NO. 24-1132

IN THE

# Supreme Court of the United States

PURDUE PHARMA L.P, ET AL.
*Petitioners*,

v.

ACCORD HEALTHCARE INC.,
*Respondent*.

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

## BRIEF IN OPPOSITION

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## QUESTION PRESENTED

In *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966) this Court held 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. As indicia of obviousness or nonobviousness, these inquiries *may* have relevancy." (emphasis added).

The district court here found Purdue's objective evidence unpersuasive because none related to the alleged novelty of the claims over the prior art, and the Federal Circuit found no clear error in that assessment.

The question presented is more accurately framed as whether the Federal Circuit must require district courts to give controlling weight to objective indicia even where the patentee fails to provide a "legally and factually sufficient connection between the evidence and the patented invention."

## PARTIES TO THE PROCEEDINGS

In addition to Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and Rhodes Technologies are also applicants.

## RULE 29.6 DISCLOSURE STATEMENT

Accord Healthcare, Inc. is a wholly owned subsidiary of Intas Pharmaceuticals.

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**Statutes**



**Rules**

Consistent with Supreme Court Rule 15.2's admonishment that counsel "have an obligation to the Court to point out in the brief in opposition, and not later, any perceived misstatements in the petition," Accord respectfully files this opposition identifying misstatements and omissions of important facts and context in Purdue's petition.

Purdue's argument hinges on the faulty premise that (i) Purdue was the first to develop oxycodone tablets with abuse-deterrent features such as resistance to crushing and syringing and (ii) the Federal Circuit applied a rigid nexus test to disregard "compelling" evidence of non-obviousness.

The record, however, showed that Bartholomaus taught abuse-deterrent formulations made by heating PEO to render the tablets crush and syringe resistant. The *only* alleged novelty of Purdue's claims was using subsequent heating (as suggested by Bartholomaus) rather than simultaneous (as done in the examples of Bartholomaus). The district court found the claims obvious because there was a clear motivation to make that modification with a reasonable expectation of success, and none of the objective indicia evidence demonstrated the non-obvious of this process difference. In other words, the evidence was not compelling because it did not have a nexus to the claimed features or any novel aspect of the invention over Bartholomaus.

To be clear, Purdue does not challenge that a nexus must be shown to "properly assess the persuasiveness of the evidence." Pet. 21. Rather Purdue appears to argue based on its faulty analysis of a number of Federal Circuit decisions that the test

has become too "rigid" because it "demands evidence of a direct connection between the objective indicia and a particular claim limitation." Pet. 3. However, contrary to Purdue's argument, the Federal Circuit did not in this, or any other case, create such a rule.

Indeed, the Federal Circuit has explicitly rejected that rigid test, making clear nexus may be to "the combination of features as a whole." *Medtronic, Inc. v. Teleflex Innovations S.A.R.L.*, 70 F.4th 1331, 1337 (Fed. Cir. 2023); *see also WBIP, LLC v. Kohler Co.,* 829 F.3d 1317, 1330 (Fed. Cir. 2016) ("the patent owner can show that it is the claimed combination as a whole that serves as a nexus for the objective evidence"); *Novartis AG v. Torrent Pharm. Ltd.*, 853 F.3d 1316, 1331 (Fed. Cir. 2017) ("In evaluating whether the requisite nexus exists, the identified objective indicia must be directed to what was not known in the prior art…which may well be the novel combination or arrangement of known individual elements.").

The Federal Circuit here made clear that nexus simply requires a "legally and factually sufficient connection between the evidence and the patented invention"—not any single limitation. 22a. This Court too has required objective evidence be attributable to the novelty of the invention. *E.g., Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 568 (1949) ("We cannot attribute Jungersen's success solely or even largely to the novelty of his process."); *Marconi Wireless Tel. Co. of Am. v. United States*, 320 U.S. 1, 36 (1943) ("it has not been established that the alleged improvement contributed in any material degree to that success"); *Textile Mach. Works v. Louis Hirsch Textile Machs.*, 302 U.S. 490,

499 (1938) ("we cannot say that the commercial success is attributable to novelty of the [invention]").

The district court did not find Purdue's evidence "compelling" as Purdue suggests. Pet. 3, 21, 28. And rather than applying a rigid nexus rule, the Federal Circuit found no clear error in a non-precedential decision that drew no dissent. No intervention by this Court is warranted.

## ARGUMENT

### I. The Federal Circuit here did not apply a rigid nexus test

Purdue's arguments are unsupported by the record, which shows no rigid nexus test was applied.

*First*, rather than requiring a "direct connection" to a single claim limitation (Pet. 3), the district court concluded after a flexible analysis there was no evidence that any novel aspect of the claimed invention (i.e., subsequent heating) was responsible for causing any commercial success as opposed to the demand for oxycodone itself or the abuse-deterrent features taught in Bartholomaus. The Federal Circuit simply found no clear error in this finding.

As the district court found and Purdue does not dispute, OxyContin sales did not increase after the introduction of the abuse-deterrent features but rather carried over from prior art OxyContin. 62a. Further, "there was no demonstrated increase in the success of OxyContin relative to other opioids when the patented features were introduced." 62a. Thus, the evidence suggested that any success was due to the demand for oxycodone, not the claimed invention.

Purdue argues that OxyContin would have been removed from the market without abuse-deterrent features such as crush-resistance. Pet. 30. But the district court considered this argument, noting it "speaks only to the importance of abuse deterrence, not to its obviousness." 62a. Purdue's argument ignores that "[i]t is undisputed that Bartholomaus teaches crush-resistant PEO [oxycodone] tablets." 19a.

The obviousness question focuses on "the *differences* between the subject matter sought to be patented and the prior art" such as Bartholomaus and whether those *differences* "are such that the subject matter as a whole would have been obvious…." 35 U.S.C. § 103 (emphasis added). Here, Purdue's evidence was unrelated to those differences.

Purdue omits from its Petition that it learned of the abuse-deterrent heated PEO tablet from Bartholomaus and his employer, Grunenthal. *See* Appx5338-5339, Appx5362-5365. Indeed, while Purdue asserts that reformulated OxyContin was the result of "a decade of research by extraordinarily talented scientists, and hundreds of millions of dollars" (Pet. 3) the record shows Purdue visited Grunenthal in 2005 (Appx5338), began work on heated PEO tablets following that visit (Appx5363) and in 2006 filed the application that resulted in the asserted patent. *E.g.*, 42a ¶ 5.

Grunenthal, not Purdue, invented an abuse-deterrent oxycodone tablet, and disclosed it in the Bartholomaus reference. Purdue did not even argue in the district court that its process, the only alleged novelty, was responsible for commercial success. In fact, it still argues only that "OxyContin's success

was due to its abuse-deterrent properties." Pet. 31. But that says nothing about whether the claims would have been obvious over Bartholomaus, which teaches those very abuse-deterrent properties.

Purdue further argues repeatedly and incorrectly that "Accord's own expert acknowledged in the proceedings below, Purdue's abuse-deterrent patents 'definitely' solved 'a long felt, but unmet need in the art.'" Pet. 8 quoting Appx5704-5705; *see also* Pet. 10, 30, 33. Accord's expert stated there "definitely [] was a long-felt need" *but* "what's disputed is that it was already out there in the prior art…We talked at length about Bartholomaus with the hardened tablet" and "Dr. Mannion spoke about…the work at Grunenthal" and "the hardening process that they used that I understand was adapted." Appx5704-5705.[1]

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[1] Purdue also omits that it licensed the Grunenthal technology (Appx5363) and asserted the issued Bartholomaus patent against generic manufacturers, arguing that reformulated OxyContin's success was due to Bartholomaus and that Bartholomaus met the long-felt need for abuse-deterrent features. *See In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d 367, 407, 427-28 (S.D.N.Y. 2014). Purdue further omits that it asserted related patents in a second litigation, and while Purdue did not even argue commercial success, a second judge also did "not find the secondary consideration evidence to be persuasive" because "the solution to the problem that was approved by the FDA in 2013 was actually devised by Bartholomäus eight years earlier, in 2005." *See Purdue Pharma*

In short, the district court's findings, which the Federal Circuit found not clearly erroneous, were not based on any overly "rigid" nexus test but on the fact that Purdue failed to show that the commercial success of OxyContin was due to any novel aspect of the claimed invention, where the evidence instead showed it was due to the active ingredient and the abuse-deterrence imparted by heating PEO taught in Bartholomaus. Indeed, as the district court found, Purdue did not even attempt to tie success to the invention. 62a (Purdue's expert "admitted on cross examination that he did not specifically consider the claimed features of OxyContin"). There is nothing rigid about holding that "[b]ald assertions of commercial success unconnected to the patented features of the claimed invention are not given patentable weight." 24a.

*Second*, Purdue incorrectly argues that the panel held skepticism "irrelevant" because abuse deterrence "is not expressly claimed in the asserted patents." Pet. 32. Rather, the panel found no clear error in the district court's analysis because "the FDA's skepticism was about applying the abuse-deterrent label, *not about the creation (even at large scale) and utility of the claimed product*." 25a (emphasis added). Again, Purdue's evidence did not address whether there was skepticism regarding the

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*L.P. v. Accord Healthcare Inc.*, No. CV 22-913-WCB, 2024 WL 4120717, at *14 (D. Del. Sept. 9, 2024).

differences between the claimed invention and the prior art—the relevant statutory inquiry.

While Purdue argues in the background "[t]here was concern that heating PEO tablets above their melting point without simultaneous compression would result in tablet deformation or puddling, altering the extended-release dissolution profile of the medication" (Pet. 7) it omits that it failed to present any evidence of such concern, other than its own inventor's testimony. On that point, the district court rightly noted such testimony "would seem to carry limited weight" because he "does not serve as a stand-in for a POSA, or for the industry." 63a; *see also* 55a ("I do not think that Dr. Mannion's testimony about his own expectations outweighs Dr. Appel's testimony about a POSA's").

*Third,* Purdue again presents an unsupported narrative regarding alleged failures of others that the district court simply rejected—a classic factual dispute. Purdue states that "Endo … withdrew its competing product, Opana® [] because it was not sufficiently abuse-deterrent." Pet. 9. But as the Federal Circuit noted, the district court "found that 'the record is not clear on why Opana was removed from the market,' and 'Purdue' did not establish by a preponderance of the evidence that Opana's removal was related to its lack of 'the claimed features.'" 26a quoting 64a-65a. The district court noted "that Opana ER used a different active ingredient [a stronger opioid, oxymorphone, Appx5705], and that it is unclear why Opana ER was withdrawn." 64a.

There was no evidence directly comparing the abuse-deterrent properties of Opana and OxyContin, or even evidence suggesting Opana was not

sufficiently abuse-deterrent (let alone tying that to any process). Indeed, as documentary evidence showed, the processes used to make each were "proprietary in nature and thus not accessible in any detail" and a "plausible explanation is that, despite its actual low level of abuse nationwide, IV oxymorphone is so rewarding to a select vulnerable group or subgroup of abusers that obtaining it is worth any effort required to do so." Appx6822-6823.

Similarly, the record showed Develco's "failure" was entirely unrelated to the issues here. Develco was working with "Drug Coated Pellets" and struggled with the dissolution profile when scaling up the process on a different piece of equipment that sprayed the coating differently. Appx6001. Thus, the district court found that if anything Develco's failures weigh in favor of scaling up the Bartholomaus formulation (rather than using a drug coated pellet) and there was no evidence "these failures—if they are failures—weigh in favor of non-obviousness." 65a.

Requiring evidence of failure be related to the lack of claimed features is not a "rigid nexus test" but simply ensures courts assess whether the alleged failures are indicative of the non-obviousness of the claimed invention. For example, failure to subsequently heat PEO or achieve a claimed property would have been highly probative that it was non-obvious to do so; failure to keep a stronger opioid on the market or scale up an entirely different technology and achieve an unclaimed desired dissolution profile is not.

## II. The Federal Circuit has not created a rigid nexus test in other cases

Purdue also omits crucial context and facts regarding holdings of other cases to suggest the Federal Circuit has enacted rigid rules where the court has simply affirmed lower court decisions based on the facts presented.

For example, in *Cubist Pharms., Inc. v. Hospira, Inc.*, 805 F.3d 1112, 1126 (Fed. Cir. 2015) the court did not simply "reason[] that the success [of daptomyacin] was mainly attributable to the drug itself" based on some rigid nexus test. Pet. 22-23. Rather, the court found no clear error where "the [district] court noted that SAE is the target infection in only about 5% of the cases in which daptomycin is administered" and thus the sales of the drug were "attributable only in small measure to the dosage and interval protocols disclosed in the dosing patents" for treating SAE. *Cubist*, 805 F.3d at 1126. In other words, where 95% of sales were for a non-patented use, the district court did not clearly err in finding commercial success unpersuasive.

Purdue also relies on *Apple Inc. v. Samsung Electronics Co.,* 839 F.3d 1034, 1056 (Fed. Cir. 2016) where, as Purdue recognizes, the *en banc* Federal Circuit *confirmed there is no rigid nexus* test by reinstating the jury's presumed nexus finding and emphasizing "[i]t is the fact finders' job to assess the probative value of the evidence presented." *Id.* at 1056 (finding "substantial evidence of a nexus between the slide to unlock feature and the iPhone's commercial success, and we are required to give this jury fact finding deference.").

And even disregarding that a stricter nexus test proposed by a dissent would *by definition not be law*, none of the dissents argued that a *stricter* nexus requirement should be adopted. They simply disagreed on whether a nexus was shown by substantial evidence under the governing law. *E.g.*, *id.* at 1069 (Judge Prost believing "no reasonable juror could" find "evidence of a nexus"); 1082 (Judge Dyk finding "[t]here was no showing of nexus between the inventive steps (over the closest prior art)"), 1088 & n.4 (Judge Reyna disagreeing survey was "substantial evidence of commercial success").

But as Judge Reyna also noted "[a]s the case before us demonstrates, different appellate judges can review the same evidence and disagree whether it is substantial evidence in support of a jury's factual findings." *Id.* at 1089. That even the Federal Circuit judges struggle to agree on whether objective indicia demonstrate non-obviousness in a particular case is evidence of a flexible and expansive test such as the one prescribed in *KSR*—not a rigid inquiry.

In that very case this Court recognized that flexibility is at the expense of uniformity. *See KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 407, 415 (2007) (rejecting test "seeking to resolve the obviousness question with more uniformity and consistency" because *Graham* "set forth a broad inquiry and invited courts, where appropriate, to look at any secondary considerations that would prove instructive."); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 18 (1966) ("What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context.").

Purdue relies on Judge Reyna's dissent in

*Apple* that "the court disagrees over the role objective indicia play in the court's analysis of the ultimate determination of obviousness" which are "important issues that should be addressed." Pet. 28 quoting *Apple*, 839 F.3d at 1089. However, Judge Reyna made no mention of nexus, instead stating that the "legal questions I see here include (1) whether an obviousness analysis involving secondary considerations (or objective indicia of non-obviousness) is a one- or two-step process[2] and (2) how much weight to accord secondary considerations in the obviousness analysis" noting "Judge Dyk cites Supreme Court precedent in making a forceful argument that secondary considerations of non-obviousness carry little weight where strong evidence of obviousness exists." *Id.* at 1089. Those issues are unrelated to nexus, not raised in Purdue's petition, and if anything, suggest a question of whether the Federal Circuit *over*emphasizes objective indicia.

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[2] Whether the evidence of obviousness and non-obviousness should be considered together as the Federal Circuit holds or "a burden-shifting analysis for determining whether a patent is obvious" should be applied in which in step one the "prima facie case of obviousness" is first assessed and in step two the prima face obviousness case must be outweighed by secondary considerations—a test rejected by the Federal Circuit. *Id.* at 1089; *see also In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig*., 676 F.3d 1063, 1075 (Fed. Cir. 2012) (rejecting burden-shifting).

Simply put, the Federal Circuit applies a broad and flexible nexus analysis requiring only a "legally and factually sufficient connection" to the claimed invention. 22a. And where the fact-finder applies an overly rigid nexus analysis, the Federal Circuit has intervened.[3]

Rather, it is Purdue that implicitly asks for a rigid rule *requiring* a fact finder to give controlling weight to objective indicia without regard to how compelling the district court finds the evidence to be or whether there is a connection to novel aspects of the claimed invention. Indeed, Purdue's dispute seems not with what the Federal Circuit *requires* lower courts to do, but what it *permits*. *E.g.*, Pet. 22

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[3] *E.g.*, *In re Huai-Hung Kao,* 639 F.3d 1057, 1073 (Fed. Cir. 2011) ("the Board's application of so strict a commensurateness requirement was improper"); *Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, 4 F.4th 1370, 1378 (Fed. Cir. 2021) ("Contrary to the Board's decision, the separate disclosure of individual limitations, where the invention is a unique combination of three interdependent properties, does not negate a nexus."); *In re Glatt Air Techniques, Inc.*, 630 F.3d 1026, 1030 (Fed. Cir. 2011) ("To the extent the PTO asserts that Glatt needed to submit commercial success evidence from multiple embodiments for that evidence to be commensurate in scope with claim 5, this position is not consistent with our precedent."); *Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1211 (Fed. Cir. 2023) (vacating finding of no nexus); *NuVasive, Inc. v. Iancu*, 752 F. App'x 985, 996 (Fed. Cir. 2018) (same); *LiquidPower Specialty Prods. Inc. v. Hughes*, 749 F. App"x 965, 968 (Fed. Cir. 2018) (same).

("courts *can* regularly point to the underlying product as the more likely 'source' of commercial success"), 23 ("the objective indicia *can* be deemed irrelevant") (emphasis added).

As this Court recognized, a flexible and expansive test means secondary considerations "*might* be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented" and that as "indicia of obviousness or nonobviousness, these inquiries *may* have relevancy." *Graham*, 383 U.S. at 17–18 (emphasis added). Whether the evidence is persuasive is inherently factual, and fact finders remain free to flexibly assess the evidence applying common sense.

The district court here applied that flexible analysis and found the evidence unpersuasive—a simple resolution of a factual dispute. Rather than applying any rigid role limiting a district court's analysis, the Federal Circuit found no clear error in the district court's factual findings in a non-precedential decision without dissent.

## CONCLUSION

This court's intervention is unnecessary, and Purdue's petition should be denied.

Respectfully Submitted,

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