No. _____

# In the
# Supreme Court of the United States

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

*Applicants*,

v.

ACCORD HEALTHCARE, INC.,

*Respondent*.

**APPLICATION DIRECTED TO THE HONORABLE JOHN G. ROBERTS FOR AN EXTENSION OF TIME WITHIN WHICH TO FILE A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

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March 10, 2025

## RULE 29.6 STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Applicants Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and Rhodes Technologies state that they have no parent corporations and no publicly held corporation owns 10% or more of their stock.

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TO THE HONORABLE JOHN G. ROBERTS, CHIEF JUSTICE OF THE SUPREME COURT OF THE UNITED STATES AND CIRCUIT JUSTICE FOR THE FEDERAL CIRCUIT:

Pursuant to 28 U.S.C. § 2101(c) and Supreme Court Rules 13.5, 22, and 30.2, Applicants Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and Rhodes Technologies (collectively, "Purdue") respectfully request a 30-day extension of time, to and including April 30, 2025, within which to file a petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case. The Federal Circuit entered its judgment on December 30, 2024. App. A ("Op."). Without an extension, the time for filing a petition for a writ of certiorari will expire on March 31, 2025. Jurisdiction to review the judgment of the Federal Circuit in this case will be invoked under 28 U.S.C. § 1254(1).

## BACKGROUND

A patent is invalid if the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time of the invention. 35 U.S.C. § 103. In *Graham v. John Deere Co. of Kansas City*, this Court held that, in assessing obviousness, courts must examine not only the "differences between the prior art and the claims at issue" but also broader, practical "indicia" of nonobviousness, such as "commercial success, long felt but unsolved needs, [and] failure of others." 383 U.S. 1, 17-18 (1966). This case concerns the proper role of those objective indicia in the obviousness analysis.

1. In the 1990s, Purdue developed the original formulation of OxyContin®, an extended-release pain medication that offered substantial medical advantages when taken as directed. Op. 2. But it quickly became clear that OxyContin, like

other opioid pain medications, was subject to severe abuse and misuse, because the tablets could be easily crushed and then snorted or liquified and injected. *Id.* The public-health crisis associated with abuse of original OxyContin seriously threatened the viability of the medication, and abuse deterrence was seen as "one of the highest unmet needs in the market"—a need that both Purdue and Purdue's competitors actively sought to address. Federal Circuit Appendix ("Appx") 6374 (Rosen 341:24-25).

After nearly a decade and hundreds of millions of dollars in research and development, Purdue invented a novel, abuse-deterrent formulation of OxyContin that addressed the acute public-health need for such a formulation. *See* Appx6854. Purdue's invention is embodied in the abuse-deterrent patents at issue in this case. Those patents claim a novel curing method in which tablets containing oxycodone and the polymer polyethylene oxide ("PEO") are "compression shaped," and then "air cured by heated air, without compression," to produce a hardened, crush-resistant tablet that deters abuse while maintaining OxyContin's unique extended-release profile. *See, e.g.*, Appx302 (cls. 1, 3); Op. 3-4.

The Food and Drug Administration ("FDA") approved Purdue's reformulated OxyContin in 2010. Op. 6. In 2013, after extensive review of post-marketing studies, FDA also approved abuse-deterrent labeling for reformulated OxyContin—the first time FDA had ever done so for any opioid pain medication. *See FDA Actions on OxyContin Products, 4/16/2013*, FDA (current as of Mar. 2, 2022), https://www.fda.gov/drugs/information-drug-class/fda-actions-oxycontin-products-

4162013. At the same time, FDA formally withdrew original OxyContin from the market, deeming it comparatively unsafe relative to reformulated OxyContin, and pronounced that it would not approve any generic version of the original formulation—underscoring the grave threat posed by the abuse problem that Purdue's patents addressed. Appx6809-17.

Reformulated OxyContin has been a resounding success, both commercially and practically—allowing patients to receive much-needed pain relief while reducing the risk of abuse and misuse of the medication. Reformulated OxyContin is both the highest-selling extended-release opioid and the most prescribed brand-name extended-release opioid on the market. Appx5401 (Sharma 368:20-25).

2. In August 2020, Accord sought FDA approval of a generic version of reformulated OxyContin, using Purdue's patented technology. Op. 7; Appx1807. Purdue filed suit, and Accord stipulated to infringement but argued that Purdue's patents were invalid for obviousness. Op. 7. Over the course of a three-day bench trial, Purdue presented extensive evidence of objective indicia of nonobviousness, including OxyContin's commercial success in a highly competitive market, Appx5367-77 (Rosen 334:23-344:21); Appx5401-02 (Sharma 368:20-369:6); FDA's initial skepticism regarding the abuse-deterrent formulation, Appx5462 (Bley 429:17-24); Appx9122; and the failure of other companies to develop a viable abuse-deterrent formulation, Appx5461-62, 5469 (Bley 428:3-429:8, 436:7-9); Appx5340 (Mannion 307:7-8). Accord's own witnesses likewise acknowledged that Purdue's abuse-deterrent patents "definitely" solved "a long felt, but unmet need in the art,"

Appx5704-05 (Appel 671:22-672:2); that reformulated OxyContin had substantial "marketplace success"; and that "[t]here's no doubt" that OxyContin's sales would have been lower without its abuse-deterrent features, Appx5690, 5693 (Hoffman 657:7-13, 660:19-22); *see also* Appx5402 (Sharma 369:3-6).

The district court nevertheless held Purdue's patents invalid for obviousness, discounting the objective indicia of nonobviousness. The court acknowledged reformulated OxyContin's commercial success, but found that success was not "due to the claimed features of the invention." Appx23-24. Instead, it attributed OxyContin's success solely to "Purdue's existing monopoly"—although Purdue had no blocking patent or other exclusivity over oxycodone that would have precluded competitors from developing an abuse-deterrent oxycodone medication. Appx23. Further, although the district court recognized that developing an abuse-deterrent product was critical to OxyContin's continued commercial viability, it concluded that "a lack of commercial failure is not the same as commercial success." *Id.* As to industry skepticism, the court agreed that FDA had displayed "skepticism" of Purdue's invention but found that skepticism irrelevant because it was "commensurate with the fact that this was the first extended-release opioid to receive abuse-deterrent labelling." Appx24. The district court similarly dismissed Purdue's evidence of failure of others, reasoning that the evidence of prior failures lacked a sufficient connection to "claimed features" of Purdue's patent. Appx25 (citation omitted).

3. The Federal Circuit affirmed. With respect to commercial success, it concluded that the district court had correctly found "no nexus between the claimed invention and the commercial success," because Purdue's new formulation replaced sales of the original formulation and the record did not demonstrate an *increase* in sales of OxyContin. Op. 22. The Federal Circuit did not acknowledge that the patented invention had preserved OxyContin's commercial viability, averting the risk that a competitor would develop an abuse-deterrent formulation that would displace OxyContin. The Federal Circuit similarly dismissed Purdue's evidence of skepticism because that evidence purportedly lacked a sufficient connection with specific claim limitations of the patent. Op. 23. It reasoned that FDA's skepticism was "about applying the abuse-deterrent label"—a feature not expressly claimed in the asserted patents. *Id.* Finally, the Federal Circuit deemed Purdue's evidence of the failure of others irrelevant. It again reasoned that Purdue "had not established a nexus between the alleged" failures "and the claimed invention," because it was not clear whether those failures were caused by a lack of "the claimed features" of Purdue's patents. *Id.* (citation omitted). At no point in its analysis did the Federal Circuit holistically consider the undisputed facts that Purdue had managed to develop a desperately needed and enormously valuable formulation in a highly competitive market in which no other competitor had succeeded in doing so.

## REASONS FOR GRANTING THE APPLICATION

The Federal Circuit's decision warrants this Court's intervention. Its rigid, short-shrift analysis of the objective indicia of nonobviousness reflects a trend in the Federal Circuit of applying stringent and inflexible rules that effectively negate the

role of the objective indicia in the obviousness inquiry. That approach conflicts with this Court's precedents holding that the objective indicia are a critical component of the obviousness analysis and requiring an "expansive and flexible approach" to the analysis, and it has undermined the protections—and incentives—afforded by patents. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007). Applicants seek a 30-day extension of time to prepare a certiorari petition that addresses this important issue of patent law.

1. The Federal Circuit's decision in this case is irreconcilable with this Court's precedents. In *Graham v. John Deere Co. of Kansas City*, this Court identified four factors that must be considered collectively before concluding that an invention is obvious and therefore invalid under 35 U.S.C. § 103: (1) "the scope and content of the prior art"; (2) "differences between the prior art and the claims at issue"; (3) "the level of ordinary skill in the pertinent art"; and (4) objective "indicia" of nonobviousness, such as "commercial success, long felt but unsolved needs, [and] failure of others." 383 U.S. 1, 17-18 (1966).

While the first three factors focus on "highly technical facts," the objective indicia of nonobviousness—sometimes called "secondary considerations"—are designed to situate the obviousness analysis in the context of the broader market and train the court's focus on practical considerations, including "economic and motivational" issues. *Id.* at 17-18, 35-36. In doing so, the objective indicia play a critical role in the obviousness analysis by helping to prevent courts from "'slipping into use of hindsight'" and "read[ing] into the prior art the teachings of the invention

at issue." *Id.* at 36 (citation omitted). Courts must therefore "look at any secondary considerations that would prove instructive" in conducting "an expansive and flexible" obviousness analysis. *KSR*, 550 U.S. at 415.

Far from conducting any such flexible analysis here, however, the Federal Circuit disregarded overwhelming and uncontested evidence of commercial success and other objective indicia by applying a rigid "nexus" requirement. In particular, the Federal Circuit gave Purdue no credit for commercial success based on the notion that Purdue merely "transferr[ed]" its sales of original OxyContin to the new formulation. Op. 22 (citation omitted). But that analysis flatly ignored the existential threat that abuse posed to original OxyContin; the fact that the patented invention preserved the commercial viability of the product; and the fact that competitors were also racing to develop abuse-deterrent formulations that could have displaced OxyContin—all of which strongly indicates that an abuse-deterrent formulation "would successfully have been brought to market sooner, in response to market forces, had the idea been obvious." *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir.), *cert. denied*, 546 U.S. 972 (2005).

Similarly, the Federal Circuit discounted FDA's skepticism because it pertained to abuse deterrence, which was not specifically claimed in the patent. Op. 23. In doing so, it again refused to consider the common-sense import of the evidence—namely, that Purdue's novel invention indisputably produced an effective abuse-deterrent formulation, overcoming FDA skepticism to solve "a long felt, but unmet need." Appx5704-05 (Appel 671:22-672:2). And the Federal Circuit likewise

ignored that Purdue's competitors actively sought—and failed—to produce abuse-deterrent formulations, again insisting that such evidence would be relevant only if directly connected to a "claimed feature[]" of Purdue's patents. Op. 23 (citation omitted). In short, the Federal Circuit refused to consider Purdue's evidence through the "expansive and flexible" lens this Court's precedents require, and as a result, it virtually eliminated the objective indicia as a meaningful component of the obviousness inquiry. *KSR*, 550 U.S. at 415.

This cramped analysis reflects a larger trend in the Federal Circuit, in which panels routinely negate the objective indicia by demanding a rigid "nexus" to specific claim limitations, while refusing to flexibly consider the evidence in the broader context of the market. *See, e.g.*, *WesternGeco LLC v. ION Geophysical Corp. (In re WesternGeco LLC)*, 889 F.3d 1308, 1331 (Fed. Cir. 2018) (discounting commercial success where patent holder purportedly failed to show that "product sales" were "a direct result of the unique characteristics of the claimed inventions"), *cert. denied*, 586 U.S. 1151 (2019). This mode of analysis has elicited criticism from some judges on the Federal Circuit and produced inconsistent results and fractured opinions across the Federal Circuit's obviousness jurisprudence.

Judge Moore, for example, has explained that "[r]equiring patentees to prove that objective evidence is tied to a specific claim element—and only that claim element—runs counter to the statutory" scheme. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331-32 (Fed. Cir. 2016). Yet other panels of the Federal Circuit apply a far more stringent and narrow analysis. In *Tokai Corp. v. Easton Enterprises, Inc.*, for

example, the majority discounted uncontested evidence of commercial success due to an alleged lack of "nexus," because some of the benefits of the patented feature existed in the prior art. 632 F.3d 1358, 1370 (Fed. Cir. 2011). In dissent, Judge Newman criticized the majority's analysis, emphasizing that it had improperly "ignored [the patentee's] evidence" of commercial success by invoking the "nexus" requirement. *Id.* at 1379; *see also, e.g.*, *Acorda Therapeutics, Inc. v. Roxane Laboratories, Inc.*, 903 F.3d 1310, 1354 (Fed. Cir. 2018) (Newman, J., dissenting) (arguing that majority improperly discounted compelling evidence of nonobviousness), *cert. denied*, 140 S. Ct. 111 (2019). Simply put, members of the Federal Circuit "disagree[] over the role objective indicia play in the court's analysis of the ultimate determination of obviousness." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1089 (Fed. Cir. 2016) (en banc) (Reyna, J., dissenting), *cert. denied*, 583 U.S. 963 (2017).

This "important issue[]" warrants this Court's review. *Id.* Obviousness is the most common challenge to patent validity in district courts and in post-grant proceedings before the U.S. Patent and Trademark Office. *See id.* at 1074 (Dyk, J., dissenting); 2A Donald S. Chisum, *Chisum on Patents* § 5.06 (2025, Lexis) ("The nonobviousness requirement of Section 103 is the most important and most litigated of the conditions of patentability."). And this Court's guidance is critical to ensuring consistent and appropriate consideration of the objective indicia when conducting the obviousness analysis. Absent this Court's intervention, the Federal Circuit's inflexible approach risks over-invalidation of patents, which will, in turn, blunt "incentive[s]" for innovation, depriving the public of critical pharmaceutical advances

like the one at issue here. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1386, 1383 (Fed. Cir. 2006).

2. Applicants respectfully request a 30-day extension of time within which to prepare and file a petition for a writ of certiorari in this case. The requested extension is warranted to permit counsel to research and, as appropriate, refine the issues for this Court's review and prepare a petition that addresses the important questions raised by this case in the most direct and efficient manner for the Court's consideration. The additional time also will assist potential amici in considering this case. In addition, the undersigned counsel has been and will be heavily engaged with the press of other matters during this period. The requested extension will not meaningfully change the timeline for oral argument or decision if certiorari is granted, as the case would not be considered on the merits until the October 2025 Term under either the existing or extended schedules.

## CONCLUSION

Accordingly, Applicants respectfully request a 30-day extension of time, to and including April 30, 2025, within which to file a petition for a writ of certiorari in this case.

Respectfully submitted,

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March 10, 2025

# APPENDIX A

NOTE: This disposition is nonprecedential.

# United States Court of Appeals for the Federal Circuit

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**PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES,**
*Plaintiffs-Appellants*

**v.**

**ACCORD HEALTHCARE, INC.,**
*Defendant-Appellee*

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2023-1953

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Appeal from the United States District Court for the District of Delaware in No. 1:20-cv-01362-RGA, Judge Richard G. Andrews.

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Decided: December 30, 2024

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GREGORY G. GARRE, Latham & Watkins LLP, Washington, DC, argued for plaintiffs-appellants. Also represented by ALEXANDER GEORGE SIEMERS, MARGARET UPSHAW; DANIEL BROWN, New York, NY; DAVID KOWALSKI, San Diego, CA; GREGORY A. CASTANIAS, JENNIFER L. SWIZE, Jones Day, Washington, DC; GASPER LAROSA, JOHN JOSEPH NORMILE, JR., New York, NY; PABLO DANIEL HENDLER, Potomac Law Group PLLC, New York, NY.

BEN MAHON, McAndrews, Held & Malloy, Ltd., Chicago, IL, argued for defendant-appellee. Also represented by BRADLEY P. LOREN, ALEJANDRO MENCHACA.

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Before PROST, REYNA, and TARANTO, *Circuit Judges*.

PROST, *Circuit Judge*.

Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and Rhodes Technologies (collectively, "Purdue") appeal from the final judgment of the U.S. District Court for the District of Delaware, which held all asserted claims of the five challenged patents invalid as obvious under 35 U.S.C. § 103. *Purdue Pharma L.P. v. Accord Healthcare, Inc.*, 669 F. Supp. 3d 286 (D. Del. 2023). We affirm.

## BACKGROUND

### I

This case involves patents related to Purdue's formulation of extended-release oxycodone, sold as Oxycontin. Oxycodone was first developed in the 1910s. J.A. 1822. In the 1990s, Purdue developed an extended-release formulation, approved by the FDA in 1995. Appellants' Br. 5. "Unfortunately, oxycodone has become one of the most frequently abused prescription medications and some formulations can be dissolved and injected intravenously." Oxycodone, https://www.ncbi.nlm.nih.gov/books/NBK547955/#:~:text=Oxycodone; Appellants' Br. 1 ("The original [OxyContin] tablets could easily be crushed and then snorted or injected to produce an immediate high, causing severe risks of addiction, overdose, and death."). Additionally, the process of creating oxycodone hydrocholoride, "a well-known molecule [that] has been synthesized for decades," Appellee's Br. 4 (citing J.A. 5066–67), results in the creation of 14-hydroxy. 14-hydroxy, an alpha beta unsaturated ketone ("ABUK"), is "a potentially genotoxic (i.e., carcinogenic)

impurity." Appellants' Br. 2. In other words, oxycodone is often abused and may be genotoxic when consumed in large quantities.

The asserted patents in this case attempt to address these two problems. The first group of patents—U.S. Patent Nos. 9,763,933 ("the Mannion '933 patent"), 9,775,808 ("the '808 patent"), and 9,763,886 ("the '886 patent") (collectively, "the Abuse-Deterrent Patents")—are directed to a crush-resistant formulation of OxyContin, "mak[ing] it hard enough to resist crushing and viscous enough to deter intravenous users." *Purdue Pharma*, 669 F. Supp. 3d at 292. These two qualities help to minimize some of the more common methods of abusing OxyContin. The second group of asserted patents—U.S. Patent Nos. 9,073,933 ("the '933 patent") and 9,522,919 ("the '919 patent") (collectively, "the Low-ABUK Patents")—are directed to a formulation and process of reducing 14-hydroxy in OxyContin, thereby reducing toxicity concerns. Each group of patents is discussed in more detail below.

A

The Abuse-Deterrent Patents, which share a common specification, claim a "formulation of oxycodone using the polymer polyethylene oxide ('PEO')." Appellants' Br. 1. Claim 3 of the '808 patent, which depends from claim 1, is illustrative. Together they recite:

> 1. A pharmaceutical composition comprising:
>
> at least one active agent comprising oxycodone or a pharmaceutically acceptable salt thereof;
>
> at least one high molecular weight polyethylene oxide (PEO), having an approximate molecular weight of from 1 million to 15 million;
>
> at least one of an additive and a film coating; and

> optionally at least one low molecular weight PEO having an approximate molecular weight of less than 1,000,000; wherein
>
> (a) the active agent and high molecular weight PEO are combined in a solid oral extended release dosage form that is (i) compression shaped, (ii) air cured by heated air, without compression, for at least about 5 minutes at a temperature above the softening temperature of the high molecular weight PEO, (iii) cooled, and (iv) hardened;
>
> (b) the high molecular weight PEO comprises at least about 30% (by weight) of the dosage form;
>
> (c) the molecular weight of each PEO is based on rheological measurements; and
>
> (d) the total weight of the dosage form is calculated by excluding the combined weight of said film coatings.

*Id.* at claim 1.

> 3. A pharmaceutical composition according to claim 1, wherein the curing temperature is from about 70° C. to about 85° C. and the curing time is from about 10 minutes to about 10 hours.

*Id.* at claim 3.

Relevant to this appeal is the curing method recited in these claims. The curing method has four general steps: (1) "the tablet must be 'compression shaped,'" e.g., *id.* at claim 1; (2) the tablet "must be 'air cured by heated air, without compression,'" e.g., *id.*; (3) "the heating must be done for 'about 10 minutes to about 10 hours,'" e.g., *id.* at claim 3; and (4) "the heating must be done above the softening temperature of PEO and at about 70–85° C or 65–90° C," Mannion '933 patent claim 3; '808 patent claim 3; '886 patent claim 6. *See* Appellants' Br. 7–8. "This process produces a hardened tablet resistant to crushing,

but also capable of dissolving and relieving pain over an extended period of time." *Id.* at 11. Purdue identifies two alleged points of novelty: (1) "[N]o one had ever cured PEO tablets using heated air without simultaneous compression or at the times and temperatures"—i.e., the claims here require the alleged novel concept of compression then heating. And (2) the recited process had the "surprising benefit" of "decreas[ing] . . . tablet density that promoted faster gelling." *Id.* Allegedly, this faster gelling makes it more difficult to abuse the oxycodone tablets because the drug becomes gelatinous in the nasal cavity (making it harder to ingest) and making it hard to expel through a syringe. *Id.* at 11–12.

B

The Low-ABUK Patents, which share a common specification, address a different problem: reducing the potential of genotoxicity from the molecule 14-hydroxy created during the manufacturing of oxycodone. "The synthesis process involves three steps: (1) oxidation of thebaine to form 14-hydroxy; (2) hydrogenation of 14-hydroxy to form oxycodone; and (3) addition of hydrochloric acid to form a salt." Appellee's Br. 4–5; *see also* Appellants' Br. 16.

By the early 2000s, the FDA had grown concerned about this potential toxicity and began requesting that drug manufactures reduce 14-hydroxy in their oxycodone products. To reduce 14-hydroxy levels, Purdue first attempted to ensure that the hydrogenation step was run to completion—i.e., ensuring "all detectable 14-hydroxy was converted to oxycodone base." Appellants' Br. 16. But this did not solve the problem. During the third step of the process, 14-hydroxy would reform in the drug. Through further research, Dr. Kupper, listed as an inventor on the Low-ABUK Patents, identified another impurity in oxycodone, known as 8α. *Id.* at 17. The Low-ABUK Patents explain that 8α is converted to 14-hydroxy under acidic conditions, such as salt formation, which explains why

residual 14-hydroxy was reappearing in the third manufacturing step. It is undisputed that "[t]he Low ABUK Patents were the first to report the presence of the molecule 8α in the synthesis of oxycodone." Appellee's Br. 5; *see also* Appellants' Br. 17 ("Dr. Kupper . . . discover[ed] a previously unknown impurity called 8α.").

Relevant to this appeal are the low levels of 14-hydroxy and the 8α limitations. The asserted Low-ABUK Patent claims have slight differences among them regarding the amount of 14-hydroxy and 8α recited. For example, claim 3 of the '933 patent, which depends from claim 1, recites:

> 1. An oxycodone hydrochloride composition which comprises at least 95% oxycodone hydrochloride, 8α, 14-dihydroxy-7, 8-dihydrocodeinone, and less than 25 ppm of 14-hydroxycodeinone.

*Id.* at claim 1.

> 3. The oxycodone hydrochloride composition of claim 1, having less than 10 ppm of 14-hydroxycodeinone.

*Id.* at claim 3.

Claim 11 of the '933 patent, which depends from claim 10, recites "removing 8α" from the composition, and claim 21 of the '919 patent recites a specific ratio involving 8α and 14-hydroxy in the composition: "the ratio of 8α, 14-dihydroxy-7, 8-dihydrocodeinone to oxycodone HCl is 0.04% or less."

## II

In 2010, Purdue developed, and the FDA approved, a new formulation of OxyContin. Four out of the five

asserted patents are listed in the FDA's Orange Book as purportedly covering this reformulation.[1]

In August 2020, Accord Healthcare, Inc. ("Accord") submitted an Abbreviated New Drug Application ("ANDA") for approval to market a generic version of OxyContin. Purdue then filed suit in October 2020, asserting that Accord had infringed, among others, the Mannion '933 patent, the '808 patent, the '886 patent, the '933 patent, and the '919 patent through the act of filing the ANDA. *See* 35 U.S.C. § 271(e)(2)(A). Accord stipulated to infringement, and the district court held a three-day bench trial in September 2021 on the sole issue of invalidity. The claims at issue were claim 3 of the Mannion '933 patent, claim 3 of the '808 patent, claim 6 of the '886 patent, claims 3 and 11 of the '933 patent, and claim 21 of the '919 patent. The court held all asserted claims were invalid as obvious.

As to the Abuse-Deterrent Patents, Accord argued that the asserted claims were obvious in view of five references: Bartholomaus,[2] McGinity,[3] and three other references referred to as "Oven Art."[4] "Bartholomaus and McGinity

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[1] "The Mannion '933, '808, '933, and '919 patents are all listed in the FDA's Orange Book for OxyContin. The '886 patent is not." *Purdue Pharma*, 669 F. Supp. 3d at 293.

[2] U.S. Patent Publication No. 2005/0031546 ("Bartholomaus"), J.A. 9417–30.

[3] U.S. Patent No. 6,488,963 ("McGinity"), J.A. 9408–16.

[4] Zezhi J. Shao et al., *Effects of Formulation Variables and Post-compression Curing on Drug Release from a New Sustained-Release Matrix Material: Polyvinylacetate-Povidone*, 6 Pharm. Dev. and Tech. 2, 257 (2001) ("Shao"), J.A. 9431–38; Nashiru Billa et al., *Diclofenac Release from Eudragit-Containing Matrices and Effects of Thermal*

broadly teach PEO matrix tablets formed with simultaneous compression and heating. The three Oven Art references broadly teach curing non-PEO matrix tablets in ovens after compression." *Purdue Pharma*, 669 F. Supp. 3d at 297. The district court summarized the dispute as follows:

> The parties disagree about whether a [person of ordinary skill in the art] would have been motivated to make PEO tablets with sequential compression and heating, and whether there would have been a reasonable expectation of success in doing so. Second, no prior art used the same combinations of curing time and temperature ranges as those disclosed in the Abuse-Deterrent Patents. The parties disagree about whether routine experimentation by a [person of ordinary skill in the art] would have yielded the times and temperatures disclosed in the patents.

*Id.* (internal citations omitted).

As to the first dispute (i.e., sequential compression and heating), the district court agreed with Accord that a person of ordinary skill in the art would be motivated "to modify Bartholomaus and McGinity because the processes disclosed in those references would not have been suitable for large-scale production," and a person of ordinary skill in the art would have "naturally turn[ed] to ovens in either scaling up Bartholomaus or adapting McGinity to more commonly available equipment." *Id.* at 297–98. The

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*Treatment*, 24 Drug Dev. and Indus. Pharm. 1, 45–50 (1998), J.A. 9439–45; Marcelo O. Omelczuk & James W. McGinity, *The Influence of Thermal Treatment on the Physical-Mechanical Properties of Tablets Containing Poly(DL-Lactic Acid)*, 10 Pharm. Rsch. 4, 542 (1992) ("Omelczuk"), J.A. 9446–96.

district court also found that a person of ordinary skill in the art would have had a reasonable expectation of success in producing hardened tablets with sequential compression and then heating the tablets. As to the second dispute (the times and temperatures for curing tablets), the district court again agreed with Accord, based on expert testimony, that the times and temperatures recited in the patents' claims would have been the "product of routine experimentation." *Id.* at 303. The court also considered Purdue's alleged secondary considerations and concluded that they do not weigh in favor of nonobviousness. Therefore, the district court concluded that the Abuse-Deterrent Patents would have been invalid as obvious over the prior art. *Id.* at 306.

As to the Low-ABUK Patents, "the parties' disputes [fell] into two categories: the obviousness of low levels of 14-hydroxy and the obviousness of the inventors' discovery of 8α." *Id.* at 312. The district court concluded that a person of ordinary skill in the art would have been motivated to lower 14-hydroxy levels based on FDA communications suggesting that it might require lower ABUK levels in the future and that such person would have had a reasonable expectation of success in doing so based on routine experimentation. *Id.* at 313–17. With respect to the 8α limitations, the court addressed the parties' arguments on a limitation-by-limitation basis. For claim 3 of the '933 patent, the claim recited only the existence of 8α in the composition, and because Purdue did not dispute 8α would be present, the court found this inherent property would have been obvious and that "the identification of 8α itself was merely routine." *Id.* at 318. With respect to claim 11 of the '933 patent (reciting "removing 8α") and claim 21 of the '919 patent (reciting a specific ratio of 8α), the court agreed with Accord's unrebutted expert testimony that a person of ordinary skill in the art "would be able to monitor the levels of 8α in order to reduce the ratio of 8α to oxycodone," and given that a person of ordinary skill in the art "would have

been able to routinely identify 8α or [a related impurity] 8β as the source of extra 14-hydroxy, . . . removing 8α, either directly or by removing 8β—is also obvious." *Id.* at 320. The court therefore concluded that the Low-ABUK Patents' asserted claims would have been obvious.

Purdue timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

## DISCUSSION

"Obviousness is a question of law, reviewed de novo, based upon underlying factual questions which are reviewed for clear error following a bench trial." *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1300 (Fed. Cir. 2007) (cleaned up). "The presence or absence of a motivation to arrive at the claimed invention, and of a reasonable expectation of success in doing so, are questions of fact." *Amgen Inc. v. Sandoz Inc.*, 66 F.4th 952, 960 (Fed. Cir. 2023). "A factual finding is only clearly erroneous if, despite some supporting evidence, we are left with the definite and firm conviction that a mistake has been made." *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 728 (Fed. Cir. 2017) (citations omitted).

"A patent for a claimed invention may not be obtained . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention . . . ." 35 U.S.C. § 103. "Obviousness is based on underlying factual findings, including: (1) the level of ordinary skill in the art; (2) the scope and content of the prior art; (3) the differences between the claims and the prior art; and (4) secondary considerations of nonobviousness, such as commercial success, long-felt but unmet needs, failure of others, and unexpected results." *Prometheus Labs., Inc. v. Roxane Labs., Inc.*, 805 F.3d 1092, 1097 (Fed. Cir. 2015) (citing *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007); *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)).

Purdue appeals the district court's obviousness conclusions regarding both the Abuse-Deterrent Patents and the Low-ABUK Patents. We address each set of patents, and the alleged district court errors identified by Purdue, in turn.

## I

For the Abuse-Deterrent Patents, Purdue argues that the district court erred in (A) finding a motivation to combine with a reasonable expectation of success and (B) dismissing Purdue's arguments related to secondary considerations. We disagree.

### A

Purdue raises a litany of arguments related to motivation to combine and reasonable expectation of success: that the district court (1) failed to consider the claims as a whole; (2) made improper "inferential leaps" by focusing solely on oven tools without addressing the effect of heating tablets without compression; (3) improperly invoked *KSR*'s obvious-to-try rationale; (4) "applied the wrong legal standard" with respect to reasonable expectation of success; (5) erred by relying on "a general discussion" in the prior art to support its conclusion that compressing, then heating, would have been obvious; and (6) erred by relying on "routine experimentation" to find that the time and temperature limitations of the Abuse-Deterrent Patent claims would have been obvious. The first of these arguments is not directed to a specific limitation in the claims; the next four arguments are directed to whether a person of ordinary skill would have found it obvious to compress and then heat the tablets (as recited by the claims) rather than simultaneously compression and heating; and the last argument is directed at the various time and temperature requirements for curing a tablet as recited in the claims.

1

We start with Purdue's argument that the district court erred by failing to analyze the claims as a whole. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1086 (Fed. Cir. 2008) ("The determination of obviousness is made with respect to the subject matter as a whole, not separate pieces of the claim."). The requirement to address "claims as a whole" has normally been invoked when a tribunal has ignored elements of the claims, looked solely to the inventive aspects of the claims, or erred by failing to address specific (rather than generalized) claim limitations. *See, e.g.*, *Para-Ordnance Mfg., Inc. v. SGS Importers Int'l, Inc.*, 73 F.3d 1085, 1087 (Fed. Cir. 1995) ("[T]he claimed invention should be considered as a whole; there is no legally recognizable 'heart' of the invention.").

The district court did not make such an error here. Purdue's argument essentially relies on a single footnote in the district court's opinion as the basis for asserting a legal error. The footnote states:

> This issue relates to both of the differences between the claims and the prior art noted previously. I discuss whether the experimentation would be routine when discussing the second difference of time and temperature ranges. For the purposes of reasonable expectation of success, I only ask whether a [person of ordinary skill in the art] could reasonably expect to make hardened tablets by combining Bartholomaus and McGinity at the claimed times and temperatures.

*Purdue Pharma*, 669 F. Supp. 3d at 301 n.5. The footnote appears during a discussion of reasonable expectation of success of the "sequential compression and heating" limitations. Purdue reads this footnote as "analyz[ing] the claim limitations in isolation—looking initially (1) to whether the change from simultaneous to sequential compression and heating would have been obvious; and then

separately (2) to whether the time and temperature parameters for the applicable process would have been obvious as discoverable through routine experimentation." Appellants' Br. 32.

We read this footnote as clarifying the specific issues the district court discussed at that portion of its opinion. As a practical matter, a court must normally address one issue at a time, and in patent cases, it is the norm for both parties and courts to discuss disputed claim limitations sequentially. Purdue's argument is particularly unpersuasive because, despite this footnote, the court substantively discussed the "time and temperature" limitations while analyzing the parties' arguments directed to the "sequential compression and heating" limitations. *See Purdue Pharma*, 669 F. Supp. 3d at 302 (discussing "how generally to find optimal ranges," the reasonable expectation of success in achieving those ranges, and the application of common sense in conjunction with the Oven Art in finding that "heating times in ovens might be longer"). Therefore, we disagree that the court erred by failing to address the claims as a whole.[5]

2

Next, Purdue argues that the district court made an improper "inferential leap" in determining that a person of ordinary skill in the art would have been motivated to

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[5] Purdue similarly argues that the court erred in its reasonable-expectation-of-success analysis based on alleged "piecemeal analysis." Appellants' Br. 42 ("[T]he district court ignored the relevant time and temperature parameters entirely."). This argument fails for the same reasons articulated here—the court did in fact address the claims as a whole. It thoroughly addressed the "time and temperature" limitations, even in discussing the "sequential compression and heating" limitations.

combine Bartholomaus and McGinity with the Oven Art when the court said, "[i]t is not much of a leap to infer that ovens would also be useful for applying heat to harden the matrix tablets." *Id.* at 300.

The court relied on multiple factual findings that all support the conclusion that it would have been obvious to try ovens for heating tablets. For example, Accord presented expert testimony on the availability of ovens and the prior use of ovens to heat tablets (including matrix tablets made from several different polymers), and "Shao specifically taught that the heat curing made its tablets harder." *Id.* at 299–300. "Plaintiffs' witnesses did not provide any testimony to the contrary." *Id.* at 299. Thus, Purdue's claims that the court relied on a "naked inference" is unsupported by the record. Appellants' Br. 34.

3

Purdue next argues that the district court legally erred by invoking *KSR*'s obvious-to-try test when it concluded that "employing a commonly available tool [i.e., ovens] to apply heat to tablets is obvious to try." *Id.* at 36 (quoting *Purdue Pharma*, 669 F. Supp. 3d at 300). *KSR* explained that a particular combination of elements may be obvious to try "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions." 550 U.S. at 421. Purdue argues that the district court ran afoul of this standard because it "made no finding that there were a finite number of predictable solutions, and the record plainly shows the opposite." Appellants' Br. 36. We again disagree.

To set the stage for this argument, Purdue frames the problem to be solved as "abuse by crushing" and identifies several possible solutions to opioid abuse unrelated to physically hardening tablets. *Id.* at 36–40 (listing antagonists, aversive agents, and covalently-bound inactive moieties). In contrast, Accord frames the problem to be solved as a scalable process for heating PEO with a finite number

of possible solutions: ovens, pan coaters, and fluid bed dryers. Appellee's Br. 21. We disagree with Purdue's framing of the problem to be solved that underlies the motivation to combine Bartholomaus and McGinity with the Oven Art at least because it ignores what was already known and taught in the prior art.

As Purdue recognizes, *KSR* involved a situation, where "there were only a very small number of possible locations for attaching the pedal sensor at issue because the prior art already taught the need to place it on a fixed, non-moving point on the pedal." Appellants' Br. 36. Baked into this characterization is the recognition that *KSR* was focused on why a person of ordinary skill would be motivated to address certain problems in view of the prior art. Indeed, the Court's detailed description of the prior art and its application in the obvious-to-try rationale supports the notion that the problem to be solved (and the possible solutions) should take into consideration the advancements and teachings already in the prior art. *See KSR*, 550 U.S. at 424–25 ("For a designer starting with Asano [a prior-art reference], the question was where to attach the sensor. The consequent legal question, then, is whether a pedal designer of ordinary skill starting with Asano would have found it obvious to put the sensor on a fixed pivot point. The prior art discussed above leads us to the conclusion that attaching the sensor where both KSR and [the inventor] put it would have been obvious to a person of ordinary skill."). *KSR* did not abstract back out to the larger problem (e.g., designing an adjustable pedal having an electronic sensor) and ask how many different ways that could be done (e.g., redesigning the whole car), completely disconnected from where the prior art would have already led a person of ordinary skill in the art.

Similarly, here, Bartholomaus and McGinity already taught making hardened tablets, including PEO anti-abuse tablets with compression and heating. We therefore conclude that Accord's and the district court's framing of

the problem—scalability of hardened tablets—is more apt here. *See* Appellee's Br. 21; *Purdue Pharma*, 669 F. Supp. 3d at 297 ("[A] [person of ordinary skill in the art] would then seek to modify Bartholomaus and McGinity because the processes disclosed in those references would not have been suitable for large-scale production."). To address this problem, Accord's expert testified "that ovens were commonly available and used to heat tablets." *Purdue Pharma*, 669 F. Supp. 3d at 299. As explained above, "Plaintiffs' witnesses did not provide any testimony to the contrary." *Id.* In other words, the court based its conclusion on unrebutted expert testimony and "the absence of testimony about other heating tools." *Id.* at 300. In this absence, the court was presented with a finite number of solutions to the problem of scalability for creating anti-abuse tablets with compression and heating. On this record, the court's reliance on the obvious-to-try rationale was a natural choice.

Because we reject the premise that the problem to be solved here is general "abuse deterrence," and Purdue's entire argument was based on this framing of the problem, we reject Purdue's argument that the district court erred as a matter of law.

4

Next, Purdue argues that the court "applied the wrong legal standard" with respect to reasonable expectation of success by asking whether a person of ordinary skill in the art "might" or "could" have reasonably expected success instead of asking whether a person of ordinary skill in the art "would" have reasonably expected success. Appellants' Br. 41. We disagree that the court applied the wrong standard.

While the district court did use the words "could" and "might" when discussing the reasonable expectation of success in some circumstances, Purdue takes these isolated uses of "could" and "might" out of context. For example, at

least two instances of the use of "could" were based on a framing of what Purdue argued—not what question the court was addressing. *Purdue Pharma*, 669 F. Supp. 3d at 301 ("Plaintiffs argue that there could not have been a reasonable expectation of success . . . ."); *id.* ("They argue that . . . a [person of ordinary skill in the art] could not have reasonably expected success."); *cf. id.* at 302 ("I was not persuaded, based on [Purdue's expert] testimony . . . that a [person of ordinary skill in the art] could not still reasonably expect . . . .").

Regardless, the court made numerous findings about what a person of ordinary skill in the art "would" have reasonably expected. *See id.* at 300 ("I consider whether a [person of ordinary skill in the art] *would* have had a 'reasonable expectation of success' . . . ."); *id.* at 301 ("I think *there is* a reasonable expectation of success . . . ." (emphasis added)); *id.* ("a [person of ordinary skill in the art] *would expect* . . . to be able to achieve . . ." (emphasis added)); *id.* at 302 ("I find there was clear and convincing evidence that a [person of ordinary skill in the art] *would* reasonably expect . . ." (emphasis added)). These findings and conclusions demonstrate that the court applied the correct legal standard and support the court's conclusion that a person of ordinary skill in the art "would reasonably expect to produce hardened tablets by heating PEO tablets to their melting points in an oven." *Id.* A few references as to what "could" be expected does not necessarily indicate the court legally erred. For example, in *Belden Inc. v. Berk-Tek LLC*, even where the Patent Trial and Appeal Board ("Board") twice opined on what "could" have been done, we still concluded that the Board's findings were sufficient because the Board "did not stop there" but additionally made findings as to what the prior art taught and what a person of ordinary skill in the art "would have recognized." 805 F.3d 1064, 1073–74 (Fed. Cir. 2015). The same is true here.

Read in context, we conclude that the court did not apply the incorrect legal standard.

5

Next, Purdue argues that the district court erred by relying on "a general discussion" in the prior art to support its conclusion that a person of ordinary skill in the art would have had a reasonable expectation of success of compressing and then heating the tablets. We disagree.

It is undisputed that Bartholomaus teaches crush-resistant PEO tablets. *Purdue Pharma*, 669 F. Supp. 3d at 299 (agreeing that Batholomaus and McGinity "each . . . discloses an effective crush-resistant tablet"). And Bartholomaus explains that "[t]he solid, abuse-proofed dosage form according to the invention is preferably produced by mixing the components (A), (B), and (C) and/optionally (D) and at least one of the optionally present further abuse-preventing components (a)-(f) and, optionally after granulation, press-forming the resultant mixture to yield the dosage form with preceding, simultaneous, or subsequent exposure to heat." J.A. 9423, [0065]; *see also id.* at [0067]. Before the district court, Accord argued that this passage supported a finding of reasonable expectation of success; Purdue disagreed arguing that this passage was "generic." *Purdue Pharma*, 669 F. Supp. 3d at 301. The court agreed that the statement was "generic" but nonetheless found it "sufficient to support a [person of ordinary skill in the art]'s expectations." *Id.*

The court did not clearly err in finding that the Bartholomaus passage supports a reasonable expectation of success. The passage refers to (1) mixing various components, including component (C), which the patent identifies as optionally PEO, J.A. 9420, [0018]; (2) press-forming the mixture (i.e. compressing); and (3) "preceding, simultaneous, or subsequent exposure to heat." J.A. 9423, [0065]. This disclosure, whether generic or not, discusses a procedure for creating hardened tablets, incorporating PEO, and recites an option for compression and subsequent heating—i.e., it identifies a method of tablet production that

mirrors the disputed limitations. We see no clear error in the court's reliance on this passage, as well as numerous other findings supported by expert testimony, to support the conclusion that "there is a reasonable expectation of success in producing a hardened tablet from sequential compression and then heating of PEO." *Purdue Pharma*, 669 F. Supp. 3d at 301.

6

Finally, Purdue argues that the court erred by relying on the doctrine of "routine experimentation" to find that the time and temperature limitations of the Abuse-Deterrent claims would have been obvious. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (cleaned up). Purdue argues that here the prior art did not teach "the general conditions"; Accord argues just the opposite.

The district court relied on the following evidence to conclude that the general conditions surrounding the time and temperature ranges were taught in the prior art:

> Of the three asserted claims, two claim curing temperatures of 70° C to 85° C, while the third claims 65° C to 90° C. All three claim heating times from ten minutes to ten hours. The times taught in Shao overlap with the time ranges in the patents, but Shao does not use PEO. The temperatures in Bartholomaus and Omelczuk are consistent with those in the asserted claims, but Bartholomaus teaches shorter and Omelczuk longer heating times. Because McGinity teaches melting the PEO, its temperatures are also consistent with those in the patent.

*Purdue Pharma*, 669 F. Supp. 3d at 302 (internal citations omitted); *see also* J.A. 9427 (Bartholomaus teaching

heating PEO to 80° C); J.A. 9416 (McGinity teaching heating "at a temperature range of about 75° C. to 130° C. . . . so that melting or softening of the PEO occurred"); J.A. 9432 (Shao teaching heating of non-PEO tables in an oven at 60° C "for varying lengths of time ranging from 10 minutes to 18 h"). The court considered the claims and found that the prior art taught general conditions that overlap with the claim limitations. Again, we see no clear error in the court's findings. Thus, we do not agree with Purdue that reliance on "routine experimentation" in these circumstances was a legal error.

B

We now turn to Purdue's argument that the court erred in its treatment of the alleged secondary considerations of nonobviousness. "[Secondary considerations] must always when present be considered in the overall obviousness analysis. But they do not necessarily control the obviousness determination. Indeed, a strong showing of obviousness may stand even in the face of considerable evidence of [secondary considerations]." *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 25 F.4th 1354, 1372 (Fed. Cir. 2022) (cleaned up). "The evidence of secondary considerations must have a nexus to the claims, i.e., there must be a legally and factually sufficient connection between the evidence and the patented invention. The patentee bears the burden of showing that a nexus exists. To determine whether the patentee has met that burden, we consider the correspondence between the objective evidence and the claim scope." *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (cleaned up).

Purdue alleges that the district court committed two legal errors. *First*, Purdue argues that the court "asked only whether the secondary considerations 'undermine' an existing finding of obviousness." Appellants' Br. 47. In *Adapt Pharma*, the plaintiffs argued that the "district court committed legal error because, according to

[plaintiffs], it concluded that the asserted claims would have been obvious before considering [plaintiffs'] evidence of [secondary considerations]." 25 F.4th at 1372. This argument is substantively identical to Purdue's first alleged legal error. And as in *Adapt Pharma*, "[w]e are not persuaded." *Id.* "[I]t is evident from the district court's opinion that it considered all of the evidence on the issue of obviousness, including the [secondary considerations], in coming to its ultimate legal conclusion. Although the district court's analysis of the [secondary considerations] in the opinion follows its discussion of the prima facie case of obviousness, there is nothing inherently wrong with that." *Id.* Nor does the use of the word "undermine" in the district court's opinion persuade us that this case is different from *Adapt Pharma*, particularly in light of *KSR*'s analogous phrasing—secondary considerations did not "*dislodge* the determination [of] . . . obvious[ness]." 550 U.S. at 426 (emphasis added).

*Second*, Purdue argues that the district court "misevaluated—and improperly dismissed—each [secondary consideration] separately." Appellants' Br. 48. Below, we address each of the secondary considerations that Purdue raises—commercial success, skepticism, failure of others, and unexpected results.

1

Purdue argues that "reformulated OxyContin—with abuse deterrent qualities—has had commercial success" and that "detailed evidence establish[es] a nexus between OxyContin's commercial success and its abuse-deterrent features." *Id.* at 48–49. Specifically, Purdue argues that "after Purdue reformulated OxyContin, [the] FDA concluded that original OxyContin was withdrawn from the market because of safety concerns related to its abuse. [The] FDA also prohibited all non-abuse-deterrent extended-release oxycodone products . . . ." *Id.* at 49 (internal citations omitted).

We see no clear error in the court's finding that Purdue failed to "prove[] commercial success due to the claimed features of the invention." *Purdue Pharma*, 669 F. Supp. 3d at 305. Here, expert testimony confirmed "that the new formulation replaced the original formulation, with all sales transferred to the new formulation." *Id.* And the court found that "there was no demonstrated increase in the success of OxyContin relative to other opioids when the patented features were introduced." *Id.* Simply stated, the court found no nexus between the claimed invention and the commercial success. Bald assertions of commercial success unconnected to the patented features of the claimed invention are not given patentable weight. *See, e.g.*, *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 316 (Fed. Cir. 1985) ("Because GC was clearly the market leader well before the introduction of the [claimed invention], its sales figures cannot be given controlling weight in determining the effect of commercial success in this case on the question of obviousness.").

2

Purdue next turns to industry skepticism as a purported secondary consideration. Specifically, Purdue argues that the FDA was skeptical about "applying an abuse-deterrent label until they had seen how [reformulated OxyContin] functioned in the real world and if it really did deter abuse." Appellants' Br. 53 (quoting J.A. 5709). Purdue alleges that the court excluded the FDA's skepticism from the weight of secondary considerations because the FDA "is not in the industry." *Id.* (citing *Purdue Pharma*, 669 F. Supp. 3d at 306).

We disagree that the court disregarded Purdue's argument simply because the FDA is not in the industry. The court merely noted that the FDA is not in the industry but weighed the evidence regardless:

> [T]he FDA, which is not in the industry, displayed an amount of skepticism commensurate with the

> fact that this was the first extended-release opioid to receive abuse-deterrent labelling. It seems natural that the FDA, as a regulatory body, would require real world studies before being satisfied that a hard tablet was indeed abuse-deterrent.

*Purdue Pharma*, 669 F. Supp. 3d at 306. Moreover, as Accord notes, 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. The asserted patents "contain[] no limitations requiring any level of abuse deterrence." Appellee's Br. 39. For these reasons, we see no clear error in the court's conclusion that "Plaintiffs have [not] proven industry skepticism by a preponderance of the evidence." *Purdue Pharma*, 669 F. Supp. 3d at 306.

3

With respect to the failure of others, Purdue identifies two products whose producers failed to "develop[] a successful abuse-deterrent formulation"—Develco and Opana. Appellants' Br. 54–55.

With respect to Develco, the court found that "the production failures of Develco seem to weigh in favor of the production-scale-based motivation to combine . . . rather than in favor of the nonobviousness of the patents." *Purdue Pharma*, 669 F. Supp. 3d at 306. With respect to Opana, the 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.'" *Id.* With respect to both Develco and Opana, "the evidence does not suggest [on this record] that these prior attempts failed because the [formulation] lacked the claimed features." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1313 (Fed. Cir. 2006). In other words, the court again concluded that Purdue had not established a nexus between the alleged secondary consideration and the claimed invention. Based on these findings, "[w]e are not

left with a definite and firm conviction that the district court erred in this regard. We thus see no clear error in the district court's finding that this evidence is not significantly probative of nonobviousness." *Adapt Pharma*, 25 F.4th at 1376.

4

Finally, with respect to unexpected results, Purdue argues that "the district court agreed that the claimed invention exhibited an unexpected property by decreasing tablet density—which Purdue's expert testified could enhance abuse deterrence by causing the tablet to gel more quickly if crushed." Appellants' Br. 57. But, according to Purdue, the court erred by "declining to afford [unexpected results] any weight." *Id.* We disagree.

In fact, the court found that Purdue "*ha[d] established* by a preponderance of the evidence the existence of unexpected results." *Purdue Pharma*, 669 F. Supp. 3d at 304. But these unexpected results did "not alone undermine the clear and convincing evidence that the invention's claimed properties [would have been] obvious." *Id.*; *see also W. Union Co. v. MoneyGram Payment Sys., Inc.*, 626 F.3d 1361, 1371 (Fed. Cir. 2010) ("[W]eak secondary considerations generally do not overcome a strong prima facie case of obviousness."). We see no reversible error in this overall assessment.

For the reasons above, we affirm the court's holding that claim 3 of the Mannion '933 patent, claim 3 of the '808 patent, and claim 6 of the '886 patent are invalid.

II

Turning to the Low-ABUK Patents, Purdue first advances two sweeping legal principles: (1) "[w]here the problem is unknown, there can be no reasonable expectation of success in solving it"; and (2) "an invention is non-obvious where the inventor discovers 'the source' of a problem." Appellants' Br. 59. Applying these principles, Purdue

contends that the Low-ABUK Patents are nonobvious because Purdue discovered the "previously unknown problem" that 14-hydroxy reappeared after its removal during the synthesis of oxycodone, and it discovered the source of the problem, the impurity 8α. *Id.* at 60.

With respect to the alleged discovery of an unknown problem, Purdue's argument necessarily fails because the problem was known. Specifically, the district court found that "testimony at trial . . . indicated that an understanding or suspicion that ABUKs were toxic existed even before September 2002." *Purdue Pharma*, 669 F. Supp. 3d at 315. While Purdue attempts to suggest a narrower problem statement—i.e., 14-hydroxy reappeared after its removal during the synthesis of oxycodone—this effectively transforms Purdue's argument from an alleged legal error to an alleged factual error. And on the factual point, the court agreed with Accord that "a [person of ordinary skill in the art] would have two clear starting points: either adding a final hydrogenation step to remove 14-hydroxy hydrochloride or attempting to remove 14-hydroxy at an earlier stage." *Id.* Even between these two starting points, the district court considered the parties' arguments, reviewed the expert testimony, and concluded that Accord had "presented clear and convincing argument that a [person of ordinary skill in the art] would try to intervene at an earlier stage of the oxycodone synthesis to ensure that all 14-hydroxy was converted to oxycodone prior to salt formation. I am also persuaded that a [person of ordinary skill in the art] would have the knowledge and skill to do so successfully." *Id.* at 316. We see no clear error in the court's factual findings on this record.

Regarding discovery of "the source" of a problem, even *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, upon which Purdue heavily relies, demonstrates that obviousness is based upon underlying factual questions. *See* 261 U.S. 45, 52 (1923) ("The issue is one largely of evidence."). "In *Eibel Process*, the invention was a machine that could

make quality paper at high speeds. At the time, paper-making machines could not operate at high speeds without producing wrinkled paper. Eibel discovered that the unequal speeds of paper stock and a wire in the machine produced the wrinkled paper. . . . The Supreme Court upheld the validity of Eibel's patent, reasoning that the discovery of the problem—unequal speeds of paper stock and the wire—was nonobvious, and thus the solution was as well." *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1352 (Fed. Cir. 2016). But even in concluding that the patent was nonobvious, the Court laid out different factual scenarios that may have led to a different conclusion:

> Had the trouble which Eibel sought to remedy been the well-known difficulty of too great wetness or dryness of the web at the dandy roll, and had he found that a higher rather than a lower pitch would do that work better, a patent for this improvement might well have been attacked on the ground that he was seeking monopoly for a mere matter of degree. But that is not this case. On the other hand, if all knew that the source of the trouble Eibel was seeking to remedy was where he found it to be, and also knew that increased speed of the stock would remedy it, doubtless it would not have been invention on his part to use the pitch of the wire to increase the speed of the stock, when such pitch had been used before to do the same thing, although for a different purpose and in less degree.

*Eibel Process*, 261 U.S. at 68.

Between *Eibel*'s discussion of different factual scenarios and *KSR*'s warning to avoid "[r]igid preventative rules that deny factfinders recourse to common sense," we believe the proper inquiry here is one of fact. In other words, even recognizing that Purdue may have discovered 8a, we disagree that, "[t]hat should have ended the inquiry." Appellants' Br. 61. Therefore, we turn to the two alleged

factual flaws that Purdue identified—i.e., the court's reliance on inherency and routine experimentation.

"[I]nherency may supply a missing claim limitation in an obviousness analysis." *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1194–95 (Fed. Cir. 2014). "It is long settled that in the context of obviousness, the 'mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not distinguish a claim drawn to those things from the prior art.'" *Persion Pharms. LLC v. Alvogen Malta Operations Ltd.*, 945 F.3d 1184, 1190 (Fed. Cir. 2019) (citation omitted). Purdue relies on *Honeywell International Inc. v. Mexichem Amanco Holding S.A. de C.V.*, 865 F.3d 1348 (Fed. Cir. 2017), for the proposition that, "that which 'may be inherent is not necessarily known' and that which is unknown cannot be obvious.'" Appellants' Br. 62 (quoting *Honeywell*, 865 F.3d at 1354). But *Honeywell* does not help Purdue because it was a case about motivation to combine. *See Cytiva BioProcess R&D AB v. JSR Corp.*, 122 F.4th 876, 890 (Fed. Cir. 2024). In *Honeywell*, the claimed invention was a composition that comprised two components. Both components were disfavored in the art for the claimed purpose, but the combination of the two components had unexpected properties. In this circumstance, even though the unexpected properties were inherent, "a person of ordinary skill in the art would not have been motivated to combine the two compounds in the first place." *Id.* Thus, *Honeywell* is not applicable here.

Instead, we turn to each of the asserted Low-ABUK Patent claims individually, as the district court did, because the disputed limitations in each claim are slightly different. *First*, "[c]laim 3 of the '933 patent requires only that 8α be present in the composition." *Purdue Pharm.*, 669 F. Supp. 3d at 318 (citing '933 patent claim 3). The court concluded that claim 3 was obvious because 8α was inherently present in the prior art compositions. Indeed, "Plaintiffs d[id] not dispute that 8α was present in prior art

compositions." *Id.* In other words, like in *Cytiva* (where we found the claims unpatentable based on an undisputedly inherent property), Purdue attempts to claim an inherent part of the composition—8α. Because this limitation was undisputedly present in the prior art, nothing more is needed because there is no "difference[] between the claimed invention and the prior art." 35 U.S.C. § 103.

*Second*, claim 21 of the '919 patent recites a different limitation with respect to 8α—"the ratio of 8α,14-dihydroxy-7,8-dihydrocodeinone to oxycodone HCl is 0.04% or less, '919 patent claim 18 (from which claim 21 depends); and claim 11 of the '933 patent recites "removing 8α,14-dihydroxy-7,8-dihydrocodeinone", '933 patent claim 10 (from which claim 11 depends). Here, the court relied on a sequence of facts to arrive at the conclusion that both limitations would have been obvious to a person of ordinary skill in the art conducting routine experimentation. *Purdue Pharm.*, 669 F. Supp. 3d at 315–20. On appeal, Plaintiffs contend it was improper for the court to rely on routine experimentation because "routine experimentation applies *only* where the claimed invention merely identifies the 'optimum or workable ranges' of previously disclosed conditions." *See* Appellants' Br. 63 (citing *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006 (Fed. Cir. 2018)) (emphasis added). We are unaware of such a brightline rule. For example, in *Merck*, we agreed that it was "reasonable for the district court to deduce from the evidence that the order and detail of the steps, if not already known, would have been discovered by routine experimentation while implementing known principles." *Merck*, 874 F.3d at 730. The disputed limitations there were not only "optimum or workable ranges" but included "the order of the steps, the simultaneous addition of base, the specific temperature range, and a final moisture content of less than 10%." *Id.*

Similarly, here, the court "looked to testimony provided by both sides' experts" and was "persuade[d] . . . that a [person of ordinary skill in the art] would have quickly postulated and easily confirmed the existence of 8α." *Purdue Pharm.*, 669 F. Supp. 3d at 319. Purdue only makes two factual arguments that allegedly undermine the court's finding of routine experimentation—i.e., that the court ignored Noramco's attempt to develop Low-ABUK oxycodone and that the court acknowledged "routine experimentation with early removal of 14-hydroxy 'would not immediately succeed.'" Appellants' Br. 63. As to Noramco, the court did not ignore this evidence. *See Purdue Pharm.*, 669 F. Supp. 3d at 317. The court simply did not find it "sufficient" to overcome Accord's expert testimony. Purdue fails to explain why the court erred in finding Noramco's failure insufficient in light of the expert testimony, and we see no clear error in the court's analysis on this point. As to Purdue's argument that a person of ordinary skill in the art "would not immediately succeed" in early removal of 14-hydroxy, we are not aware of a test for routine experimentation that requires a person of ordinary skill in the art to "immediately succeed." Absent an argument why the district's analysis was clear error, we conclude it was "reasonable for the district court to deduce from the evidence that the [disputed claim limitations] . . . would have been discovered by routine experimentation while implementing known principles." *Merck*, 874 F.3d at 730.

Having confirmed that the district court did not err in its determination that routine experimentation would lead a person of ordinary skill to "quickly postulate[] and easily confirm[] the existence of 8α," and because the remainder of the court's analysis with respect to claim 21 of the '919 patent and claim 11 of the '933 patent is not contested, we affirm the district court's holding that the challenged claims of the Low-ABUK Patents would have been obvious. *See Purdue Pharm.*, 669 F. Supp. 3d at 319–20.

## CONCLUSION

We have considered Purdue's remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm the district court's final judgment, holding claim 3 of the Mannion '933 patent, claim 3 of the '808 patent, claim 6 of the '886 patent, claims 3 and 11 of the '933 patent, and claim 21 of the '919 patent invalid as obvious under 35 U.S.C. § 103.

**AFFIRMED**