).

Finally, Accord quibbles with the facts of Purdue's failure-of-others evidence, BIO7-8, but it does not contest that multiple manufacturers were vigorously seeking to develop their own abuse-deterrent formulations of opioid pain medications, to little avail. Under this Court's "expansive and flexible approach" to obviousness, *KSR*, 550 U.S. at 415, that evidence should have weighed against obviousness.

Ultimately, Accord suggests the Federal Circuit did not apply a rigid rule because it merely affirmed factual "findings" that were not "clearly erroneous." BIO6. But analysis of the objective indicia will virtually always be couched in such terms—and will often end up summarily buried in a "non-precedential decision." BIO3. Those trappings do not change the fundamental problem: In this case, and others, the Federal Circuit over-invalidates patents by dismissing objective evidence of non-obviousness out of hand, based on inflexible standards that have no grounding in common sense or this Court's precedent.

After years of hard work and ingenuity, backed by major financial investment, Purdue succeeded in developing an abuse-deterrent formulation of oxycodone that no one else could—even though

sophisticated competitors in the market had an enormous financial incentive to be the first to make that discovery. Yet the Federal Circuit's rigid "nexus" requirement rendered Purdue's success meaningless. That decision cannot stand. This Court should grant review to "clarify its approach to objective indicia of non-obviousness and restore both flexibility and balance" to the obviousness inquiry. Crouch, *supra.*

II. THE QUESTION PRESENTED IS RECURRING AND IMPORTANT

The importance of the question presented counsels strongly in favor of this Court's review. Accord does not dispute that proper analysis of the objective indicia of non-obviousness is crucial to preserving the integrity and strength of the patent system. Obviousness is the most common type of challenge to patent validity, *see* Pet.34, and the objective indicia are central to that analysis. Without further guidance from this Court, the Federal Circuit will continue to apply its rigid approach, undermining an important check on hindsight bias and inviting the over-invalidation of patents.

The downstream effects of the Federal Circuit's approach are already materializing. As a leading patent scholar recently explained, "fewer and fewer patentees [are] relying upon secondary considerations because of the difficulties of proving nexus." Crouch, *supra.* This has serious implications for inventors of all stripes—but especially those of technically complex products like pharmaceuticals, where the risk of hindsight bias and misunderstandings about the differences between the patented invention and the prior art are particularly high. Uncertainty as to whether genuinely novel inventions will receive

patent protection undermines incentives for developing new and potentially transformative products and stifles American ingenuity. The public, in turn, will bear the brunt of the harm.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

DANIEL G. BROWN
LATHAM & WATKINS LLP
1271 Avenue of the Americas
New York, NY 10020
(212) 906-1200

GREGORY G. GARRE
Counsel of Record
MARGARET A. UPSHAW
ALEXANDER G. SIEMERS
TIMOTHY J. BORGERSON
LATHAM & WATKINS LLP
555 11th Street, NW
Suite 1000
Washington, DC 20004
(202) 637-2207
gregory.garre@lw.com

Counsel for Petitioners

June 17, 2025