No. _____

In the Supreme Court of the United States

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

v.

ACCORD HEALTHCARE, INC.,
Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In *Graham v. John Deere Co.*, this Court established four factors for evaluating whether a patent is obvious, and therefore invalid, under 35 U.S.C. § 103. 383 U.S. 1 (1966). The first three factors examine technical aspects of the invention and the prior art. To help avoid hindsight bias and an overly narrow approach to obviousness, *Graham* also requires courts to evaluate a fourth factor focused on "economic and motivational" considerations—known as the objective "indicia" of non-obviousness or "secondary considerations." *Id.* at 17-18, 36. These include "commercial success, long felt but unsolved needs, [and] failure of others." *Id.* at 17-18. As this Court explained in *KSR International Co. v. Teleflex Inc.*, courts must analyze "any secondary considerations that would prove instructive" in conducting an "expansive and flexible" analysis of obviousness. 550 U.S. 398, 415 (2007).

Despite this clear instruction, the Federal Circuit has adopted a rigid "nexus" requirement to dismiss out of hand clear objective indicia of non-obviousness. It doubled down on that practice in this case. Invoking lack of "nexus," the Federal Circuit held that Purdue's novel abuse-deterrent formulation of OxyContin was obvious even though the formulation indisputably filled a long-felt need in the market, was initially met by skepticism by the Food & Drug Administration, and averted the impending collapse of OxyContin sales. The question presented is:

Whether, as this Court has held, the objective indicia of non-obviousness should be analyzed flexibly to combat hindsight bias or instead subject to the Federal Circuit's rigid rules restricting the inquiry.

RULE 29.6 STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Petitioners 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.

RELATED PROCEEDINGS

The following proceedings are directly related to this petition:

Purdue Pharma L.P. v. Accord Healthcare, Inc., No. 23-1953, United States Court of Appeals for the Federal Circuit, judgment entered December 30, 2024 (2024 WL 5244764).

Purdue Pharma L.P. v. Accord Healthcare, Inc., Civil Action No. 20-1362-RGA, United States District Court for the District of Delaware, order entered April 11, 2023 (669 F. Supp. 3d 286) and judgment entered April 26, 2023.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and Rhodes Technologies (collectively, "Purdue") respectfully petition this Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App.1a-33a) is not reported but available at No. 23-1953, 2024 WL 5244764 (Fed. Cir. Dec. 30, 2024). The decision of the district court (App.34a-95a) is published at 669 F. Supp. 3d 286. The final judgment of the district court (App.96a-98a) is unreported.

JURISDICTION

The court of appeals entered its judgment on December 30, 2024 (App.1a-33a). On March 13, 2025, Chief Justice Roberts extended the time to file a petition for a writ of certiorari to April 30, 2025. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Relevant constitutional and statutory provisions are reproduced in the petition appendix. App.99a-101a.

INTRODUCTION

The Federal Circuit in recent years has systematically negated a critical check against hindsight bias in determining whether a patent is "obvious"—and therefore invalid—under 35 U.S.C. § 103. This has destabilized the patent system and swung the pendulum too far in the direction of invalidating patents earned through hard work, ingenuity, and investment. The decision below, which held that Purdue's patents claiming its groundbreaking abuse-deterrent formulation of OxyContin were obvious, is the latest example of this troubling trend. This Court should grant certiorari to bring the Federal Circuit in line with this Court's precedent and preserve the incentives for innovation that the patent system is designed to protect.

In *Graham v. John Deere Co.*, this Court made clear that, in conducting the obviousness inquiry, courts must evaluate "economic and motivational" considerations—known as the objective "indicia" of non-obviousness or "secondary considerations"—to assess whether a patented invention was truly obvious at the time of invention. 383 U.S. 1, 36 (1966). These indicia consist of a range of practical considerations, including "commercial success, long felt but unsolved needs, [and] failure of others." *Id.* at 17-18. The objective indicia act as an indispensable check on hindsight bias, which can easily infect the more technical aspects of the obviousness inquiry and lead to the over-invalidation of patent claims.

Contrary to that precedent, however, the Federal Circuit has eroded the role of the objective indicia in the obviousness analysis in the years since *Graham* was decided. Most strikingly, in this case and many

others, the Federal Circuit has invented and deployed a stringent analysis and so-called "nexus" test that demands evidence of a direct connection between the objective indicia and a particular claim limitation, while foreclosing recourse to broader inferences and common-sense. The Federal Circuit's cramped and rigid approach has no basis in this Court's precedent, and it has led to fractured and inconsistent decisions in the Federal Circuit. Whatever its intentions, the "nexus" requirement has become a straightjacket on the objective indicia that, in practice, has neutralized even compelling objective indicia of non-obviousness and distorted the obviousness analysis as a whole.

This case epitomizes the problems with the Federal Circuit's "nexus" requirement. Purdue invested nearly a decade of research by extraordinarily talented scientists, and hundreds of millions of dollars, in completely reformulating OxyContin so that it would deter misuse and abuse of the drug. That new abuse-deterrent formulation—produced through a novel curing process—addressed a long-felt and pressing public-health need and produced a formulation with undisputed commercial success. After rigorous studies, Purdue's new formulation received approval from the Food & Drug Administration ("FDA") for abuse-deterrent labeling—the first FDA-approved label of its kind for any opioid pain medication. Once the new formulation was available, the FDA withdrew its approval for, and refused to approve, any formulation that was *not* abuse-deterrent.

Accord Healthcare, Inc. ("Accord") sought to piggyback on that success. Unable to develop its own abuse-deterrent formulation, Accord copied Purdue's invention and sought FDA approval through an

Abbreviated New Drug Application. After Purdue sued, Accord stipulated to infringement but claimed Purdue's patents were obvious, despite the decade-long effort to develop a solution in the face of the growing and overwhelming public-health need for an abuse-deterrent formulation of an oxycodone pain medication—when there were no patents covering the use of oxycodone generally.

In the proceedings below, Purdue presented extensive evidence related to the objective indicia of non-obviousness—including original OxyContin's withdrawal from the market, the reformulation's substantial commercial success, the fact that competitors were racing to develop their own abuse-deterrent versions of opioid pain-relief medications, and FDA's initial skepticism of Purdue's invention. Even Accord's own witnesses recognized that the patented invention addressed a long-felt but unmet need and that OxyContin sales would have been substantially lower absent the abuse-deterrent features—strong indicators that Purdue's invention was not in fact obvious. But the Federal Circuit gave this evidence no weight. Instead, it applied its rigid "nexus" rule and inexplicably deemed the evidence "unconnected to the patented features of the claimed invention." App.24a.

Apart from the illogic of that reasoning, the Federal Circuit's decision starkly conflicts with this Court's precedents admonishing courts to consider the objective indicia as a check against hindsight bias and to conduct an "expansive and flexible" analysis of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007). And it is only one of many decisions in which the Federal Circuit has applied its "nexus" test to arbitrarily limit consideration of the objective

indicia. By diminishing the objective indicia's role in the obviousness inquiry, these decisions threaten to erode patent protections and diminish incentives to invest in research and development. This Court should grant certiorari to provide much-needed clarity on the role of the objective indicia in the obviousness inquiry and to reject the Federal Circuit's artificial and unduly rigid analysis.

STATEMENT OF THE CASE

A. Purdue's Groundbreaking Invention

1. In the 1990s, Purdue developed the original formulation of OxyContin®, an extended-release pain medication with the active ingredient oxycodone hydrochloride. Federal Circuit Appendix ("Appx") 5038; Appx8926. OxyContin provided critical pain relief to millions of people when taken as directed. But, by the early 2000s, it became clear that OxyContin, like other opioid pain medications, was vulnerable to abuse and misuse. App.2a. Tablets could be crushed into a powder that could be either snorted or liquified and injected to achieve an immediate high by those who abused it.

To address this serious public-health risk, Purdue invested nearly a decade and hundreds of millions of dollars in developing a tablet that both deterred abuse and preserved the essential extended-release feature of the original OxyContin formulation. Appx6854; *see also* Appx8915-8916; Appx5531. This combination—an effective yet abuse-deterrent opioid pain medication—was "one of the highest unmet needs in the market." Appx5374 (Rosen 341:24-25); *see also* Appx5376 (343:22-23).

Purdue explored a range of possibilities to meet that need and produce an abuse-deterrent tablet.

Initially, Purdue focused on adding an antagonist to the original formulation that would negate the opioid's euphoric effects if the tablet were tampered with. *See* Appx5450-5453. But that approach failed. *See* Appx5337-5338. Purdue also experimented extensively with the use of polymers to harden the tablets. Purdue began by preparing batches with the polymer Eudragit, which was used in the original OxyContin formulation, as well as the polymer polyethylene oxide ("PEO"). *Id.*; Appx5344-5346. These initial batches with PEO failed: One batch containing PEO "did not process on the melt extruder"; another "produced an immediate [rather than extended] release dissolution profile." Appx8893. Given those results, PEO was "not progressed further" at that time. *Id*.

Despite those setbacks, Purdue ultimately returned to its experimentation with PEO-based formulations. Eventually, it succeeded in developing the hardened, abuse-resistant formulation claimed in the patents at issue. Purdue's abuse-deterrent patents recite a pharmaceutical composition (or a method for producing such a composition) comprising an "extended release dosage form" with PEO and oxycodone, made by a specific curing method. Appx302 (cl. 1). That curing method requires that the tablet first be "compression shaped," and then "air cured by heated air, without compression"—for example, in an oven. *See, e.g.*, *id.*; Appx106 (19:11-12, 19:43-47); *see also* Appx5352. The heating must be done for "about 10 minutes to about 10 hours," above the softening temperature of PEO. Appx175-176 (cls. 1, 3); Appx302 (cls. 1, 3); Appx434 (cls. 1-3, 5-6). Applying this method results in a stronger, abuse-

deterrent formulation of OxyContin. Appx1805-1806 (¶¶ 41, 44-45).

Purdue's process is unique. Before Purdue's invention, no one had ever cured PEO-based tablets without simultaneous compression of the tablet. Appx1818-1819. That was for good reason: There 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. Appx5353-5354. Indeed, the closest prior art—Bartholomaus—taught the curing of PEO-based tablets with *simultaneous* compression and heating using an unwieldy contraption, in which the inventor placed a tablet press *inside* a heating cabinet. Appx5248-5261; Appx9417-9430. While that process produced a hardened tablet, it was not suitable for large-scale production, and thus not commercially viable. *See* App.8. By contrast, Purdue's groundbreaking formulation was commercially viable, abuse-deterrent, and medically effective.

2. In late 2007, Purdue sought FDA approval for reformulated OxyContin through a New Drug Application. Appx5351. FDA approved Purdue's new formulation in 2010, but it did not approve abuse-deterrent labeling at that time. Appx5462. Rather, skeptical that the new formulation would actually deter abuse, FDA required Purdue to conduct extensive post-marketing studies. Appx6814. Three years later, after scrutinizing Purdue's studies, FDA approved labeling stating that reformulated OxyContin has abuse-deterrent properties—the first time it had ever approved such a label for any opioid pain medication. *See* U.S. FDA, *FDA Actions on OxyContin Products, 4/16/2013*, (current as of 2022),

https://www.fda.gov/drugs/information-drug-class/fda-actions-oxycontin-products-4162013; Appx5462; Appx6809-6818.

At the same time, FDA formally withdrew original OxyContin from the market as comparatively unsafe, underscoring the existential threat that OxyContin faced if an abuse-deterrent formulation were not developed. Appx6809-6818. FDA also prohibited all non-abuse-deterrent extended-release oxycodone products, including generic versions of original OxyContin. *Id.* In other words, without Purdue's new invention, OxyContin sales would have gone to zero.

3. Purdue's reformulated OxyContin was a resounding commercial success—allowing patients to receive much-needed pain relief while reducing the risk of abuse and misuse of the medication. Whereas the original formulation was withdrawn from the market due to safety concerns, reformulated OxyContin is both the highest-selling extended-release opioid and the most-prescribed brand-name extended-release opioid on the market. Appx5401 (368:20-25).

As 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." Appx5704-5705 (Appel 671:22-672:2). And, as another Accord witness conceded, "[t]here's no doubt" that OxyContin's sales would have been lower without its abuse-deterrent features. Appx5693 (Hoffman 660:19-22); *see also* Appx5402 (Sharma 369:3-6). Indeed, given the specter of abuse, Purdue's invention was critical to preserving OxyContin as a viable product for sale in the marketplace.

In particular, because of the acute need and high market demand for abuse-deterrent opioids, any competitor that could have beat Purdue in developing an abuse-deterrent extended-release opioid would have undercut, and likely supplanted, original OxyContin sales. Despite the overwhelming incentives to develop such a product, however, no other manufacturer managed to do so.

Endo Pharmaceuticals, for example, *withdrew* its competing product, Opana® ER ("Opana"), because it was not sufficiently abuse-deterrent. *See* Appx5339-5340; Appx5366 (Mannion 306:22-307:8, 333:1-7); Appx5469 (Bley 436:5-9); Appx6819-6825 at Appx6819; News Release, U.S. FDA, *FDA requests removal of Opana ER for risks related to abuse* (June 8, 2017), https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-related-abuse. Meanwhile, as evidenced by this litigation, Accord resorted to copying Purdue's invention, rather than develop its own abuse-deterrent product.

In short, only Purdue succeeded in filling the long-felt but unmet need of developing an abuse-deterrent, extended-release opioid pain medication. And it did so at great expense.

B. Proceedings Below

1. In August 2020, Accord sought FDA approval to manufacture and sell a generic version of OxyContin, using Purdue's patented abuse-deterrent technology. Appx1807. Purdue filed this infringement action, and Accord stipulated to infringement. Appx1808. Accord argued, however, that Purdue's patents were invalid for obviousness.

The district court held a three-day bench trial on Accord's obviousness defense. At trial, Accord's own expert acknowledged that PEO could turn into "a puddle" if heated at too high a temperature without compression, Appx5265 (Appel 233:6-9), echoing Purdue's evidence about the substantial risks of tablet deformation that made its novel curing method far from obvious, *see, e.g.*, Appx5353-5354 (Mannion 320:10-321:5).

Purdue also presented extensive evidence of objective indicia of non-obviousness, including reformulated OxyContin's commercial success in a highly competitive market, Appx5367-5377 (Rosen 334:23-344:21); Appx5401-5402 (Sharma 368:20-369:6); FDA's initial skepticism regarding the abuse-deterrent formulation, Appx5462 (Bley 429:17-24); Appx9122; and the failures of other manufacturers to develop a comparable product, Appx5461-5462, Appx5469 (Bley 428:3-429:8, 436:5-9); Appx5340 (Mannion 307:3-8). Purdue's witnesses testified, for example, that abuse deterrence was "one of the highest unmet needs in the market," Appx5374 (Rosen 341:24-25); that "[w]ithout abuse-deterrent features, the OxyContin sales would have been significantly lower," Appx5402 (Sharma 369:3-6); and that Purdue's competitors were not "able to achieve th[e] equivalent abuse-deterrent profile as reformulated oxycodone," Appx5469 (Bley 436:4-9).

Accord's own witnesses similarly acknowledged that Purdue's abuse-deterrent patents "definitely" solved "a long felt, but unmet need in the art," Appx5704-5705 (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, Appx5693 (Hoffman 657:7-13, 660:19-22); *see also* Appx5402 (Sharma 369:3-6).

2. The district court nevertheless found all of the asserted claims invalid for obviousness. App.35a. Without seriously considering the risks of tablet deformation, the court declared that it was "not much of a leap to infer that ovens would" be "useful" for scaling up Bartholomaus's simultaneous heating process. *Id*. at 50a.

The district court then discounted each of Purdue's objective indicia of non-obviousness. It reasoned that reformulated OxyContin's commercial success was solely due to "Purdue's existing monopoly," *id.* at 62a—even though Purdue had *no* patent or monopoly on oxycodone that would have precluded competitors from developing an abuse-deterrent oxycodone medication. The court recognized, but discounted, the importance of developing an abuse-deterrent product to maintaining OxyContin's commercial viability, asserting that "a lack of commercial failure is not the same as commercial success." *Id.* Yet, the court ignored evidence that reformulated OxyContin contained only two ingredients from the original formulation. *Compare* Appx8330-8332, *with* Appx1807 (¶ 49). It thus failed to appreciate that reformulated OxyContin was an entirely *new* product that supplanted original OxyContin sales because of its innovative abuse-deterrent features.

As to industry skepticism, the court agreed that FDA had displayed "skepticism" but dismissed it as "commensurate with the fact that this was the first extended-release opioid to receive abuse-deterrent labelling." App.63a. The court further dismissed evidence of the failure of others, reasoning that the

evidence of prior failures lacked a sufficient connection to "claimed features" of Purdue's patent. *Id.* at 64a-65a (citation omitted). The district court thus concluded that the objective indicia could not overcome the court's initial finding of obviousness.

3. The Federal Circuit affirmed. It first concluded that Purdue's novel curing process would have been "obvious to try" given the market need to develop a scalable, abuse-deterrent product. *Id.* at 15a-17a. It then considered the objective indicia.

As 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 abuse-deterrent formulation replaced sales of the original formulation and the record did not demonstrate an *increase* in OxyContin sales. *Id.* at 24a. The Federal Circuit did not acknowledge that the patented invention had preserved OxyContin's commercial viability, averting both the risk that FDA would pull OxyContin from the market for safety reasons (as it ultimately did) and the risk that a competitor would fill that void with its own abuse-deterrent oxycodone formulation—completely displacing Purdue. Nor did the Federal Circuit acknowledge Accord's admission that "[t]here's no doubt" that OxyContin's sales would have been lower without its abuse-deterrent features. Appx5693 (Hoffman 660:19-22).

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. App.25a. It reasoned that FDA's skepticism was "about applying the abuse-deterrent label"—a feature not expressly claimed in the asserted patents, even though abuse

deterrence was the undisputed purpose and result of the unique process claimed in those patents. *Id.*

Finally, the Federal Circuit deemed Purdue's evidence of 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 unclear whether those failures were caused by a lack of "the claimed features" of Purdue's patents. App.26a (citation omitted). At no point did the Federal Circuit holistically consider the undisputed facts that Purdue had managed to develop a desperately needed and enormously valuable abuse-deterrent formulation in a highly competitive market in which no other competitor had succeeded in doing so.

REASONS FOR GRANTING THE WRIT

This Court's precedents have long made clear that the objective indicia are an indispensable element of the obviousness analysis, and are critical to combatting hindsight bias and ensuring an expansive and flexible assessment of patent validity. Yet Federal Circuit panels routinely and increasingly are invoking home-grown limits on these indicia—like the Federal Circuit's stringent and artificial "nexus" requirement—that negate the role of the objective indicia in the obviousness analysis and ignore the broader marketplace dynamics necessary to understand whether an invention is truly obvious. The decision below exemplifies this concerning trend, which has resulted in the over-invalidation of patents and, in turn, undermined incentives to invest in the development of novel and transformative products, like the innovations at issue here. This Court's review

is needed to restore the objective indicia to their proper role in the obviousness analysis.

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

A. The Objective Indicia Are Critical To The Obviousness Analysis

Because a patent, once issued, "shall be presumed valid," 35 U.S.C. § 282(a), any party attempting to show that an issued patent is invalid bears the heavy burden of proving the facts supporting that defense by "clear and convincing evidence." *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95-96 (2011). A patent is invalid if a party establishes by clear-and-convincing evidence that 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(a).

In *Graham v. John Deere Co.*, this Court identified four factors that must be considered collectively before concluding that a patented invention is invalid for obviousness. 383 U.S. 1, 17-18 (1966). Those factors are (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 non-obviousness, such as "commercial success, long felt but unsolved needs, [and] failure of others." *Id.* As this Court reaffirmed in *KSR International Co. v. Teleflex Inc.*, *Graham* "set[s] forth a broad inquiry," which requires courts to consider "any secondary considerations that would prove instructive." 550 U.S. 398, 415 (2007).

Graham stressed that the objective indicia of non-obviousness—including commercial success, long felt but unsolved needs, and failure of others—are important to the obviousness analysis for two reasons. 383 U.S. at 35-36. First, by "focus[ing] attention on economic and motivational" issues that are "more susceptible of judicial treatment," the objective indicia "lend a helping hand to the judiciary" in assessing the complex subject matter often at issue in patent cases. *Id.* Second, and relatedly, the objective indicia help prevent courts from "'slipping into use of hindsight'" and impermissibly "read[ing] into the prior art the teachings of the invention in issue." *Id.* at 36 (citation omitted). This check is necessary because obviousness must be assessed from the perspective of a person having ordinary skill in the art "*before* the effective filing date of the claimed invention." 35 U.S.C. § 103(c)(2)(A) (emphasis added); *Graham*, 383 U.S. at 35-36. Accordingly, a "factfinder should be aware . . . of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." *KSR*, 550 U.S. at 421. The objective indicia are essential to resisting that distortion and thus form "a critical piece of the obviousness analysis." *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1358 (Fed. Cir. 2013).

To accomplish these goals, courts must examine the objective indicia with an eye to "how the patented device is viewed in the marketplace, by those directly interested in the product." *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1391 (Fed. Cir. 1988); *see Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997) (similar). This broader, common-sense perspective has a salutary

effect on what would otherwise risk becoming an opaque and arcane exercise based on "highly technical facts." *Graham*, 383 U.S. at 35-36.

Evidence of commercial success, for example, supports the common-sense notion that "an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art." *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). Similarly, evidence that an invention filled a long-felt, unmet need weighs against obviousness because "it is reasonable to infer that the need would not have persisted had the solution been obvious." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1332 (Fed. Cir. 2016).

Meanwhile, evidence that others tried but failed to develop a claimed invention can carry "significant weight," given that "'there can be little better evidence negating an expectation of success than actual reports of failure.'" *Eurand, Inc. v. Mylan Pharms. Inc. (In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.)*, 676 F.3d 1063, 1081 (Fed. Cir. 2012) (citation omitted).

This practical approach toward evaluating obviousness is well-rooted in this Court's jurisprudence. Decades before *Graham*, the Court noted that, where the patented process was "immediately generally accepted" as a great "advance" and "largely replaced all earlier processes," that was "persuasive evidence" of the inventiveness of the patent. *Mins. Separation v. Hyde*, 242 U.S. 261, 270 (1916). And, even earlier, the Court explained that evidence that an invention had "wrought a revolution in dental practice" and was being used "in preference to older devices" raised an "inference" that

it was "in truth, invention." *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 495 (1876); *see also Reiner v. I. Leon Co.*, 285 F.2d 501, 504 (2d Cir. 1960) (Hand, J.) (identifying "sign posts" for non-obviousness, including "how long did the need exist" and "how many tried to find the way"). In short, "evidence of secondary considerations may often be the most probative and cogent evidence in the record." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

To perform their intended role, however, the objective indicia must be analyzed practically and flexibly. This is nothing new. As in all aspects of the obviousness analysis, "[r]igid preventative rules that deny factfinders recourse to common sense . . . are neither necessary under [this Court's] case law nor consistent with it." *KSR*, 550 U.S. at 421.

Indeed, in *KSR*, this Court emphasized the importance of conducting an expansive and flexible obviousness analysis. The *KSR* Court rejected the Federal Circuit's "rigid" "teaching, suggestion, motivation" or "TSM test" for analyzing the technical *Graham* factors. *Id.* at 407, 415. Under the TSM test, prior art references were required to address "the precise problem that the patentee was trying to solve," in order to show a motivation to combine. *Id.* at 413-14 (citation omitted). This Court rejected that approach, explaining that it was "inconsistent" with the "expansive and flexible approach" required in assessing obviousness. *Id.* at 415. Courts should instead flexibly consider "design incentives and other market forces" that might "prompt variations" of the prior art. *Id.* at 417. In other words, even as to the technical obviousness factors, courts must maintain a broad, flexible, and common-sense perspective.

The necessary corollary is that the objective indicia of *non*-obviousness must also be viewed through the same expansive and flexible lens, with an eye to market forces and practical considerations that *undercut* a finding of obviousness. Indeed, if anything, the objective indicia are an even more natural place for a flexible, common-sense analysis than the technical obviousness factors. That is the whole point of the inquiry—as a check on hindsight bias by conducting a more holistic, real-world inquiry. Only by applying a flexible lens to all aspects of the obviousness inquiry can the objective indica serve as a meaningful check on hindsight bias.

B. The Federal Circuit Routinely Negates The Objective Indicia Of Non-obviousness Through Rigid Requirements Like Its Home-Grown "Nexus" Test

Despite the importance of the objective indicia, the Federal Circuit has increasingly eschewed the flexible and common-sense approach required by this Court's precedents. In its place, the Federal Circuit has developed an overly exacting and rigid analysis of the objective indicia, including a specific "nexus" requirement of its own creation that demands that evidence of objective indicia have a strict connection to a specific claim limitation. That test renders the objective indicia meaningless in many cases—including this one. In doing so, it undermines the Court's holding in *Graham*, creates an imbalance with *KSR*'s expansive analysis of the other obviousness factors, and leaves the obviousness inquiry vulnerable to hindsight bias. Unsurprisingly, this deviation from the Court's precedent has produced inconsistent results and fractured opinions.

1. In the wake of *Graham*, the Federal Circuit (and its predecessor, the U.S. Court of Customs and Patent Appeals) initially recognized the importance of the objective indicia. The Federal Circuit emphasized, for example, that the objective indicia "serve as insurance against the insidious attraction of the siren hindsight," *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983), and that they "may often establish that an invention appearing to have been obvious in light of the prior art was not," *Stratoflex*, 713 F.2d at 1538.

The Federal Circuit also routinely cautioned that objective indicia "must always when present be considered en route to a determination of obviousness" and that "a court must not stop until *all* pieces of evidence . . . have been fully considered and each has been given its appropriate weight." *Id.* at 1538-39; *see also In re Mageli*, 470 F.2d 1380, 1383 (C.C.P.A. 1973) (explaining that evidence of objective indicia "is always to be considered"). And it often reiterated that "[s]econdary considerations may be the most pertinent, probative, and revealing evidence available to the decision maker in reaching a conclusion on the obviousness/nonobviousness issue." *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 (Fed. Cir. 1985).

In applying the *Graham* framework, the Federal Circuit also understood that an appropriately flexible approach was not an indiscriminate one: Objective indica such as commercial success and failure of others must have some connection to the patented invention to be probative of non-obviousness. For example, the Federal Circuit sensibly concluded that where "commercial success of a product" has a clear "cause[] unrelated to patentable inventiveness," such

as "skillful marketing of the product," the success is unlikely to be probative of non-obviousness. *Ritchie v. Vast Res., Inc.*, 563 F.3d 1334, 1336 (Fed. Cir. 2009). The Federal Circuit thus held that, for the objective indicia to be probative of non-obviousness, there must be "a sufficient relationship"—or "nexus"—between the objective indicia and the patented invention. *Demaco Corp.*, 851 F.2d at 1392.

The burden to establish this "nexus" was never meant to be high, however. In early Federal Circuit cases involving commercial success, for example, patentees needed only to provide evidence or testimony that supported an "inference" that the "claimed invention itself was responsible for [the] commercial success." *Id.* at 1393 (citation omitted). For instance, "testimony as to the advantage" of the patented feature could support an inference that the patented feature—and not some other feature or external cause—was "responsible for" the product's commercial success. *Id.* (citation omitted). Conversely, if a patentee failed to show that the marketed product "correspond[ed] to the system disclosed in the patent," evidence of commercial success would carry little weight. *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983).

In line with this broad and flexible approach, the Federal Circuit often afforded a "presumption of nexus" when the marketed product embodied the patented invention: "When a patentee can demonstrate commercial success, usually shown by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent, it is presumed that the commercial success is due to the patented invention."

J.T. Eaton & Co. v. Atlantic Paste & Glue Co., 106 F.3d 1563, 1571 (Fed. Cir. 1997).

At this point, "the burden shifts to the challenger to prove that the commercial success is instead due to other factors extraneous to the patented invention, such as advertising or superior workmanship." *Id.*; *see Demaco Corp.*, 851 F.2d at 1394 ("A patentee is not required to prove as part of its prima facie case that the commercial success of the patented invention is not due to factors other than the patented invention itself." (emphasis omitted)). Merely gesturing to other "market forces" alone was not enough; challengers were themselves required to "make a convincing case that those market forces indeed were the likely cause of success." *Crocs, Inc. v. International Trade Comm'n*, 598 F.3d 1294, 1310-11 (Fed. Cir. 2010). Absent such a showing, courts would presume nexus and draw common-sense inferences regarding the import of the evidence in the obviousness analysis.

Accordingly, as conceived, the Federal Circuit's "nexus" requirement was merely shorthand to effectuate *Graham*'s common-sense evaluation of the objective indicia and properly assess the persuasiveness of the evidence.

2. Over time, however, the Federal Circuit's "nexus" test has warped into a rigid rule used to categorically dismiss even compelling evidence of objective indicia of non-obviousness. This approach undermines the role of the objective indicia in the obviousness analysis, has flipped the burden of proof on obviousness from challenger to patentee, and has created a glaring incongruity between *KSR*'s expansive analysis of the technical obviousness

factors and the Federal Circuit's cramped approach to the objective indicia of *non*-obviousness.

As currently applied, the "nexus" test often requires direct evidence of a strict connection to a particular claim element. For example, in the context of commercial success, panels have stated that a patentee must show "that the driving force behind the product sales was a direct result of the unique characteristics of the claimed inventions." *WesternGeco LLC v. ION Geophysical Corp.*, 889 F.3d 1308, 1330-31 (Fed. Cir. 2018) (discounting commercial success); *see also In re DBC*, 545 F.3d 1373, 1384 (Fed. Cir. 2008) (similar).[1] That rule frequently forecloses any meaningful consideration of the objective indicia, because courts can regularly point to the underlying product as the more likely "source" of commercial success, while ignoring the role that the invention itself played in that success.

Cubist Pharmaceuticals, Inc. v. Hospira, Inc., is illustrative. 805 F.3d 1112 (Fed. Cir. 2015). There, the Federal Circuit affirmed a district court's decision discounting evidence of commercial success in a pharmaceuticals case by reasoning that the success

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[1] In line with its more restrictive approach, the Federal Circuit has cabined the "presumption of nexus" to circumstances where the product is "coextensive" with the claimed features. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1129-30 (Fed. Cir. 2000). That subsidiary nexus inquiry has itself spawned inconsistency and confusion. *See* Jason Reinecke, *Assessing Evidence of Secondary Considerations*, 68 Vill. L. Rev. 633, 637 (2023) (explaining that the Federal Circuit has "applied multiple tests" to determine whether a product is coextensive). And, as a practical matter, panels often ignore the presumption entirely—as the Federal Circuit did here.

was "mainly attributable to [the drug] itself," rather than the novel dosing and interval protocol patents at issue. *Id.* at 1126. But by that logic, the objective indicia can be deemed irrelevant in virtually every case involving a pharmaceutical improvement, because by definition, the *drug* is the baseline necessity driving sales. The Federal Circuit's rigid analysis thus fails to give meaningful weight to the role that improvements may play in cementing a product's place in the market, foreclosing threats from competitors, or otherwise strengthening a company's position in ways that support an inference of novelty. *See also, e.g.*, *E.I. du Pont De Nemours & Co. v. MacDermid Printing Sols., L.L.C.*, 657 F. App'x 1004, 1011 (Fed. Cir. 2016) (summarily affirming district court's finding that du Pont failed to show nexus because it was already a dominant player in the market); *Galderma Laboratories, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740 (Fed. Cir. 2013) (finding novel medication obvious even though it had "quickly gained and maintained market share" in an "overall declining market" and against stiff competition from generic formulations (citation omitted)). That result is diametrically opposed to the "broad" and "flexible" inquiry established by *Graham*. *KSR*, 550 U.S. at 399, 415.

Furthermore, in some cases, the Federal Circuit has required patentees to affirmatively *disprove* other potential causes of commercial success before attributing success to the patented invention. In *In re DBC*, for example, the Federal Circuit dismissed evidence of "substantial" "sales" because a patentee had not provided "evidence" that those sales "were *not* merely attributable to the increasing popularity of mangosteen fruit"—the patented invention's key

ingredient—"or the effectiveness of the marketing efforts employed." 545 F.3d at 1384 (emphasis added); *see also In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996) (speculating that sales may have been "due to lower manufacturing costs" or "features of the product" "unrelated to the patented subject matter").

The Federal Circuit again took a stringent approach in *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, where Wrigley faced an obviousness challenge from Cadbury regarding Wrigley's patent for chewing gum that produced a "cooling sensation." 683 F.3d 1356, 1362 (Fed. Cir. 2012). Despite evidence that Wrigley's patented cooling system threatened to cost Cadbury millions in sales, and a Cadbury internal report identifying the cooling system as a "key driver" of consumer loyalty, the Federal Circuit found no "nexus" between Wrigley's patent claim and its commercial success. *Id.* at 1369 (Newman, J., concurring in part, dissenting in part). Specifically, the court concluded that the evidence failed to demonstrate that "the success of Wrigley's product was *directly attributable*" to the unique formula of the patented invention. *Id.* at 1364 (emphasis added). The Federal Circuit similarly invoked "nexus" to dismiss Wrigley's evidence that Cadbury had copied its patented product, noting that the evidence did not show that it was the patented invention's "novel combination" of elements that "led Cadbury to copy Wrigley's Chewing gums." *Id.* at 1364. Dissenting in part, Judge Newman found the majority's conclusion "that nexus was not established hard to fathom." *Id.* at 1369 (citation omitted).

Cases like *DBC* and *Wrigley* make clear that the Federal Circuit's "nexus" test has swallowed the holistic, common-sense analysis that *Graham*

requires. And that is particularly true in the context of novel improvements to the prior art, where direct evidence of a specific "nexus" may be difficult—if not impossible—to obtain.

Though problematic in itself, this development is particularly concerning because of the imbalance it creates with courts' expansive analysis of the other *Graham* factors. Under *KSR*, "design incentives and other market forces"—untethered to any particular teaching in the prior art or claim limitation of the patent—can supply a motivation to combine and demonstrate obviousness. 550 U.S. at 417. Yet comparable evidence of market forces showing *non*-obviousness is deemed irrelevant absent proof that it is a "direct result" of a particular claim limitation. *WesternGeco*, 889 F.3d at 1331. That imbalance has unduly skewed the obviousness analysis in favor of the over-invalidation of patents. *See infra* at 35-36; *see also* Ryan T. Holte & Ted Sichelman, *Cycles of Obviousness,* 105 Iowa L. Rev. 107, 141-42 (2019) (finding that after *KSR*, "obviousness determinations became about 20% more likely in the district courts" and 10% more likely in the Federal Circuit).

3. The Federal Circuit's unduly restrictive approach, as exemplified by its rigid "nexus" test, has elicited substantial criticism from a portion of its bench and generated a host of split opinions.

In *WBIP*, for example, Judge Moore wrote for the panel to explain 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. 829 F.3d at 1331-32. In doing so, she emphasized that "appellate-created categorical rules and hierarchies as to the relative weight or significance of proffered evidence" risk

distorting the "highly fact-dependent" analysis that obviousness requires. *Id.* at 1331. The panel thus rejected an argument that objective evidence of non-obviousness had to be tied to the specific features of a product not disclosed in the prior art, as opposed to a novel combination of features, explaining that "proof of nexus is not limited to only when objective evidence is tied to the supposedly 'new' feature(s)." *Id.*

Other judges have voiced their concerns with the Federal Circuit's rigid approach in dissent. In *Tokai Corp. v. Easton Enterprises, Inc.*, for example, the majority affirmed summary judgment on obviousness after discounting the patentee's uncontested evidence of commercial success because of lack of "nexus." 632 F.3d 1358, 1370 (Fed. Cir. 2011). Judge Newman dissented, arguing that the majority improperly "ignore[d]" the patentee's "evidence that its commercial success was due to its improved child-safety mechanism" by applying an unduly stringent nexus requirement. *Id.* at 1379.

Similarly, in *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, Judge Lourie explained, in a dissent from denial of rehearing en banc, that the majority had applied an "unsound" nexus rule that "holds in effect that commercial success for an improvement is irrelevant when a prior patent dominates the basic invention." 405 F.3d 1338, 1339 (Fed. Cir. 2005). And in *Media Technologies Licensing, LLC v. Upper Deck Co.*, Judge Rader likewise criticized the majority, which had found a lack of nexus, for finding a patent obvious "[w]ithout even so much as a cursory review of . . . unexpected results, the skepticism of experts, the commercial success, the flattery of copying, or any

other objective facts." 596 F.3d 1334, 1339-40 (Fed. Cir. 2010) (dissenting).[2]

The Federal Circuit's en banc decision in *Apple Inc. v. Samsung Electronics Co.*, only underscores the confusion. 839 F.3d 1034 (Fed. Cir. 2016). There, a majority of the Federal Circuit held that the Apple iPhone's commercial success was attributable in part to Apple's patented slide-to-unlock feature, such that the success provided objective evidence of that feature's non-obviousness. *Id.* at 1054-56. In affirming the "nexus" between the slide-to-unlock feature and the iPhone's success, the majority relied on contextual evidence, including the prominence of the slide-to-unlock feature in advertising and a video of a crowd "burst[ing] into cheers" when Steve Jobs highlighted the feature at the iPhone's product launch. *Id.* at 1055-56 (alteration in original) (citation omitted).

But several judges disagreed with this more flexible approach, advancing a stricter view of the "nexus" requirement that would have required Apple to provide direct evidence that the iPhone's success was due to the slide-to-unlock feature. *See id.* at 1068 (Prost, J., dissenting) (arguing that Apple failed to "establish a nexus" between its commercial success and "the patented feature"); *id.* at 1080, 1082 (Dyk, J., dissenting) (arguing that there must be "a nexus to

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[2] *See also, e.g.*, *Acorda Therapeutics, Inc. v. Roxane Laboratories, Inc.*, 903 F.3d 1310, 1353-54 (Fed. Cir. 2018) (Newman, J., dissenting) (arguing that majority improperly discounted compelling evidence of non-obviousness); *Sanofi-Aventis Deutschland GMBH v. Mylan Pharms. Inc.*, 791 F. App'x 916, 930 (Fed. Cir. 2019) (Newman, J., dissenting) (criticizing majority for ignoring continued commercial success of reformulated drug).

what is new in comparison to the prior art" and criticizing majority for "elevating secondary considerations of nonobviousness beyond their role").

As Judge Reyna explained in dissent, it is apparent that members of the Federal Circuit "disagree[] over the role objective indicia play in the court's analysis of the ultimate determination of obviousness"—an "important issue[]" that demands further review. *Id.* at 1089. Yet the majority decision in *Apple* did not "claim to change the law or lead to a greater understanding of the law." *Id.* at 1087. As a result, confusion reigns and inconsistent and inflexible treatment of the objective indicia persists. *See supra* at 22-27; *In re Cyclobenzaprine*, 676 F.3d at 1075 (explaining that the court "has inconsistently articulated" the standards for assessing the objective indicia); Dmitry Karshtedt, *Nonobviousness: Before and after*, 106 Iowa L. Rev. 1609, 1639 (2021) ("It is no secret that the treatment of secondary considerations at the Federal Circuit is highly panel-dependent . . . .").

4. In short, the Federal Circuit's "nexus" requirement has become a rigid tool that panels have repeatedly invoked to brush aside compelling evidence of objective indicia in many cases.

That evolution should look familiar to this Court. In *KSR*, this Court rejected the Federal Circuit's "teaching, suggestion, or motivation" test for obviousness insofar as it transformed *Graham*'s "'functional approach'" into "a rigid rule that limits the obviousness inquiry." 550 U.S. at 415, 419 (citation omitted). In doing so, it recognized that the Court of Customs and Patent Appeals had "captured a helpful insight" when it "first established" that test. *Id.* at 418. Yet, as the Court explained, "[h]elpful

insights . . . need not become rigid and mandatory formulas . . . incompatible with [this Court's] precedents." *Id.* at 419.

Just as the Court stepped in to restore a flexible and expansive approach to the technical *Graham* factors in *KSR*, it should now step in to do the same for the objective indicia of non-obviousness. This Court has not hesitated to intervene when Federal Circuit rules ossify to the point of undermining their utility. *See, e.g.*, *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 555 (2014) (rejecting Federal Circuit approach to attorneys' fees that "superimpose[d] an inflexible framework onto statutory text that is inherently flexible"); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393-94 (2006) (rejecting Federal Circuit's categorial rule for granting permanent injunctions in lieu of traditional equitable test); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 737-38 (2002) (rejecting Federal Circuit's "*per se*" approach to prosecution history estoppel in favor of "flexible" application). Here, the Court's intervention is especially critical because a cramped application of the objective indicia severely undermines their role as a common-sense check on hindsight bias.

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

The decision below exemplifies the Federal Circuit's trend of negating the objective indicia of non-obviousness by applying a rigid inquiry that eliminates the objective indicia as a meaningful part of the analysis. App.22a (citing *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019)). The record reflects that Purdue's reformulated,

abuse-deterrent OxyContin addressed a severe public-health need and preserved the commercial viability of a highly valuable medication, fending off competitors who would have undercut Purdue's market position had they developed their own abuse-deterrent opioid medication. Yet the Federal Circuit gave that evidence no weight.

To start, the Federal Circuit disregarded Purdue's evidence of commercial success on the basis of its "nexus" requirement. According to the panel, there was "no nexus between the claimed invention and the commercial success." App.24a. This makes no sense. The record demonstrates that abuse deterrence was "one of the highest unmet needs in the market," Appx5374, and healthcare providers viewed abuse-deterrent information as "the most important data" they reviewed, Appx5376. As Accord's own expert admitted, Purdue's abuse-deterrent patents "definitely" solved "a long felt, but unmet need in the art." Appx5704-5705 (Appel 671:22-672:2).

The original formulation of OxyContin faced an existential threat in the marketplace because of the well-known abuse epidemic. As is evidenced by FDA's subsequent withdrawal of its approval for the original formulation of OxyContin, the patented invention was essential to preserving OxyContin's commercial viability. As Accord's own witness testified, "[t]here's no doubt" that OxyContin's sales would have been lower without its abuse-deterrent features. Appx5690, Appx5693 (Hoffman 657:7-13, 660:19-22); *see also* Appx5402 (Sharma 369:3-6) (explaining that "[w]ithout abuse-deterrent features, the OxyContin sales would have been significantly lower").

After FDA approved reformulated OxyContin's abuse-deterrent labeling, it both withdrew original

OxyContin from the market and prohibited all non-abuse-deterrent extended-release oxycodone products. Appx6809-6818. This alone establishes a direct connection between reformulated OxyContin's commercial success and the abuse-deterrent features achieved through the patented invention. Yet the Federal Circuit discounted all of this because the record did not demonstrate an *increase* in OxyContin sales. App.24a.

The Federal Circuit's complete dismissal of this evidence is irreconcilable with this Court's precedents. This Court has found, going back more than a century, that evidence that a new product was "generally accepted" as a great "advance" or "replaced all earlier processes" is "persuasive evidence" of non-obviousness. *Mins. Separation*, 242 U.S. at 270; *see also Smith*, 93 U.S. at 495 (evidence that invention was being used "in preference to older devices" raised inference of inventiveness). Here, the reformulated version of OxyContin literally led to the withdrawal of FDA's approval for the initial formulation, and so replaced that product. So the nexus between Purdue's invention and the commercial success of reformulated OxyContin could not be more clear. Yet the panel refused to draw the straightforward inference that reformulated OxyContin's success was due to its abuse-deterrent properties—and that this success was a strong indicator of *non*-obviousness.

The Federal Circuit's rigid application of objective indicia stands in stark contrast to the flexible approach the panel applied to the technical *Graham* factors. The panel inferred, for example, that Purdue's novel heating approach was "obvious to try" based on market pressures to develop a scalable product, applying *KSR*'s broad approach. App.14a-

15a. But it refused to engage in any practical assessment of how market incentives demonstrated *non*-obviousness in the context of the objective indicia. As this case illustrates, *KSR*'s flexible approach must be applied evenhandedly to the technical and non-technical factors alike to prevent over-invalidation of non-obvious patents.

The Federal Circuit's error is underscored by considering what would have happened if a competitor, rather than Purdue, had developed an abuse-deterrent formulation of an oxycodone pain medication. The competitor would have reaped the benefit of Purdue's sales, replacing OxyContin as the market leader—and perhaps displacing Purdue's non-abuse-deterrent formulation altogether. Meantime, OxyContin's approval would have been withdrawn (as it was when Purdue introduced its abuse-deterrent formulation). This would have been an extraordinary commercial success for the separate company. The result is no different simply because Purdue succeeded in avoiding a commercial disaster as a result of its hard-earned abuse-deterrence invention.

The panel repeated the same flawed analysis with respect to Purdue's evidence of FDA skepticism and the failure of other manufacturers to develop a comparable product. Again, the panel held that the evidence purportedly lacked a sufficient connection to specific claim limitations of the patent, without ever considering the evidence more broadly to determine what, if any, inferences it might support. It reasoned that FDA's skepticism was "about applying the abuse-deterrent label," and concluded such skepticism was irrelevant because "abuse deterrence" is not expressly claimed in the asserted patents. App.25a. In doing so, it refused to consider the common-sense fact that

Purdue's novel invention produced an effective abuse-deterrent formulation, overcoming FDA skepticism to solve "a long felt, but unmet need." Appx5704-5705 (Appel 671:22-672:2).

Similarly, the panel simply ignored Purdue's evidence that its competitors sought—and failed—to produce abuse-deterrent formulations, once more insisting that such evidence would be relevant only if directly connected to a "claimed feature[]" of Purdue's patents. App.26a (citation omitted); *see also* App.64a-65a (finding that competitor's failure to develop comparable drug formulation "due to difficulties with scaling" was irrelevant, even though court had found a "production-scale-based motivation to combine"). But again, that analysis skips over the flexible and expansive inquiry *KSR* requires, ignoring the common-sense inference that if Purdue's invention had truly been obvious, its competitors, which were actively trying to develop comparable products to stem a public-health tragedy and replace Purdue in the market, would have succeeded in doing so.

The objective indicia of non-obviousness are especially powerful in this case. And they are directly tied to the patented invention. It is undisputed that there was a long-felt but unmet need for a commercially viable abuse-deterrent oxycodone medication. And there was a huge financial incentive for developing such a product—the potential to overtake Purdue's position as the market leader in extended-release oxycodone and capture its sales. So if Purdue's invention was so obvious, why did others fail to develop the product and supplant Purdue? The answer is, well, obvious.

II. THE QUESTION PRESENTED IS RECURRING AND IMPORTANT

The question presented is also exceptionally important.

1. This Court has long recognized the "great[] public importance" of the question of patent validity, *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330 (1945), and routinely grants review of questions related to the implementation of the Patent Act. *See, e.g.*, *Amgen Inc. v. Sanofi*, 598 U.S. 594, 599 (2023) (addressing the degree of specificity required by the Patent Act's "enable[ment]" clause); *KSR*, 550 U.S. at 415 (considering standard for obviousness inquiry); *Microsoft Corp.*, 564 U.S. at 95 (considering standard of proof for invalidity defenses, including obviousness).

Proper administration of the obviousness analysis is a critical component of the patent system. 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, and it is becoming more common. *See Apple*, 839 F.3d 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."); Jason Reinecke, *Assessing Evidence of Secondary Considerations*, 68 Vill. L. Rev. 633, 635 (2023) ("[N]onobviousness is so important in United States patent law that it is in dispute in almost every patent case."). The objective indicia are, in turn, "a critical piece of the obviousness analysis," *Leo Pharm. Prods.*, 726 F.3d at 1358, which "must always when present be considered," *Stratoflex*, 713 F.2d at 1538.

Courts are thus routinely confronted with the question of how to analyze the objective indicia.

While this Court has recognized the importance of the objective indicia, it has yet to provide meaningful guidance on how they should be analyzed, including with respect to any nexus requirement. The Federal Circuit has filled the void by demanding an inflexible "nexus," and ignoring the common-sense, holistic inquiry that this Court established in *Graham*. Without clear guidance on how to apply the *Graham* factors, obviousness has become a "vexing doctrine" that courts and litigants alike struggle to understand and apply. *See* Daralyn J. Durie & Mark A. Lemley, *A Realistic Approach to the Obviousness of Inventions*, 50 Wm. & Mary L. Rev. 989, 990-1015 (2008).

2. Unless this Court intervenes, the Federal Circuit will continue to apply its flawed analysis and undermine the role of the objective indicia in the obviousness inquiry. *See, e.g.*, *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1359 (Fed. Cir. 2017) (Reyna, J., dissenting-in-part) (explaining that under the majority's approach to objective indicia, "it is hard to imagine a situation in which" the objective indicia could ever "make a difference"). That, in turn, will render the inquiry susceptible to hindsight bias by judges and ultimately result in the over-invalidation of patents, to the detriment of the system as a whole.

That risk is especially acute for technically complex products like pharmaceuticals. Where the process embodied in the patent is particularly complex or nuanced—as in the fields of chemistry and pharmaceutical development—it is all the more important to give the objective criteria their due weight. Otherwise, patents for genuinely surprising,

commercially successful products that fill a long-felt but unmet need may face invalidation due to hindsight bias or misunderstandings about differences between the patented invention and the prior art. *See, e.g.*, *Novo Nordisk A/S v. Caraco Pharm. Laboratories, Ltd.*, 719 F.3d 1346, 1360 (Fed. Cir. 2013) (Newman, J., concurring in part, dissenting in part) (arguing that the obviousness inquiry must account for "the realities and challenges of discovering a new medicinal product").

This dynamic will erode the incentives to innovate that the patent system is designed to protect. *See* U.S. Const. art. I, § 8, cl. 8 (conferring on Congress the power to "promote the Progress of Science and useful Arts" by securing exclusive rights for inventors). Without any assurance that they will be able to recoup their investments, companies will hesitate to take risks to develop cutting-edge technology. *See Novo Nordisk A/S*, 719 F.3d at 1365-66 (Newman, J., concurring in part, dissenting in part). This is especially true for the pharmaceutical industry, where patents are crucial to ensuring that companies can recover the significant costs of research and development. *See, e.g.*, Iain M. Cockburn et al., *Patents and the Global Diffusion of New Drugs*, 106 Am. Econ. Rev. 136, 138-39 (2016). And the ultimate result will be to deprive the public of transformative innovations like those at issue here.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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April 30, 2025

APPENDIX

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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

Plaintiffs-Appellants

v.

ACCORD HEALTHCARE, INC.,

Defendant-Appellee

2023-1953

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

Decided: December 30, 2024

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-hy-droxy. 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]

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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 Treatment*, 24 Drug Dev. and Indus. Pharm. 1, 45–50 (1998), J.A. 9439–45; Marcelo O.

"Bartholomaus and McGinity 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

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Omelczuk & James W. McGinity, *The Influence of Thermal Treatment on the Physical-Mechanical Properties of Tablets Containing Poly(DLLactic Acid)*, 10 Pharm. Rsch. 4, 542 (1992) ("Omelczuk"), J.A. 9446–96.

more commonly available equipment." *Id.* at 297–98. The 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 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

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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.

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 antiabuse 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 antiabuse 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 Bartholomaus 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-dihy-droxy-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-di-hydroxy-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-hy-droxy, 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

[669 F. Supp. 3d 286]

UNITED STATES DISTRICT COURT,
D. Delaware

PURDUE PHARMA L.P., Purdue Pharmaceuticals L.P., and Rhodes Technologies, Plaintiffs,

v.

ACCORD HEALTHCARE INC., Defendant.
Civil No. 21-11558-LTS

Signed April 11, 2023

TRIAL OPINION

ANDREWS, UNITED STATES DISTRICT JUDGE:

Plaintiffs Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and Rhodes Technologies brought this patent infringement action under 35 U.S.C. § 271(e)(2)(A) against Defendant Accord Healthcare. (D.I. 1 ¶ 2). I held a three-day bench trial from September 19 to September 21, 2022. The parties narrowed the issues to invalidity for obviousness of each of six asserted claims from five remaining patents.

The asserted patents fall into two groups, each of which shares a substantively identical specification. (D.I. 89-1 ¶¶ 10, 21). One group consists of U.S. Patent Nos. 9,763,933 ("the Mannion '933 patent"), 9,775,808 ("the '808 patent"), and 9,763,886 ("the '886 patent"). The parties refer to these patents as the "Tamper Resistant" or "Abuse-Deterrent Patents." I refer to them as the "Abuse-Deterrent Patents." The claims at issue are claim 3 of the Mannion '933 patent,

claim 3 of the '808 patent, and claim 6 of the '886 patent.

The second group consists of U.S. Patent Nos. 9,073,933 ("the '933 patent") and 9,522,919 ("the '919 patent"). The parties (and I) refer to these as the "Low ABUK Patents." The claims of the "Low ABUK Patents" at issue are claims 3 and 11 of the '933 patent and claim 21 of the '919 patent.

For the following reasons, I find all six of the asserted claims invalid for obviousness under 35 U.S.C. § 103.

I. BACKGROUND

Purdue holds New Drug Application ("NDA") No. 022272 for OxyContin (oxycodone hydrochloride). OxyContin is an extended-release analgesic. (D.I. 89-1 ¶ 32). The Abuse-Deterrent Patents relate to an abuse-deterrent reformulation of OxyContin that make it hard enough to resist crushing and viscous enough to deter intravenous users. (D.I. 106 at 3, 5). The reformulation was approved in 2010, and the Food and Drug Administration ("FDA") approved an abuse-deterrent label for the reformulation in 2013, following postmarketing studies. (D.I. 107 ¶ 20). I will refer to the pre-reformulation version of OxyContin as "Original OxyContin."

The Low-ABUK Patents relate to compositions of oxycodone containing 8α-14-dihydroxy-7,8-dihydrocodeinone ("8α") and having particularly low levels of the impurity 14-hydroxycodeinone ("14-hydroxy"). (*Id.* ¶¶ 48-49). 14-hydroxy is an alpha beta unsaturated ketone ("ABUK"), a class of compounds thought to be genotoxic. The evolution of the scientific understanding of these compounds'

genotoxicity is a factual issue in this case. (D.I. 100 ¶ 158).

Accord submitted an Abbreviated New Drug Application ("ANDA") No. 213564 for approval to market a generic version of OxyContin. Plaintiffs then initiated this lawsuit. (D.I. 1 ¶¶ 1-2). The Mannion '933, '808, '933, and '919 patents are all listed in the FDA's Orange Book for OxyContin. The '886 patent is not. (*Id.* ¶ 1).

II. LEGAL STANDARD

A patent claim is invalid as obvious under 35 U.S.C. § 103 "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 to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007). "As patents are presumed valid, a defendant bears the burden of proving invalidity by clear and convincing evidence." *Shire, LLC v. Amneal Pharms., LLC*, 802 F.3d 1301, 1306 (Fed. Cir. 2015) (citations omitted). "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined." *KSR*, 550 U.S. at 406, 127 S.Ct. 1727 (internal citation and quotation marks omitted).

A court is required to consider secondary considerations, or objective indicia of nonobviousness, before reaching an obviousness determination,

as a "check against hindsight bias." *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1078-79 (Fed. Cir. 2012). "Such 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." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966).

III. THE ABUSE-DETERRENT PATENTS

A. The Asserted Claims

The claims at issue are claim 3 of the Mannion '933 patent, claim 3 of the '808 patent, and claim 6 of the '886 patent. Claim 3 of the Mannion '933 patent is a product-by-process claim that depends on claim 1. Claims 1 and 3 read,

> 1. A pharmaceutical composition comprising:
>
> at least one active agent;
>
> at least one high molecular weight polyethylene oxide (PEO) having an approximate molecule weight of from 1 million to 15 million;
>
> optionally at least one additive;
>
> optionally at least one 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.

. . .

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.

(Mannion '933 patent at 158:61-159:16, 159:20-23).

Claim 3 of the '808 patent is a product-by-process claim that depends on claim 1. The two claims read,

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 molecule weight of from 1 million to 15 million;

at least one 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.

. . .

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.

('808 patent at 159:37-57, 159:61-64).

Claim 6 of the '886 patent is a method claim, which depends on claims 5, 3, 2, and

1. The claims read,

1. A method of producing a plurality of solid oral extended release pharmaceutical dosage forms comprising the steps of:

mixing at least one active agent, at least one high molecular weight polyethylene oxide (PEO) having an approximate molecular weight of from 1 million to 15 million, to provide a PEO composition;

compressing the PEO composition to provide a plurality of shaped matrix compositions;

curing the shaped matrix compositions by exposure to heated air at a curing temperature that is at least the softening temperature of the high molecular weight PEO for a curing time of at least about 5 minutes, to provide a plurality of cured matrix compositions;

cooling the cured matrix compositions;

optionally combining any of the matrix compositions with at least one additive, before or after curing; and

optionally providing the cured matrix compositions with at least one film coating, after curing and cooling; wherein

(a) the molecular weight of each PEO is based on rheological measurements;

(b) the high molecular weight PEO comprises at least about 30% (by weight) of each dosage form;

(c) the total weight of each dosage form is calculated by excluding the combined weight of said film coatings.

(d) each cured matrix composition comprises a solid oral pharmaceutical dosage form that provides an extended release of at least one active agent.

2. A method according to claim 1, wherein the curing temperature is at least about 60° C. and the curing time is at least 10 minutes.

3. A method according to claim 2, wherein the high molecular weight PEO has an approximate molecular weight of from 1 million to 8 million.

> . . .
>
> 5. A method according to claim 3, wherein the high molecular weight PEO comprises at least about 50% (by weight) of each dosage form.
>
> 6. A method according to claim 5, wherein the curing temperature is from about 65° C. to about 90° C. and the curing time is from about 10 minutes to about 10 hours.

('886 patent at 171:35-172:22, 172:26-32).

B. Findings of Fact

1. Both Original OxyContin and the reformulation that the Abuse-Deterrent Patents concern are extended-release matrix tablets. (Tr. at 204:16-21;[1] '886 Patent at 171:42-50). Matrix tablets contain an active ingredient embedded in a polymer matrix. (Tr. at 202:23-203:9)
2. Polyethylene oxide (PEO) is among the most commonly used matrix polymers. (Tr. at 204:6-8).
3. With respect to the Abuse-Deterrent Patents, a person of ordinary skill in the art ("POSA") has an advanced degree and substantial experience drawn from the fields of medicine, chemical engineering, polymers, pharmaceutical sciences, pharmaceutics, pharmacokinetics, and pharmacology. (D.I. 89-1 at ¶ 134).
4. The Abuse-Deterrent Patents are directed to compositions and methods of producing abuse-

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[1] The transcript is available at D.I. 102-105. It is consecutively paginated.

deterrent pharmaceutical formulations. (D.I. 89-1 ¶¶ 21-22).

5. For purposes of this action, the priority date of the patents is August 25, 2006. (D.I. 89-1 ¶¶ 24, 27, 30).
6. Abuse by crushing was a known issue with OxyContin. (DTX-008).
7. United States Patent No. 6,488,963 to McGinity ("McGinity") is prior art to the Abuse-Deterrent Patents under 35 U.S.C. § 102(b). (D.I. 89-1 ¶ 120).
8. A POSA would have understood that, because McGinity's tablets were made from melted PEO, they had increased breaking strength that provided resistance to crushing. (Tr. at 220:17-26).
9. McGinity teaches that its formulations can be used on "analgesics" (DTX-009 at 6:10), which a POSA would understand includes oxycodone. (Tr. at 220:7-16).
10. McGinity teaches melting PEO in a hot-melt extruder to create hardened tablets. (DTX-009 at 8:8-28). At the time of the invention, hot melt extruders, though known, were not common. (Tr. at 219:3-13). They could be used at contract manufacturers. (Tr. at 257:17-19).
11. U.S. Patent Publication No. 2005/0031546 ("Bartholomaus") is prior art to the Abuse-Deterrent Patents under 35 U.S.C. § 102(b). (DTX-010; D.I. 89-1 ¶ 123).
12. Bartholomaus teaches pressing PEO tablets in a "heating cabinet." (DTX-010 at [0117]). A POSA would understand that the purpose of

the heating was to melt the PEO. (Tr. at 227:5-13).

13. The method disclosed in the examples in Bartholomaus was not scalable. (Tr. at 226:7-26, 332:5-24).
14. Bartholomaus contemplates pressing tablets and heating them as separate steps. (Tr. at 227:20-228:4; DTX-010 at [0067]).
15. 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") is prior art to the Tamper Resistant Patents under 35 U.S.C. § 102(b). (D.I. 89-1 ¶ 126). Shao discloses matrix tablets made with the polymer Kollidon-SR (polyvinylacetate-povidone). (DTX-011 at 0001).
16. Nashiru Billa et al., *Diclofenac Release from Eudragit-Containing Matrices and Effects of Thermal Treatment*, 24 Drug Dev. and Indus. Pharm. 1, 45-50 (1998) ("Billa") is prior art to the Tamper Resistant Patents under 35 U.S.C. § 102(b). (D.I. 89-1 ¶ 127). Billa discloses matrix tablets made with the polymer EUDRAGIT (ethyl acrylate-methyl methacrylate copolymer). (DTX-012 at 0002).
17. 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;" together with Billa and Shao, the "Oven Art") is prior art to the Tamper Resistant Patents under 35 U.S.C.

§ 102(b). (D.I. 89-1 ¶ 128). Omelczuk discloses matrix tablets made with the polymer PLA (poly(DL-lactic acid)). (DTX-014 at 0001).

18. The Oven Art teaches heating various non-PEO polymers in ovens (Tr. at 229:20-25, 231:11-22, 232:1-11), though not to their melting points. (Tr. at 286:5-14, 287:6-8).
19. Shao concluded that the curing process increased the hardness of the tablets. (DTX-011 at 0005; Tr. at 230:9-20).
20. Both Bartholomaus and the Oven Art disclose cooling and hardening the tablet. (Tr. at 240:8-11).

C. Conclusions of Law

As a preliminary matter, the parties treat the three asserted Abuse-Deterrent claims as though they rise and fall together. Neither party contends that their arguments or my analysis should apply differently to the product-by-process than to the method claims. Therefore, I too will treat the three claims together. For the following reasons, I conclude that each of the three claims is invalid for obviousness under 35 U.S.C. § 103.

Defendant relies on five pieces of prior art in arguing for the obviousness of the Abuse-Deterrent Patents. Bartholomaus and McGinity 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. The parties generally agree on two ways in which the Abuse-Deterrent Patents depart from the prior art. First, the prior art that used PEO (Bartholomaus and McGinity) taught simultaneous compression and

heating (D.I. 99 at 5; D.I. 106 at 7), while the prior art that taught sequential compression and heating (the Oven Art) used polymers other than PEO. (D.I. 99 at 10-11; D.I. 106 at 13). The parties disagree about whether a POSA 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. (D.I. 99 at 6; D.I. 106 at 13). The parties disagree about whether routine experimentation by a POSA would have yielded the times and temperatures disclosed in the patents. I focus in turn on each difference between the asserted claims and the prior art, though some of the parties' arguments are common to both.

1. Sequential Compression and Heating

The first gap between the Abuse-Deterrent Patents and the prior art can be bridged by combining the PEO tablets of Bartholomaus and McGinity with the heating techniques taught in the Oven Art. With all elements of the claim present in the prior art, "[a] party seeking to invalidate a patent on the basis of obviousness must 'demonstrate by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012) (quoting *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 1014 (Fed. Cir. 2009)).

a. Motivation to Combine

In arguing for a POSA's motivation to combine the prior art, Defendant asserts that a POSA would look to Bartholomaus and McGinity in the first place because abuse by crushing was a known problem. (D.I. 99 at 7-8). A POSA would then seek to modify Bartholomaus and McGinity because the processes disclosed in those references would not have been suitable for large-scale production. (*Id.* at 13). For example, Defendant's expert, Dr. Leah Appel, testified that the Bartholomaus method applies heat by placing a tablet press in a heated chamber, but scaling this to produce many tablets at once would require a large space heated to a high temperature—and it is unclear how one would operate a tablet press in those conditions. (Tr. at 226:1-18). Dr. Appel also testified that the hot melt extruders used in McGinity were "niche" at the time of invention—they were available at some facilities, but access to one was not a given. (*Id.* at 219:3-13). Researchers might have to contract with other companies in order to use one. (*Id.* at 258:8-16). Dr. Appel testified that ovens, by contrast, were a common and readily accessible tool for heating tablets. (*Id.* at 219:14-19). Defendant argues that a POSA would therefore naturally turn to ovens in either scaling up Bartholomaus or adapting McGinity to more commonly available equipment. The Oven Art would have provided guidance for a POSA on how to cure matrix tablets in an oven, leading to the claimed invention.[2]

Plaintiffs respond with several critiques of Dr. Appel's analysis. First, Plaintiffs argue that a POSA

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[2] Defendant also argues—in a footnote—for collateral estoppel on the factual issue of whether simultaneous and

presented with Bartholomaus and McGinity would not have a motivation to modify those references, because each of those references discloses an effective crush-resistant tablet. (D.I. 106 at 10). As to McGinity, Plaintiffs also challenge the idea that hot-melt extruders were niche, arguing that they were available at certain facilities that could be contracted with. (*Id.* at 8). Second, Plaintiffs assert that even if a POSA sought to modify Bartholomaus and McGinity, the POSA would not have a motivation to combine Bartholomaus and McGinity with the Oven Art in particular, because the Oven Art did not use PEO and did not teach heating matrix tablets to their polymers' melting points. (*Id.* at 13). Third, Plaintiffs argue that a POSA would never have looked to Bartholomaus and McGinity in the first place and would instead have sought to add an antagonist. (*Id.* at 15). Plaintiffs' expert, Dr. Bley, testified that the prior art reference Mansbach "teaches that antagonists are the way to go and particularly for opioid analgesics . . . if there's an antagonist available, that's the preferred path." (Tr. at 425:23-

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sequential heating and compression are equivalent. (D.I. 99 at 14 n.7). In prior litigation, Plaintiffs successfully argued that a sequential heating process infringed, under the doctrine of equivalents, a patent that disclosed simultaneous heating. *See In re Oxycontin Antitrust Litig.*, 994 F. Supp. 2d 367, 419 (S.D.N.Y. 2014). Plaintiffs respond that this case involved different patents and products. (D.I. 106 at 9). The application of collateral estoppel here was barely briefed. I think it is extremely unlikely that collateral estoppel applies. Whether or not it does, I do not think a factual determination that simultaneous and sequential processes are equivalent is necessary for a finding of obviousness. Therefore, I do not address the application of collateral estoppel and disregard the factual findings that Defendant offers in footnotes.

25; PTX-131 at S19). Dr. Bley also testified that he himself, as a POSA in the field at the relevant time, did not pursue crush resistant tablets, characterizing Dr. Appel's analysis as "hindsight-driven." (*Id.* at 398:16-399:14).[3]

On the first issue of whether a POSA would want to modify Bartholomaus and McGinity, the parties agree that the processes taught by those references successfully produced hardened tablets. (D.I. 99 at 11; D.I. 106 at 10). They disagree on how this success relates to the Abuse-Deterrent Patents. Defendant argues that the processes' viability would make them a good starting point for a POSA trying to develop hardened tablets, while Plaintiffs contend that the successful processes would be a POSA's ending point. Plaintiffs' position fails to address the crux of Defendant's argument. Defendant is arguing that while the processes were successful for "one-off tablets" (Tr. at 228:20-229:7), a POSA would have sought a process that could be scaled up. Plaintiffs do not make a plausible argument that a POSA would not want to develop a scalable process. Plaintiffs also do not make a plausible argument that a POSA would have options other than modifying Bartholomaus and McGinity if they wanted to produce hardened tablets at scale.[4] I also do not think the option to contract

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[3] Plaintiffs also argue, in a single paragraph, that the problem of crushable tablets is not a sufficient "known problem" to support a motivation to modify the prior art. (D.I. 106 at 17). I do not think this is the case, and the briefing on this argument was so summary that I will not address it further.

[4] I note that the question of a POSA's options for producing hardened tablets at scale is distinct from the issue of whether a POSA would want to pursue hardened tablets at all, which I discuss below.

with third-party research or manufacturing facilities—in the case of McGinity's hot-melt extruders—would negate the motivation to adapt the method to ovens.

A POSA's "[m]otivation to combine may be found in many different places and forms." *Par Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1197 (Fed. Cir. 2014) (quoting *Allergan, Inc. v. Sandoz, Inc.*, 726 F.3d 1286, 1292 (Fed. Cir. 2013)). "[I]t often may be the case that market demand, rather than scientific literature, will drive design trends." *KSR*, 550 U.S. at 419, 127 S.Ct. 1727. I think that a desire to manufacture hardened tablets at scale and with minimal switching costs is a motivation to modify the prior art. Finding otherwise would run the risk of "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation," which *KSR* cautioned against. *Id.* Therefore, while it is true that Bartholomaus and McGinity's processes resulted in hardened tablets, I find that a POSA would not stop at their teachings.

Plaintiffs also contend regarding the motivation to modify Bartholomaus and McGinity that "the claims are not limited to commercial manufacturing." (D.I. 106 at 8). However, it is not necessary for commercial manufacturing to be claimed for it to serve as a motivation to combine. In *Alcon Research Ltd. v. Apotex, Inc.*, the Federal Circuit found that known "antihistaminic efficacy" would be a valid motivation to combine certain allergy treatment prior art references. 687 F.3d 1362, 1368-69 (Fed. Cir. 2012). However, the patent at issue claimed the treatment for its ability to "stabiliz[e] conjunctival mast cells"—a different allergy treatment mechanism. *Id.* at 1363-64. I also note that whether the inventors of the

Abuse-Deterrent Patents themselves were motivated a desire to produce at a commercial scale is immaterial. The Federal Circuit has "repeatedly held that the motivation to modify a prior art reference to arrive at the claimed invention need not be the same motivation that the patentee had." *Id.* at 1368.

Overall, I find that Defendant presented clear and convincing evidence of a POSA's motivation to modify Bartholomaus and McGinity. I am convinced by Dr. Appel's testimony that a POSA would seek a commercially viable process for producing hardened tablets.

Second, Plaintiffs argue that even with a motivation to modify Bartholomaus and McGinity, a POSA would not combine them with the Oven Art in particular. I find that Dr. Appel presented clear and convincing testimony that ovens were commonly available and used to heat tablets. Plaintiffs' witnesses did not provide any testimony to the contrary. Plaintiffs did not attempt to show, for example, that a POSA would not have access to ovens, or that other equipment would be a more natural choice than ovens for heating tablets.

I do not think Defendant's theory of obviousness is hampered by the fact that ovens had only been used to heat polymers other than PEO. The Oven Art taught the use of ovens to heat matrix tablets made from several different polymers. (DTX-011 at 0001; DTX-012 at 0002; DTX-014 at 0001). Shao specifically taught that the heat curing made its tablets harder. (DTX-011 at 0005). It is not much of a leap to infer that ovens would also be useful for applying heat to harden the matrix tablets disclosed by Bartholomaus and McGinity. At the very least, in the absence of testimony about other heating tools,

employing a commonly available tool to apply heat to tablets is obvious to try. *See KSR*, 550 U.S. at 421, 127 S.Ct. 1727. While the Oven Art does not teach heating tablets to their melting points, Bartholomaus and McGinity both teach hardening PEO by heating it to its melting point. (DTX-009 at 8:8-28; DTX-010 at [0117]). Dr. Appel credibly testified that a POSA combining these references would seek the same result in an oven. (Tr. at 233:6-13).

I turn to Plaintiffs' third argument, that a POSA would not be motivated to combine Bartholomaus and McGinity with the Oven Art because adding an antagonist would have been a more obvious path. (D.I. 106 at 17). Plaintiffs offer evidence that OxyContin had approved antagonists at the time of the invention (Tr. at 419:8-420:8), and the prior art explicitly taught using an antagonist for abuse deterrence (Tr. at 417:25-419:5). Plaintiffs also offer evidence that both Dr. Bley and Purdue itself first pursued paths other than physical abuse deterrence. (Tr. at 422:3-25, 304:18-305:4). However, a path does not need to be the most obvious or preferred path in order to be obvious. "[C]ase law does not require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention." *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) (quoting *In re Beattie*, 974 F.2d 1309, 1311 (Fed. Cir. 1992)).

Dr. Bley's testimony about his own research may support the viability of the antagonist route, but it does not undermine the viability of the hardness route. Plaintiffs do not, as far as I can tell, argue that the prior art taught *away* from hardened opioid formulations for abuse deterrence—they simply

argue that the prior art taught an alternative. I likewise find that the Mansbach reference on which Plaintiffs rely encourages the use of an antagonist, but does not teach away from using physical abuse deterrence. The passage that Dr. Bley discussed at trial, (Tr. 425:3-25), says, "For drugs of abuse without an approved antagonist, countermeasures against physical tampering may represent the best means to reduce the risk of oral or parenteral abuse." (PTX-131 at S19). While this passage certainly suggests that a POSA should pursue physical abuse deterrence for drugs without an approved antagonist, it says nothing about the inverse of that statement—that a POSA should *not* use such methods for drugs *with* an approved antagonist. Therefore, I do not find that the prior art discourages physical abuse deterrence and I am not persuaded by Plaintiffs' third argument.

Overall, through Dr. Appel's testimony, I find Defendant has presented clear and convincing evidence of a motivation to combine Bartholomaus and McGinity with the Oven Art.

b. Reasonable Expectation of Success

Having found a motivation to combine the prior art references, I consider whether a POSA would have had a "reasonable expectation of success" in "achiev[ing] the claimed invention." *Kinetic Concept*, 688 F.3d at 1360. Defendant notes that a POSA would need to balance opposing considerations in arriving at the claimed invention, ensuring that the PEO would harden, the active ingredient would not degrade, and the method would be practical. (D.I. 99 at 17). Defendant asserts that a POSA would reasonably expect there to be an optimal time and temperature that balances these considerations,

discoverable through routine experimentation.[5] (*Id.* at 16-17). In general support of its obviousness argument, Defendant also notes that Bartholomaus "teaches that its formulations can be made using compression followed by heating." *Id.* at 10. Specifically, Defendant points to passages of Bartholomaus that refer to "subsequent exposure to heat." (DTX-010 at [0065], [0067]). In fact, Bartholomaus notes, "In direct tableting with subsequent exposure to heat, the formed tablets are briefly heated at least to the softening temperature . . . and cooled again." (*Id.* at [0067]).

Plaintiffs argue that there could not have been a reasonable expectation of success in arriving at the claimed invention. Plaintiffs criticize Dr. Appel's testimony as conclusory (D.I. 106 at 18) and the passages about subsequent exposure to heat from Bartholomaus as "generic." (*Id.* at 8-9). Plaintiffs point to testimony by Dr. Richard Mannion, a named inventor on each of the Abuse-Deterrent Patents, that he had reasons to doubt that the method would work. (*Id.* at 19). Specifically, Dr. Mannion testified that heating the tablets without compression might cause them to change shape or stick together. (Tr. at 320:1-18).[6] Plaintiffs also note that Dr. Appel's trial

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[5] his 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 POSA could reasonably expect to make hardened tablets by combining Bartholomaus and McGinity at the claimed times and temperatures.

[6] Dr. Mannion also testified more generally about challenges associated with PEO tablets, including achieving the same

demonstrative does not suggest the same time and temperature ranges disclosed in the patent. They argue that this indicates that a POSA could not have reasonably expected success. (D.I. 106 at 19-20).

"Obviousness does not require absolute predictability of success . . . all that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988). I think there is a reasonable expectation of success in producing a hardened tablet from sequential compression and then heating of PEO. I am persuaded by Dr. Appel's testimony that a POSA would understand that applying heat to melt PEO would cause it to harden. I think a POSA could reasonably expect similar success by simply changing the heating tool.

I also find that Bartholomaus's discussion of subsequent exposure to heat contributes to a reasonable expectation of success—a POSA would expect, upon reading Bartholomaus, to be able to achieve similar results with other heating methods. The statement in Bartholomaus is generic, as Plaintiffs contend, but I find it nevertheless sufficient to support a POSA's expectations. Plaintiffs argue that the sentence in question "makes no sense" because the phrase "cooled again" suggests some undisclosed "prior heating step." (D.I. 106 at 8).

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extended release profile as original OxyContin (Tr. at 308:16-25) and abuse by hot water extraction. (Tr. at 310:12-311:7). I do not treat this testimony as part of the reasonable expectation of success analysis because it does not relate to claimed aspects of the invention. The patents do not claim a particular extended release profile, nor do they claim tablets that cannot have their contents extracted with hot water. I do address this testimony as part of the secondary consideration of skepticism, *infra* pp. 305–06.

I disagree. Just as one might say, "I threw a boomerang, and it came back again," having only thrown the boomerang once, saying that tablets have been "heated . . . and cooled again" seems to be a commonplace, if somewhat vernacular, construction in English.

I do not think that Dr. Mannion's testimony about his own expectations outweighs Dr. Appel's testimony about a POSA's. It is possible that heating tablets without simultaneously compressing them could change their properties, causing some of the problems Dr. Mannion listed. It is also possible that applying heat with an oven rather than with the equipment used by Bartholomaus or McGinity would simply not work. Neither of these possibilities seem likely given Dr. Appel's credible testimony. I appreciate that the prior art does not support a guarantee of success—but the law does not require a guarantee. I was not persuaded, based on Dr. Mannion's testimony about his concerns as an individual fact witness, that a POSA could not still reasonably expect the process to produce hardened tablets.

Plaintiffs' argument about Dr. Appel's trial demonstrative seems irrelevant. I think the demonstrative was clearly intended as an example of how generally to find optimal ranges through experimentation. It was not intended to be indicative of how a POSA would approach the specific task of combining Bartholomaus and McGinity with the Oven Art. Further, there is no need to show that a POSA would know the precise temperatures and times in the patent before trying the method—only that a POSA might reasonably expect to achieve success in that range. *See Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377, 1381 (Fed.

Cir. 2021) (noting that obviousness does not require a showing that "a skilled artisan would have precisely predicted" the claimed dosage of a drug, merely a showing of "a reasonable expectation of success in achieving the specific invention claimed"). Here, common sense, as well as the Oven Art, would suggest that heating times in ovens might be longer than, for example, the times in Bartholomaus, which heated through direct contact. Unlike in *Teva v. Corcept*, nothing in the prior art taught against the times and temperatures in the Abuse-Deterrent Patents. *See id.* at 1379-80.

In sum, I find there was clear and convincing evidence that a POSA would reasonably expect to produce hardened tablets by heating PEO tablets to their melting points in an oven. Further, I find a POSA might reasonably expect the optimal heating times for its combined process to align with those in the patent.

2. Time and Temperature Ranges

I turn now to the second difference between the prior art and the claims at issue: the curing times and temperatures disclosed in the patents. Of the three asserted claims, two claim curing temperatures of 70° C to 85° C, while the third claims 65° C to 90° C. (Mannion '933 patent at 159:21-22; '808 patent at 159:62-63; '886 patent at 172:30). All three claim heating times from ten minutes to ten hours. (Mannion '933 patent at 159:22-23; '808 patent at 159:63-64; '886 patent at 172:31). The times taught in Shao overlap with the time ranges in the patents, but Shao does not use PEO. (DTX-011 at 0002). The temperatures in Bartholomaus and Omelczuk are consistent with those in the asserted claims, but Bartholomaus teaches shorter and Ornelczuk longer

heating times. (DTX-010 at [0117]; DTX-014 at 0002). Because McGinity teaches melting the PEO, its temperatures are also consistent with those in the patent. (DTX-009 at 13:1-13).

Defendant argues that the times and temperatures in the patent are the product of routine experimentation. Thus, even though the exact ranges and combinations claimed are not present in the prior art, they can be found obvious. Dr. Appel testified regarding how a POSA would conduct these routine experiments to find an optimal range. (Tr. at 232:21-235:2). Plaintiffs respond that more than routine experimentation is required because of the large range of possible times and temperatures.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges [of a result effective variable] by routine experimentation." *In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (quoting *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955)). Plaintiffs do not challenge the idea that time and temperature are result-effective—that is, that they "would . . . have been recognized by one of ordinary skill to affect a particular result." *Id.* at 1296.

I am persuaded by Dr. Appel's testimony that testing the curing procedure for various periods of time is simple and routine. Her testimony aligns with common sense. Plaintiffs have not offered any contrary evidence that arriving at a range of ten minutes to ten hours would be beyond the routine skill and creativity of a POSA.

On the whole, I am persuaded that Defendant has presented clear and convincing evidence the patents

are obvious over the prior art of Bartholomaus, McGinity, and the Oven Art. The two primary differences between the patent and the prior art can be overcome by combining the prior art references and engaging in routine experimentation. Defendant offered clear and convincing evidence that a POSA would be motivated to combine the references and would have had a reasonable expectation of success in doing so. Next, I turn to secondary considerations of nonobviousness.

3. Secondary Considerations

Plaintiffs have offered evidence of four secondary considerations of nonobviousness: unexpected results, commercial success, skepticism, and failure of others. A patentee is not required to present evidence of secondary considerations. *See Prometheus Lab'ys., Inc. v. Roxane Lab'ys., Inc.*, 805 F.3d 1092, 1101-02 (Fed. Cir. 2015). There must be enough evidence, however, for a finding that a given secondary consideration exists by a preponderance of the evidence. *See Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1053 (Fed. Cir. 2016) (en banc). If there is, then the probative value of each secondary consideration will be considered in light of the evidence produced. That does not mean, though, that the burden of persuasion on the ultimate question of obviousness transfers to the proponent of the secondary consideration. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 (Fed. Cir. 2007). That burden stays always with the patent challenger. *Id.* at 1359-60.

a. Unexpected Results

"In considering unexpected results, courts ask whether 'the claimed invention exhibits some

superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.'" *Forest Lab'ys., LLC v. Sigmapharm Lab'ys., LLC*, 918 F.3d 928, 937 (Fed. Cir. 2019) (quoting *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995)). These results support a conclusion of nonobviousness where "[t]he unexpected properties of the claimed formulation, even if inherent in that formulation, differ in kind from the prior art." *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1307 (Fed. Cir. 2015) ("*Allergan v. Sandoz II*"). "[E]vidence of unexpected results and other secondary considerations will not necessarily overcome a strong prima facie showing of obviousness." *Sud-Chemie, Inc. v. Multisorb Techs.*, 554 F.3d 1001, 1009 (Fed. Cir. 2009).

Plaintiffs argue that the decrease in tablet density caused by their novel manufacturing process enhanced the abuse-deterrent properties of the tablet. Plaintiffs contend that even though the decrease in density is not claimed, its unexpectedness may still support nonobviousness under *Allergan v. Sandoz II*. (D.I. 106 at 20). Plaintiffs' fact witness Dr. Mannion testified that the Abuse-Deterrent Patents' specifications describe determining a tablet's density because a more porous tablet would be "potentially, more resistant to abuse." (Tr. at 326:2-11). Plaintiffs' expert Dr. Bley likewise testified that a more porous tablet could gel more quickly if it were crushed, making it more difficult to abuse by injection or inhalation. (*Id.* at 403:24-407:7). Plaintiffs also note that the patent examiner cited the surprising decrease in density as a reason for allowing the claims. (D.I. 89-1 ¶ 140).

Defendant does not seem to dispute that the decrease in density was unexpected. Dr. Appel agreed that curing a tablet usually results in an increase in density. (Tr. at 264:4-25). However, Defendant argues that the decrease in density does not contribute to abuse deterrence and is therefore irrelevant to obviousness. (D.I. 109 at 8). Dr. Appel provided testimony that in other contexts, a decreased density in a gel could lead to faster drug release, and that it was unclear that the decrease in density from the patented process had any significant impact. (Tr. at 675:1-676:1).

While I find that Plaintiffs have established by a preponderance of the evidence the existence of unexpected results, I do not find that the nature of these results is sufficient to undermine Defendant's clear and convincing evidence of obviousness. Specifically, I am not persuaded that Plaintiffs have established by a preponderance of the evidence that the decrease in density constituted a "superior property or advantage." *Forest Lab'ys*, 918 F.3d at 937. The testimony on the impact of a decrease in tablet density was too speculative for me to credit Dr. Bley's opinions above Dr. Appel's—at most, they seem to be in equipoise. Further, even if Plaintiffs had proven that the decrease in density was beneficial to abuse-deterrence, any increased gelling benefit the decrease in density might offer would not alone undermine the clear and convincing evidence that the invention's claimed properties are obvious.

b. Commercial Success

"Commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in

the art. Thus, the law deems evidence of (1) commercial success, and (2) some causal relation or 'nexus' between an invention and commercial success of a product embodying that invention, probative of whether an invention was nonobvious." *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). When others are "legally barred from commercially testing" the ideas of the claimed invention, "[f]inancial success is not significantly probative of that question." *Id.* at 1377. Even when commercial embodiments of the invention enjoy commercial success, the "failure to link that commercial success to the features of [the] invention that were not disclosed in [the prior art] undermines the probative force of the evidence." *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008).

Plaintiffs' expert, Mr. Arun Sharma, testified that OxyContin was and has continued to be the most commercially successful extended-release opioid in the United States. (Tr. at 359:23-25, 368:11-15). Plaintiffs argue that OxyContin's dominance of the extended-release opioid market is due to its combination of "Original OxyContin's medical advantages to patients, along with the additional public-health benefits of being abuse deterrent." (D.I. 106 at 21-22). Plaintiffs contend that because of the FDA and the public's desire for abuse-deterrent properties, "[a]bsent [the abuse-deterrent] features, there would be no OxyContin and no commercial success at all." (*Id.* at 22). They also argue, citing only to other district court cases, that Accord's choice to file an ANDA for OxyContin, rather than for another opioid, and rather than developing their own formulation, is "strong evidence of commercial success." (*Id.* at 21).

Defendant argues that Plaintiffs have shown no nexus between OxyContin's commercial success and the asserted claims. (D.I. 109 at 8-9). Defendant notes that Mr. Sharma admitted on cross-examination that he did not specifically consider the claimed features of OxyContin. (Tr. at 382:15-383:5). Defendant's expert, Mr. Ivan Hofmann, also noted that the new formulation replaced the original formulation, with all sales transferred to the new formulation. (*Id.* at 653:3-9).

Based on the testimony of Plaintiffs' and Defendant's experts, I cannot conclude that reformulated OxyContin's commercial success was the result of anything other than Purdue's existing monopoly. Plaintiffs' argument that Original OxyContin would have been withdrawn absent the innovations of the Abuse-Deterrent Patents cannot support a finding of nonobviousness—the argument speaks only to the importance of abuse deterrence, not to its obviousness. I also note that there was no demonstrated increase in the success of OxyContin relative to other opioids when the patented features were introduced. While the abuse-deterrent reformulation clearly did not drive customers away from OxyContin, a lack of commercial failure is not the same as commercial success.

I am also completely unpersuaded by the argument that Accord's choice to file an ANDA for OxyContin in particular could be evidence of OxyContin's commercial success or nonobviousness. The argument requires numerous unfounded assumptions. Further, the argument implies that it ought to be artificially more difficult to challenge a patent on obviousness grounds through ANDA litigation than through other channels.

In all, I do not find that Plaintiffs have proven commercial success due to the claimed features of the invention by a preponderance of the evidence.

c. Skepticism

"Evidence of industry skepticism weighs in favor of non-obviousness. If industry participants or skilled artisans are skeptical about whether or how a problem could be solved or the workability of the claimed solution, it favors non-obviousness." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1335 (Fed. Cir. 2016).

Plaintiffs offer two examples of skepticism, by Dr. Mannion and by the FDA. Specifically, as I discussed above, Dr. Mannion was skeptical that heating PEO tablets after compression would work. He was concerned they might not hold shape (Tr. at 320:1-18), might not achieve the original extended release profile (*id.* at 308:16-25), and might be abused by hot water extraction (*id.* at 310:12-311:7). The FDA, meanwhile, required postmarketing studies before approving abuse-deterrent labeling. (D.I. 106 at 23). Defendant responds that neither of these instances of skepticism represents the kind of "industry skepticism" used in an obviousness analysis. (D.I. 109 at 8).

I agree with Defendant. Dr. Mannion's own testimony, as a named inventor, would seem to carry limited weight. He does not serve as a stand-in for a POSA, or for the industry. Likewise, the 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. Therefore, I do not find that Plaintiffs have proven industry skepticism by a preponderance of the evidence.

d. Failure of Others

The failure of others may serve to "negat[e] an expectation of success." *In re Cyclobenzaprine*, 676 F.3d at 1081. "The purpose of evidence of failure of others is to show 'indirectly the presence of a significant defect in the prior art, while serving as a simulated laboratory test of the obviousness of the solution to a skilled artisan.'" *Id.* at 1082 (quoting *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1578-79 (Fed. Cir. 1991)). However, for the failure of others to be probative, it should be the case that "these prior attempts failed because the devices lacked the claimed features." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1313 (Fed. Cir. 2006).

Plaintiffs note two failures of others: Accord's own attempts to develop an abuse-deterrent oxycodone formulation by acquiring Develco, and Grunenthal's crush resistant technology, which was used in the withdrawn opioid product, Opana ER. (D.I. 106 at 23-24). Defendant responds that its efforts with Develco failed due to difficulties with scaling and production. (Tr. at 674:12-14). It also notes that Opana ER used a different active ingredient, and that it is unclear why Opana ER was withdrawn. (Tr. at 673:7-22).

First, if anything, the production failures of Develco seem to weigh in favor of the production-scale-based motivation to combine that I found above, rather than in favor of the nonobviousness of the patents. Second, I agree with the Defendant that the record is not clear on why Opana was removed from

the market. Plaintiffs did not establish by a preponderance of the evidence that Opana's removal was related to its lack of "the claimed features." *Ormco*, 463 F.3d at 1313.[7] Even if Opana was withdrawn because its different manufacturing process made it insufficiently abuse-deterrent, I am not sure that indicates a failure by Grunenthal. Specifically, Grunenthal seemed satisfied with the results of its manufacturing process, as evidenced by the fact that a product made with its technology was released to market. The record does not indicate that Grunenthal tried and failed to make a more abuse-deterrent or otherwise superior product. Thus, this seems to be at most an issue of Grunenthal's standards, and not of a POSA's ability to invent the claimed product. I do not find that these failures—if they are failures—weigh in favor of nonobviousness.

IV. THE LOW-ABUK PATENTS

A. The Asserted Claims

The claims at issue are claims 3 and 11 of the '933 patent and claim 21 of the '919 patent. Claim 3 of the '933 patent and claim 21 of the '919 patent claim pharmaceutical compositions, while claim 11 of the '933 patent is a method claim for preparing such compositions. Claim 3 of the '933 patent depends on claim 1. The two claims read,

> 1. An oxycodone hydrochloride composition, which comprises at least 95% oxycodone

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[7] I note also that the claims do not specify any particular level of abuse deterrence or ability to withstand crushing forces. I address Plaintiffs' argument that Opana was removed because it was not sufficiently abuse deterrent, but I am not sure the argument is relevant to the nonobviousness of anything actually claimed by the patents.

hydrochloride, 8α,14-dihydroxy-7,8-dihydrocodeinone, and less than 25 ppm of 14-hydroxycodeinone.

. . .

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

('933 patent at 34:27-30, 33-34). Claim 11 of the '933 patent depends on claim 10. Those claims read,

10. A process for preparing an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone, comprising removing 8α,14-dihydroxy-7,8-dihydrocodeinone from an oxycodone base composition and converting the oxycodone base composition to an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone.

11. The process of claim 10, comprising combining hydrochloric acid and the oxycodone base composition in a solvent to form a solution, and isolating the oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone from the solution.

('933 patent at 34:52-63).

Claim 21 of the '919 patent depends on claim 18. The claims read,

18. A pharmaceutically acceptable formulation comprising oxycodone HC1, 8α, 14-dihydroxy-7,8-dihydrocodeinone, and less than 100 ppm of 14-hydroxycodeinone, wherein the ratio of 8α,14-dihydroxy-7,8-dihydrocodeinone to

oxycodone HC1 is 0.04% or less as measured by HPLC.

. . .

21. The pharmaceutically acceptable formulation of claim 18, comprising less than 15 ppm of 14-hydroxycodeinone.

('919 patent at 36:7-11, 16-17).

B. Findings of Fact

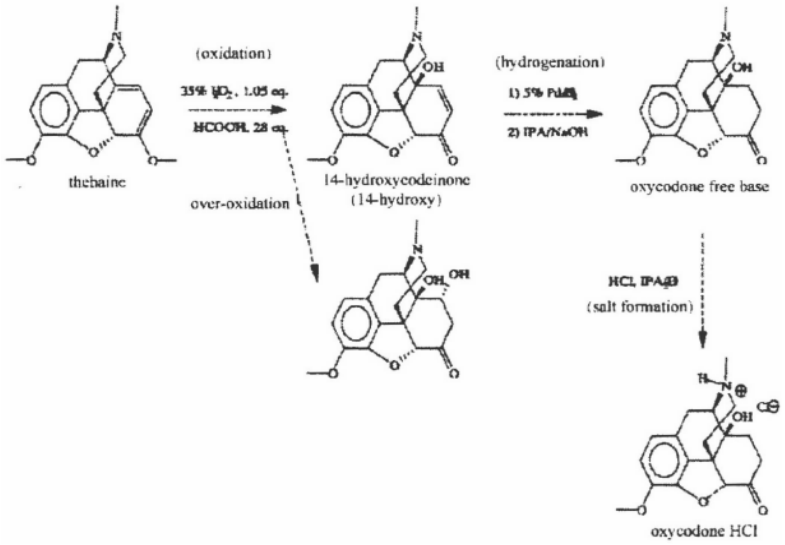
1. The earliest effective filing date of the Low ABUK patents is March 30, 2004. (D.I. 89-1 ¶¶ 13, 16). The Low ABUK patents are entitled to an invention date of June 11, 2003, which is the first time Plaintiffs reduced the complete invention to practice. (Tr. at 510:19-514:8; PTX-641 at 57; *see also* PTX-371).
2. A POSA for the purposes of the asserted claims of the Low ABUK patents is an organic chemist with experience in synthetic and analytical chemistry. Such a person would have knowledge of the publicly-disclosed chemical reactions relevant to the field, how to search the relevant literature, and how to accomplish such chemical reactions. (D.I. 89-1 ¶ 95).
3. Roland Kraßnig et al., *Optimization of the Synthesis of Oxycodone and 5-Methyloxycodone*, 329 Archiv der Pharmazie. 6, 325 (1996) ("Krassnig") is prior art to the asserted patents under 35 U.S.C. § 102(b). (D.I. 89-1 ¶ 61; DTX-019). Krassnig teaches that the naturally occurring compound thebaine can be oxidized to form 14-hydroxy, which can be hydrogenated into oxycodone. (DTX-019).

4. U.S. Patent No. 6,177,567 ("Chiu") is prior art to the asserted patents under 35 U.S.C. § 102(b). (D.I. 89-1 ¶ 67; DTX-022). Chiu teaches both measuring the 14-hydroxy content of a composition to determine the completeness of hydrogenation with high performance liquid chromatography ("HPLC") and extending hydrogenation if the 14-hydroxy content is higher than desired. (DTX-022 at 15:60-16:4).
5. V. S. Ramanathan et al., *Dihydrocodeine, Dihydrocodeinone, 14-Hydroxydihydrocodeinone & Their Derivatives*, 2 Indian J. Tech. 10, 350 (1964) ("Ramanathan") is prior art under 35 U.S.C. § 102(b). (D.I. 89-1 ¶ 72; DTX-023). Ramanathan teaches that the salt 14-hydroxy hydrochloride can be hydrogenated into oxycodone hydrochloride. (Tr. 67:20-69:10).
6. Bohumil Proksa, *10-Hydroxythebaine*, 332 Archiv der Pharmazie 10, 369 (1999) ("Proksa") is prior art under 35 U.S.C. § 102(b). (D.I. 89-1 ¶ 77; DTX-020). Proksa discloses byproducts from the oxidation of thebaine, including 8ß and other uncharacterized compounds. (DTX-020; Tr. at 38:16-39:14, 46:22-47:13).
7. U.S. Patent No. 6,864,370 ("Lin") has a priority date of June 5, 2003. (DTX-024). It is prior art. Lin teaches the synthesis of oxycodone hydrochloride in high yields and purities. *Id.*
8. Ulrich Weiss, *Derivatives of Morphine. II. Demethylation of 14-hydroxycodeinone. 14-*

Hydroxymorphinone and 8,14-Dihydroxy-dihydromorphinone, 22 J. Organic Chemistry 11, 1505 (1957) ("Weiss") is prior art to the asserted patents under 35 U.S.C. § 102(b). (D.I. 89-1 ¶ 81; DTX-021). Weiss discloses that 8ß can form from the hydration of 14-hydroxy, and can undergo acid-catalyzed dehydration to form 14-hydroxy in the presence of hydrochloric acid. (DTX-021; Tr. at 50:17-51:7).

9. Ikuo Iijima et al., *The Oxidation of Thebaine with m-Chloroperbenzoic Acid. Studies in the (+)-Morphinan Series. III*, 60 Helvetica Chimica Acta 7, 2135 (1977) ("Iijima") is prior art under 35 U.S.C. § 102(b). (PTX-310). Iijima discloses the ring-opening of an epoxide as a possible mechanism for the formation of 8ß. (PTX-310; Tr. at 53:1-55:10).

10. Prior art oxycodone hydrochloride synthesis involved three major reactions: (1) the oxidation of thebaine to form 14-hydroxy (the "oxidation step"); (2) the hydrogenation of 14-hydroxy to form oxycodone free base (the "hydrogenation step"); and (3) the addition of hydrochloric acid to the oxycodone free base composition to form oxycodone hydrochloride (the "salt formation step"). (D.I. 89-1 ¶ 98; JTX-004 at Figure 1; JTX-005 at Figure 1; Tr. at 34:7-35:8).



11. The intermediate product 14-hydroxy is an "alpha beta unsaturated ketone" or "ABUK," a class of compounds understood at the time of the invention to be highly reactive and potentially genotoxic. (D.I. 89-1 ¶ 113; Tr. at 59:23-60:9, 465:3-18). By 2000, named inventor Dr. Robert Kupper was concerned that ABUKs, which had certain structural features similar to other, genotoxic compounds, might also be genotoxic, based on his prior experience. (Tr. at 463:24-25, 465:3-18).
12. A POSA would understand that not all the intermediate 14-hydroxy would necessarily be turned into oxycodone during the hydrogenation step. (Tr. at 74:4-74:15). 14-hydroxy remaining after the hydrogenation step would be turned into 14-hydroxy hydrochloride by the salt formation process. (Tr. 69:21-70:5).

13. At least by September 3, 2002, the FDA began requesting that opioid manufacturers either reduce the levels of ABUKs in opioid products to under 10 ppm or provide testing demonstrating that they were not genotoxic. (PTX-560 at P4107528; Tr. at 493:15-494:7). This information went to multiple opioid manufacturers. (Tr. at 493:15-494:7). The FDA also made clear that "the issue is general and will affect all products containing opioid derivatives." (PTX-560 at P4107528).
14. A POSA seeking to modify the three-step prior art oxycodone synthesis process to achieve lower 14-hydroxy levels in the final oxycodone composition would have had two options. First, a POSA could have used the teachings of Ramanathan to hydrogenate the composition again after the salt formation step, which would turn any of the 14-hydroxy hydrochloride into oxycodone hydrochloride. (Tr. at 70:6-71:8). Second, since 14-hydroxy is an intermediate product, a POSA could have tried to intervene during or after hydrogenation to ensure that no 14-hydroxy would remain in the composition prior to the salt formation step. (Tr. at 74:4-75:4).
15. The first path would not be desirable, because it would be costly, likely reduce yield, and possibly introduce impurities. (Tr. at 73:16-74:3, 587:3-18). A POSA would prefer to solve the problem at an earlier stage. (Tr. at 73:23-25).
16. Taking the second path would cause 14-hydroxy to reappear during the salt formation. A POSA motivated to lower 14-hydroxy levels

would attempt to determine why 14-hydroxy was reappearing. (Tr. at 74:4-75:19).

17. 8β,14-dihydroxy-7,8-dihydrocodeinone ("8β") was known in the prior art to form as a byproduct during the oxidation step. (D.I. 89-1 ¶ 78; DTX-020; DTX-021; Tr. at 46:22-47:13).
18. 8α is a stereoisomer of 8β. (D.I. 98, Ex. 1 ¶ 102). 8α had always been present in oxycodone compositions but had not been described prior to the Low-ABUK Patents. (Tr. at 94:19-95:4).
19. A POSA would have contemplated a limited number of reaction mechanisms to explain the presence of 8β. (Tr. at 47:24-48:19, 50:1-50:16, 176:14-177:3). Two likely candidates, which were described in the prior art, would be the ring-opening of an epoxide (Tr. at 47:24-49:25; PTX-310), and the hydration of 14-hydroxy (Tr. at 50:1-51:7; DTX-032). A POSA considering either possibility would also predict the presence of 8α. (Tr. at 51:11-52:25; Tr. 53:1-54:16).
20. A POSA would understand that both 8β and 8α could undergo dehydration reactions to form 14-hydroxy, (Tr. at 76:25-81:25), and that the conditions of the salt formation step would cause such reactions. (Tr. at 101:15-19).
21. A POSA would understand that 8α would dehydrate under milder conditions and more rapidly than 8β, forming more 14-hydroxy more easily. (Tr. at 84:10-19).
22. A POSA would have the knowledge and experience to hypothesize that either 8α, 8β, or both were most likely responsible for the

reappearance of 14-hydroxy. (Tr. at 76:16-24, 81:10-25). A POSA would be able to test and confirm this hypothesis through routine experimentation. (Tr. at 77:29-85:2).

23. A POSA seeking to lower 14-hydroxy levels would seek to convert 8α and 8β into 14-hydroxy through dehydration prior to the completion of hydrogenation, so that the resulting 14-hydroxy would then be converted into oxycodone by the hydrogenation. (Tr. at 76:16-77:24, 87:16-88:1). A POSA would have the knowledge and experience to understand from Weiss and Ramanathan how to dehydrate 8β and 8α into 14-hydroxy. (Tr. at 50:6-16, 88:2-11). Dehydration that targeted 8β would automatically convert 8α as well. (Tr. at 100:17-101:3).
24. A POSA would recognize that forcing the dehydration of 8α and 8β either before or during the hydrogenation would be effective. (Tr. at 88:12-89:6). A POSA would have understood from Chiu that the hydrogenation could be performed in acidic conditions to allow the dehydration of 8α and 8β to occur simultaneously. (Tr. at 89:7-12).

C. Conclusions of Law

1. Invention Date of the Low ABUK Patents

The parties dispute whether the Lin reference, dated June 5, 2003, is prior art to the Low-ABUK Patents. They do not dispute that the Low-ABUK Patents were reduced to practice on June 11, 2003. This would ordinarily make Lin prior art, but "[p]re-AIA section 102(g) allows a patent owner to antedate

a reference by proving earlier conception and reasonable diligence in reducing to practice." *Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1007 (Fed. Cir. 2016). "Whether a patent antedates a reference is a question of law based on subsidiary findings of fact." *Id.* at 1009. "An idea is sufficiently definite for conception 'when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue.'" *Creative Compounds, LLC v. Starmark Lab'ys.*, 651 F.3d 1303, 1312 (Fed. Cir. 2011) (quoting *Burroughs Wellcome Co. v. Barr Lab'ys.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994)).

The patent holder has the burden of producing evidence to support an earlier conception. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576-77 (Fed. Cir. 1996). Where "a party seeks to prove conception via the oral testimony of a[n] . . . inventor, the party must proffer evidence corroborating that testimony." *Shu-Hui Chen v. Bouchard*, 347 F.3d 1299, 1309 (Fed. Cir. 2003). Specifically, "the inventor must provide independent corroborating evidence in addition to his own statements and documents." *Brown v. Barbacid*, 276 F.3d 1327, 1335 (Fed. Cir. 2002) (cleaned up). The sufficiency of the evidence of earlier conception is determined under the "rule of reason." *Mahurkar*, 79 F.3d at 1577. The "rule of reason" requires "examin[ing] all pertinent evidence to determine the credibility of the inventor's story." *Brown*, 276 F.3d at 1335 (internal quotations omitted).

Plaintiffs offer testimony by named inventors Mr. Lonn Rider and Dr. Robert Kupper to meet their burden of production. (D.I. 106 at 30-31). They also offer Mr. Rider's lab notebooks and internal communications about the efforts to lower 14-hydroxy

levels. (*Id.*). Plaintiffs argue, based on this evidence, that conception of the invention occurred no later than February 6, 2003, the date on which Mr. Rider wrote a memo to his supervisor about his efforts to lower 14-hydroxy levels. (D.I. 107 ¶ 63). Plaintiffs assert that the inventors were diligent after the February 6 conception, and certainly between the operative period of June 5-11, which allows the asserted patents to antedate Lin. (D.I. 106 at 30).

Defendant does not dispute that the Low ABUK Patents are entitled to a priority date of at least as early as June 11, 2003, when the invention was reduced to practice. (D.I. 100 ¶ 53). Defendant provides little argument against the antedating other than to say Plaintiffs are not entitled to a February 2003 invention date. (*Id.*)

Despite Defendant's conclusory response, I do not think that Mr. Rider's and Dr. Kupper's testimony, to the extent that they are corroborated by various documents, satisfy Plaintiffs' burden of production for conception. Dr. Kupper merely testified that as of November 2002, he thought "either 8α or 8β" was likely responsible for 14-hydroxy in the final product. (Tr. at 481:3-482:16). His testimony was corroborated by an internal report, but I do not find that it demonstrates conception of every feature of the claimed invention. (PTX-356). Dr. Kupper did not testify regarding the February 6 memo.

Mr. Rider testified more definitively that as of February he had concluded "[t]hat 8α was the source of the 14-hydroxycodeinone." (Tr. at 504:11-14). Plaintiffs offered Mr. Rider's verified laboratory notebook and auxiliary data as corroboration. (PTX-352; PTX-354). However, Mr. Rider did not testify as to the interpretation or contents of his notes or the

auxiliary data. Meanwhile, his February 6, 2003, memo to his supervisor said that "it [was] difficult to be certain" that 8α was responsible for the challenges in reducing 14-hydroxy, and that it "warrant[ed] further investigation." (PTX-352 at P4193989). The memo does not seem to corroborate Mr. Rider's testimony. It describes "a general goal or research plan" rather than "a specific, settled idea, a particular solution to the problem at hand." *Burroughs Wellcome*, 40 F.3d at 1228.

I conclude that Plaintiffs have not met their burden of producing sufficient, corroborated evidence that the Low-ABUK Patents were conceived of on February 6, 2003. Plaintiffs further did not present evidence of conception on any other date between February 6 and June 11. Therefore, the priority date of the patents remains the uncontested date of reduction to practice, June 11, 2003, and the Lin reference is prior art.

2. Obviousness of the Low-ABUK Patents

The asserted claims of the Low-ABUK Patents differ from each other in scope and content. Claim 3 of the '933 patent requires a composition of at least 95% oxycodone HC1, 8α, and levels below 10 ppm of 14-hydroxy. ('933 patent at 34:27-39, 33-34). Claim 21 of the '919 patent adds the requirement that the ratio of 8α to oxycodone HC1 be 0.04% or less, but allows up 15 ppm 14-hydroxy. ('919 patent at 36:7-11, 16-17). Claim 19 of the '933 patent is a method claim. It requires that the final product have less than 25 ppm of 14-hydroxy and be made by a particular process that includes removing 8α from an oxycodone base before salt formation and employing hydrochloric acid in the salt formation step. ('933 patent at 34:52-63).

Broadly, the parties' disputes fall into two categories: the obviousness of low levels of 14-hydroxy and the obviousness of the inventors' discovery of 8α.[8] I address the 14-hydroxy and 8α arguments in turn, noting where they are interrelated.[9]

First, I discuss whether a POSA would have been motivated to achieve low levels of 14-hydroxy by modifying the prior art. "For a patent to be obvious, 'some kind of motivation must be shown . . . so that the jury can understand why a person of ordinary skill would have thought of either combining two or more references or modifying one to achieve the patented method.'" *Shire*, 802 F.3d at 1306 (quoting *Innogenetics, N.V. v. Abbott Lab'ys.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008)). Then, I consider whether a POSA would have been able to do so by combining the teachings of the prior art and engaging in routine experimentation.

Second, I discuss whether the discovery of 8α renders the purified compositions patentable. I consider whether the various 8α limitations were inherently disclosed in the prior art. I also consider whether a POSA would have identified 8α as a matter

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[8] Neither party presents any argument that the 10, 15, and 25 ppm requirements should be analyzed separately. Thus, I consider only the obviousness of levels of 14-hydroxy below 10 ppm, since the other thresholds would seem to follow. The parties likewise do not argue that other claim limitations, such as turning oxycodone free base into a hydrochloride salt or using hydrochloric acid to form a hydrochloride salt, are missing from the prior art or render the invention nonobvious.

[9] Defendant continues to refer to factual findings from *In re OxyContin* in footnotes. (*See, e.g.,* D.I. 99 at 26 n.11). I continue to disregard these findings for the same reasons described in *supra* n.1.

of course while attempting to lower levels of 14-hydroxy, and whether explicit identification of 8α was necessary to arriving at the rest of the claimed inventions.

For the reasons below, I find the three asserted claims of the Low-ABUK Patents invalid for obviousness under 35 U.S.C. § 103

a. 14-Hydroxy

i. Motivation to Lower 14-Hydroxy

Defendant argues that a POSA would have been motivated to modify the prior art as of September 12, 2002, based on a communication from the FDA sent to multiple opioid manufacturers about future ABUK restrictions. (D.I. 99 at 23-24; PTX-560). Plaintiffs as a preliminary matter contend that Defendant waived its argument that the September FDA communication provided a motivation to modify, because Defendant "never identified that date or a purported evidentiary basis for it during fact or expert discovery, and it contradicts Accord's issues in the Pretrial Order." (D.I. 106 at 33). Plaintiffs assert that Accord changed its position about the timing of the motivation to combine because Plaintiffs successfully proved an earlier invention date (June 11, 2003) at trial. (*Id.* at 34). Defendant responds that it has always stated that the FDA provided the motivation and that Plaintiffs suffered no prejudice from Defendant's not specifically naming September 12, 2002, since testimony and evidence offered by Plaintiffs alluded to FDA communications about

ABUKs as early as January 2003, which was still before June 11. (D.I. 109 at 11 & n.5).[10]

I do not find that Defendant waived the argument to a September 2002 motivation to combine. As far as I can tell, Defendant did not identify any specific date for a motivation to modify in the Pretrial Order, so failure to identify September 12 does not seem like a problem. Defendant did identify the FDA as the source of the motivation, which is consistent with its current argument. (D.I. 89-3 ¶ 74). While Defendant referred to "2003 and 2004" as the time period over which the FDA "became concerned," (*id.* at ¶ 11), I do not think this vague language rules out the possibility that murmurings about ABUKs in the industry began in late 2002 or early 2003—especially when evidence and testimony by Plaintiffs' witness support that idea. In the single case cited by Plaintiffs, a party did not express any intent to raise the issue of an earlier priority date until post-trial briefing. *UCB, Inc. v. Watson Lab'ys*, 2017 WL 11646645 at *40 (D. Del. Nov. 14, 2017). Here, the POSA's motivation was always at issue—as Plaintiffs acknowledge. (D.I. 89-2 ¶ 32).

Defendant's argument for a September 2002 motivation to combine relies on testimony by Plaintiffs' witness, Dr. Kupper. Dr. Kupper testified regarding an internal Rhodes email on September 12,

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[10] Defendant also claims in a footnote that Plaintiffs only started arguing for the June priority date after Defendant submitted its Proposed Findings of Fact. (D.I. 109 at 11 n.5). It is not clear to me whether this is the case, though I note that Plaintiffs did not identify June 11 as a possible invention date in their statement of issues of fact. (*See* D.I. 89-2). I do not think it matters. If it is the case, it would only support my finding of no waiver.

2002, which he agreed indicated that the "FDA was concerned about ABUK impurities." (Tr. at 493:20-22). The email stated that the FDA wanted Purdue to reduce morphinone, another ABUK, to levels of "less than 10 parts per million (ppm), or 0.001%" in the opioid product Palladone. (PTX-560 at P4107528). The email mentioned that the "issue is general and will affect all products containing opioid derivatives." (*Id.*). Dr. Kupper testified that he understood from the email that other manufacturers had also been told they would have to lower ABUK levels. (Tr. at 494:5-7). Defendant's expert, Dr. Stephen Martin, testified that "[C]ompounds related to [ABUKs] were long known . . . to be genotoxic. So there would always be some kind of concern about reactivity of this functional group." (Tr. at 60:6-60:9).

Plaintiffs argue that because the FDA did not specifically require ABUK levels below 10 ppm until December 2003, a POSA would not have been motivated to achieve such levels until December 2003 at the earliest. (D.I. 106 at 34-35). As for the 2002 communication, Plaintiffs argue that a subsequent internal email indicated that Purdue was proceeding under the assumption that existing approved products would not be affected. (D.I. 106 at 34; D.I. 107 ¶ 82). Plaintiffs also note that the 2002 communication related to "lowering the amount of a different ABUK (morphinone) in a different unapproved product (Palladone) that had a different active ingredient (hydromorphone)." (D.I. 106 at 34; PTX-560 at P4107528). Plaintiffs argue that Purdue initially objected to the stringent requirement by proposing a more relaxed requirement of 0.05% (500 ppm) and stating it would attempt to test whether

ABUKs were genotoxic. (D.I. 106 at 34; PTX-560 at P4107529).

FDA communications can "introduce[] a market force incentivizing" a particular invention. *Endo Pharms., Inc. v. Actavis LLC*, 922 F.3d 1365, 1376 (Fed. Cir. 2019). Indeed, a requirement that a product meet a particular threshold is likely to be a strong market force, since failure to meet that requirement would exclude the product from the market completely, rather than merely making it less competitive. As I also noted in my discussion of the Abuse-Deterrent Patents, *supra* p.12, "it often may be the case that market demand, rather than scientific literature, will drive design trends." *KSR*, 550 U.S. at 419, 127 S.Ct. 1727. Thus, an FDA letter creating market forces may serve as a motivation to combine.

Defendant's evidence is clear and convincing. I think an awareness that the FDA might impose low-ABUK requirements would immediately motivate a POSA to seek a way to lower the levels of ABUKs in a pharmaceutical product. Even if the requirements were in the future, I think a POSA would be motivated to get ahead of the requirements. Further, the knowledge that the FDA was considering a threshold of 10 ppm would motivate a POSA to try to achieve that level in particular. It is true that the 2002 FDA email concerns a different product, but the email also clearly says, "While this was a Palladone-specific teleconference, the FDA informed us that this issue is general and will affect all products containing opioid derivatives." (PTX-560 at P4107528). Indeed, when the email was forwarded to Dr. Kupper, it was with an allusion to that sentence and its "implications." (*Id.*). Dr. Kupper further admitted on cross examination that he "understood from [the

email] that the FDA had communicated that same information to other manufacturers" (Tr. at 494:5-7), demonstrating that a POSA, and not just a Purdue or Rhodes employee, would have been motivated.

I am not persuaded by Plaintiffs' observation about Purdue's understanding that any future requirements would not affect approved products. The inquiry is not what Purdue understood from the communication but what a POSA would have understood. I also do not find Purdue's attempt to negotiate with the FDA on the strictness of the requirements to weigh against a POSA's motivation to modify the prior art. Purdue's response suggesting a 500 ppm threshold and proposing continued testing to determine toxicity suggests to me only that Purdue sought to keep its options for solving the problem open. Pursuing all available options seems like the prudent response for a company facing new regulations on a highly profitable class of products. In the absence of FDA acceptance of a higher threshold, I would still expect a POSA to prepare for the possibility of a lower threshold of 10 ppm. Likewise, the possibility of testing ABUKs for toxicity as an alternative option would not reduce a POSA's motivation to pursue other solutions.

Although not the focus of Defendant's argument, testimony at trial also indicated that an understanding or suspicion that ABUKs were toxic existed even before September 2002. Dr. Martin testified that a POSA would potentially be concerned about ABUKs anyway given their structure. (Tr. at 59:23-60:18). Dr. Kupper mentioned that he first became concerned about ABUKs based on their molecular structure. (Tr. at 464:24-465:15). Certainly, a statement by Dr. Kupper, an inventor on

the patent, is not on its own probative of a POSA's motivation to modify the prior art. However, Dr. Kupper's concerns were consistent with Dr. Martin's expert testimony. I am not convinced that concerns about potential toxicity on their own would motivate a POSA to incur the cost of developing a purified product. I do, however, think that such concerns in the field would serve to make the possibility of future FDA requirements a credible, and perhaps even expected, threat, thus making the motivation to combine all the stronger.

On the whole, I find that Defendant presented clear and convincing evidence that a POSA would have been motivated to modify the prior art process of synthesizing oxycodone to achieve ABUK levels below 10 ppm.

ii. Routine Experimentation

I now turn to whether, provided with this motivation, a POSA could reasonably have expected to arrive at the asserted claims through routine experimentation. Defendant asserts that a POSA 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. (D.I. 99 at 26, 30). Dr. Martin testified that pursuing the latter path would lead a POSA to try to ensure that all 8α and 8β in the composition dehydrated into 14-hydroxy before the hydrogenation step was complete. (*Id.* at 30). Defendant argues that because achieving the claimed invention from either starting point would require only routine techniques, a POSA would have a reasonable expectation of success. (D.I. 109 at 12).

Plaintiffs respond that a POSA would not have a reasonable expectation of success through the first option of adding a final hydrogenation step. (D.I. 106 at 36). Plaintiffs' expert witness, Dr. James Wuest, testified that a POSA would know that adding a hydrogenation step would reduce yield and potentially introduce impurities. (Tr. at 587:6-18). Plaintiffs argue that a POSA pursuing the second option of earlier removal of 14-hydroxy would be quickly stymied by a lack of knowledge of 8α. (D.I. 106 at 37-38). Specifically, they argue that a POSA would not be led to ensure the dehydration of 8α and 8β because a POSA would not know that 8α was the source of the problem and would not think that 8β could be. Without such knowledge, Plaintiffs contend, the POSA could not have a reasonable expectation of success at lowering 14-hydroxy levels by ensuring the dehydration of 8α and 8β. (*Id.*).

"When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp." *KSR*, 550 U.S. at 421, 127 S.Ct. 1727. Thus, evidence of obviousness may be sufficient when "it indicates that the possible options skilled artisans would have encountered were 'finite,' 'small,' or 'easily traversed,' and that skilled artisans would have had a reason to select the route that produced the claimed invention." *In re Cyclobenzaprine*, 676 F.3d at 1072 (quoting *Ortho-McNeil Pharm., Inc. v. Mylan Lab'ys., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008)). An invention is obvious over prior art if "the order and detail of the steps, if not already known, would have been discovered by routine experimentation while

implementing known principles." *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 730 (Fed. Cir. 2017). The obviousnesss inquiry "not only permits, but *requires*, consideration of common knowledge and common sense." *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013) (quoting *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006)).

I was persuaded by Dr. Martin's testimony that a POSA seeking to reduce 14-hydroxy levels would have a finite, small, and easily identified set of options. Dr. Wuest never testified, and Plaintiffs never argued, that a POSA would have had other options for reducing 14-hydroxy or that a POSA would not have known where to start. Based on both Dr. Wuest's and Dr. Martin's testimony, however, I am skeptical that a POSA would have pursued adding an extra hydrogenation step to directly convert 14-hydroxy hydrochloride into oxycodone hydrochloride. Both testified that doing so would be expensive and potentially introduce other impurities. Plaintiffs argue that this cuts against Defendant's theory of obviousness. I disagree. If anything, a POSA's disinclination for adding an extra hydrogenation step would only further narrow the set of feasible options.

I find that Defendant has presented clear and convincing argument that a POSA 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 POSA would have the knowledge and skill to do so successfully. 14-hydroxy was a known intermediate product. It seems well within a POSA's skill to more completely eliminate a known byproduct with a known method of conversion. It is

true that this path would not immediately succeed—as the inventors themselves found, 14-hydroxy would reappear. However, Dr. Martin clearly testified that such a roadblock would be within the skill of a POSA to address.

Dr. Martin clearly and convincingly outlined that a POSA would have been trained to propose reaction mechanisms to explain the results of their experiments. (Tr. at 47:17-48:5). Dr. Wuest agreed that he trained students to propose reaction mechanisms. (Tr. at 602:16-603:2). Dr. Martin further testified, and Dr. Wuest agreed, that the possible reaction mechanisms at issue in this case would have been familiar to a POSA. (Tr. at 48:6-50:16, 603:3-8, 605:2-8, 608:23-609:6). Dr. Martin explained how a POSA would "analyze the reaction mixture," a procedure he characterized as routine, to test the limited number of possibilities in order to determine the source of the 14-hydroxy problem. (Tr. at 77:25-78:17, 79:17-81:9). As I discuss further below, Dr. Martin explained that solving a problem that the POSA now understood would be well within the POSA's skill. (Tr. at 87:16-89:12).

Plaintiffs do not offer any path along which a POSA would be led astray. Dr. Wuest only testified that no prior art reference was on its own a perfect fit and asserted that a POSA would face "obstacles." (Tr. at 600:13-14). As far as I can tell, Plaintiffs' reasoning leads to the conclusion that a POSA would simply have given up in the face of 14-hydroxy's reappearance. However, given my finding that a POSA would have been motivated to solve the issue of 14-hydroxy, I think a POSA would have "good reason to pursue the known options within his or her technical grasp" and to modify the prior art in readily

apparent ways. *KSR*, 550 U.S. at 421, 127 S.Ct. 1727. Therefore, I find Dr. Martin's testimony as to what a POSA would have done more credible. Further, because only routine techniques and commonly possessed training would be required, I find that the POSA would have had a reasonable expectation of success.

Plaintiffs also make something akin to a "failure of others" argument to "negat[e] an expectation of success."[11] *In re Cyclobenzaprine*, 676 F.3d at 1081. Plaintiffs presented evidence that oxycodone HC1 manufacturer Noramco received a communication from the FDA in December 2003 requiring lower levels of 14-hydroxy. (DTX-115 at 0002). In response, Noramco characterized the task as "a technical and scientific challenge." (*Id.*). Plaintiffs introduced deposition testimony from earlier litigation indicating that Noramco did not finish developing its low-ABUK oxycodone until 2007, despite the project starting in 2003. (Tr. at 548:17-20). Defendant responds that Plaintiffs' evidence "shows Noramco was merely cautious." (D.I. 109 at 19).

I agree with Defendant. I do not find the Noramco evidence sufficient to contradict Dr. Martin's testimony that a POSA would have had a reasonable expectation of success. Noramco's characterizing the

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[11] Although "failure of others" is usually a secondary consideration of nonobviousness, *Graham*, 383 U.S. at 17-18, 86 S.Ct. 684, Plaintiffs do not present this evidence as an independent secondary consideration. Instead, they characterize Noramco's failure as evidence that a POSA would not have had a reasonable expectation of success. (D.I. 106 at 39-40; Tr. at 754:19-24). Some cases have treated failure of others in this way. *See Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1354 (Fed. Cir. 2003).

task as a challenge, like Purdue's earlier suggestion of a higher ABUK content threshold, seems like the expected and prudent behavior of a company facing a likelihood of stricter regulations. Noramco's desire to keep its options open seems reasonable and expected. The fact that Noramco took years to develop low-ABUK oxycodone is far from probative. The record, including the video deposition testimony by Noramco employees, is simply not clear on whether the time-consuming aspects of development had anything to do with the claimed invention. I do not find that Dr. Martin's testimony is contradicted by a single, incomplete anecdote that Noramco protested the requirements and took a long time to develop the product.

b. 8α

I now turn to the issue of whether the disclosure of 8α, either as an independent claim limitation not disclosed in the prior art, or as a necessary step to reaching the 14-hydroxy limitations, renders the patent nonobvious. Because I find that the discovery of 8α itself would have been routine for a POSA, I do not find that the explicit disclosure of 8α renders the claims patentable.

Defendant argues that although no claim limitations relating to 8α are in the prior art, 8α was inherently present in prior art oxycodone compositions. (D.I. 99 at 27). Defendant argues further that identifying 8α was itself a routine endeavor, and that a POSA could have arrived at the claimed inventions without discovering 8α at all. (D.I. 99 at 36, 38).

Plaintiffs respond that 8α is not merely an inherent property of oxycodone formulations but

rather a "foundational discovery" in achieving low-ABUK oxycodone. (D.I. 106 at 32). Plaintiffs assert that the 8α limitations consequently "cannot be viewed in isolation from the remainder of the claims." (*Id.*). They reason that the explicit disclosure of 8α renders the invention patentable, even if 8α can be found inherently in the prior art. (*Id.* at 30). Plaintiffs also note the field's "longstanding examination of oxycodone and its impurities," suggesting that if 8α were obvious it would already have been discovered. Plaintiffs further repeatedly note that 8α's level of reactivity is "surprising." (*See, e.g., id.* at 30). They argue that a POSA could not have known how reactive 8α would be, and without that knowledge, could not have realized that 8α needed to be removed in the way the inventors did. (*Id.* at 32).

"[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). However, it "may not be established by probabilities or possibilities." *Id.* (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981)). A limitation "necessarily must be present" to be inherent. *Par Pharm.*, 773 F.3d at 1196. It is true that when "[t]he unexpected properties of the claimed formulation . . . differ in kind from the prior art," the formulation may be nonobvious. *Allergan v. Sandoz*, 796 F.3d at 1307. However, "merely recit[ing] the unknown properties of an otherwise obvious formulation" is not sufficient. *Id.*

Because each of the asserted claims has different 8α-related limitations, I consider the claims one by one.

Claim 3 of the '933 patent requires only that 8α be present in the composition. Plaintiffs do not dispute that 8α was present in prior art compositions. (*See* D.I. 106 at 27-28). Therefore, combined with my findings about 14-hydroxy above, I find that Defendant presented clear and convincing evidence that Claim 3 is obvious. Plaintiffs object to the idea that finding 8α inherently present in the prior art is sufficient to establish a conclusion of obviousness because "it was only after the inventors identified 8α and its surprising properties that they were able to achieve the high purity and low levels of 14-hydroxy as claimed." (D.I. 106 at 32-33). However, I am persuaded by Defendant's evidence that the identification of 8α itself was merely routine. As a factual matter, I find that a POSA would have had the knowledge and skill not only to identify 8α and determine its role but also to achieve low-ABUK levels without even identifying 8α. Further, claim 3 in particular does not contain any reference to the role or purpose of 8α in the composition. The patent does not claim the fact that 8α converts to 14-hydroxy. Plaintiffs cite to no law that indicates I should consider claim 3 to encompass that discovery. They simply repeatedly state that the claim "cannot be viewed in isolation." (*Id.* at 25, 32).

Plaintiffs say that Defendant's theory that a POSA would inevitably discover 8α is "premise[d] . . . on the teachings of the patent." (*Id.* at 38). However, Plaintiffs' argument is equally tautological—since Plaintiffs never identified how a POSA could have been led astray, Plaintiffs' argument seems to simply be that a POSA would not have discovered 8α because 8α was nonobvious. For the purposes of determining that a POSA would have the knowledge and skill to

discover 8α, I look to testimony provided by both sides' experts. The experts' testimony persuades me that a POSA would have quickly postulated and easily confirmed the existence of 8α. Plaintiffs once again would have a POSA give up rather than engage in routine experimentation, even in the face of external motivation.

Plaintiffs' protests that "[t]here is no evidence that anyone was trying to reduce the level of 8β to achieve low 14-hydroxy" miss the point. (D.I. 107 ¶ 87). As discussed previously, the motivation to achieve low 14-hydroxy came from the FDA in 2002, so one would not expect evidence that anyone was trying to reduce the level of 8β before then. There is no evidence in the record of what anyone other than the inventors was actually doing after 2002, so a lack of evidence that anyone was trying to reduce 8β is unremarkable. To the extent that Plaintiffs use this observation to argue that a POSA would have known 8β could not possibly be the source of the problem (D.I. 106 at 38), I think that a POSA with such a belief would only be led more inevitably toward identifying 8α as a source of 14-hydroxy. As with the choice between an extra hydrogenation step and an earlier intervention, the improbability of one explanation for 14-hydroxy's reappearance would only serve to further narrow a POSA's limited set of viable options. I conclude that a POSA would seek to dehydrate 8α and 8β based on the credible testimony of Dr. Martin, not based on any evidence or lack thereof of what a particular pharmaceutical manufacturer tried.

I likewise do not find Plaintiffs' arguments about the prior art studies of impurities persuasive, since those studies did not purport to be exhaustive. Proksa, for example, explicitly notes that it only

identified two of the impurities detected in the synthesis of oxycodone. (DTX-020 at 0001). Dr. Martin testified that a POSA would know how to analyze a mixture and identify its component compounds using HPLC, mass spectrometry, or NMR spectrometry. (Tr. at 79:17-81:9). Plaintiffs presented no evidence that 8α would not be identifiable with these routine techniques if a POSA bothered to try. Likewise, there was no evidence presented to suggest that anyone, POSA or otherwise, tried and failed to identify 8α.

8α's surprising reactivity also does not change the balance.[12] Both experts testified that a POSA would have expected 8α to be more reactive than 8β. (Tr. at 84:10-19, 575:5-24). The degree to which 8α was more reactive may have been surprising, but even if 8α were only as reactive a POSA would have expected, Dr. Martin's testimony convincingly indicates that a POSA would still have gone down the path that led to the invention. Said another way, 8α's surprising reactivity made it a surprisingly important component of the solution to lowering 14-hydroxy, but a POSA would have recognized it as a component of the solution even without the reactivity.

Claim 21 of the '919 patent additionally imposes a purity requirement that "the ratio of 8α,14-dihydroxy-7,8-dihydrocodeinone to oxycodone HC1 is 0.04% or less as measured by HPLC." ('919 Patent at 36:16-

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[12] Surprising or unexpected results, like failure of others, are ordinarily secondary considerations of nonobviousness *Sud-Chemie*, 554 F.3d at 1009. However, Plaintiffs do not present them as such. Again, I address the argument that Plaintiffs actually make: that because 8α's surprising reactivity was what kept 14-hydroxy levels high, a POSA would not have thought to look to 8α as the problem.

17). Defendant argues that equally low levels were inherently disclosed in Lin. (D.I. 99 at 28-29). Defendant also argues that even if not disclosed in Lin, the low levels would still have been obvious. (D.I. 106 at 19). Plaintiffs note that the parties stipulated, "The prior art does not disclose, expressly or inherently, a composition wherein the ratio of 8α to oxycodone is 0.04% or less as measured by HPLC." (D.I. 89-1 ¶ 102). Plaintiffs also argue that Defendant cannot rely on Lin since doing so requires assumptions and is "pure speculation." (D.I. 106 at 32).

I think that the stipulation in the parties' Joint Statement of Uncontested Facts is conclusive on the issue of whether the limitation was inherently disclosed by Lin or any other reference—I must take as a fact that no prior art reference disclosed 8α levels below 0.04%. However, I still find that the limitation on the levels of 8α is obvious. As Plaintiffs themselves argue, "the amount of 14-hydroxy depends on the levels of 8α, and the levels of 8α, 14-hydroxy, and other unintended side-reaction impurities can affect oxycodone purity." (D.I. 106 at 25). In fact, Dr. Martin testified that a POSA, having found that any 8α in the composition could be converted to 14-hydroxy during salt formation, would seek to reduce the ratio of 8α to oxycodone to well below 0.04%. This would be necessary to ensure the low 14-hydroxy levels that the FDA was seeking. (Tr. at 99:19-100:7). Dr. Martin also testified that a POSA would be able to monitor the levels of 8α in order to reduce the ratio of 8α to oxycodone. (*Id.* at 100:8-16). Dr. Wuest did provide any testimony to suggest that a POSA would not be able to do so. Therefore, I find that the limit on the level of 8α relative to oxycodone

would likewise be obvious to POSA conducting routine experimentation.

Finally, claim 11 of the '933 patent requires "removing [8α] from an oxycodone base composition." ('933 Patent 34:54-55). Defendant argues that 8α is always removed during the salt formation step, because it is always converted to 14-hydroxy. (D.I. 99 at 29). Plaintiffs argue briefly that a POSA who did not intend to reduce levels of 8β would not have "removed" 8α but generally do not separately address claim 11. (D.I. 106 at 38).

The parties unfortunately do not address each other's arguments on removal head on, with Defendant arguing that 8α is always removed by the salt formation itself and Plaintiffs suggesting that removal of 8α could only occur if a POSA decided to remove 8β. However, I do not think this dispute matters. Whether or not 8α was removed in the prior art, its removal in the invention itself is still the result of applying routine techniques to what a highly skilled POSA would have seen as a simple problem—albeit one that nobody had previously given any thought to. Given that I have found that a POSA would have been able to routinely identify 8α or 8β as the source of extra 14-hydroxy, I find that removing 8α, either directly or by removing 8β, is also obvious.

I do not think Defendant's theory is hindsight-driven. This is not a case where a POSA would have to repeatedly choose correctly in a branching maze of paths forward. Instead, Defendant presented clear and convincing evidence that all a POSA would have had to do was repeatedly choose the only path forward, rather than giving up. Plaintiffs' expert did not provide plausible evidence to the contrary.

The parties do not offer any argument about secondary considerations of nonobviousness for any of the Low-ABUK patents.

V. CONCLUSION

For the foregoing reasons, I find 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 for obviousness under 35 U.S.C. § 103.

The parties shall submit a final judgment consistent with this memorandum opinion within one week.

IN THE UNITED STATES DISTRICT COURT,
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., and RHODES TECHNOLOGIES,	)	
Plaintiffs,	)	C.A. No. 20-1362
v.	)	(RGA) (JLH)
ACCORD HEALTHCARE INC.,	)	
Defendant.	)	

FINAL JUDGMENT

WHEREAS this patent infringement action was brought by Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and Rhodes Technologies ("Plaintiffs") alleging, inter alia, that the filing of Abbreviated New Drug Application ("ANDA") No. 213564 by Accord Healthcare Inc. ("Defendant") infringed U.S. Patent Nos. 9,763,933 ("the Mannion '933 patent"), 9,775,808 ("the '808 patent"), 9,763,886 ("the '886 patent"), 9,073 ,933 ("the '933 patent"), and 9,522,919 ("the '919 patent") (D.I. 1);

WHEREAS this matter came before the Court for a bench trial to resolve the questions of (1) whether claim 3 of the Mannion'933 patent is invalid for obviousness, (2) whether claim 3 of the '808 patent is invalid for obviousness, (3) whether claim 6 of the '886 patent is invalid for obviousness, (4) whether claims

3 and 11 of the '933 patent are invalid for obviousness, and (5) whether claim 21 of the '919 patent is invalid for obviousness;

WHEREAS the Court held a bench trial in the above-captioned action from September 19 to September 21, 2022;

WHEREAS the Court issued an opinion setting forth its findings of fact and conclusions of law on April 11, 2023 (D.I. 118).

IT IS HEREBY ORDERED AND ADJUDGED:

(1) that claim 3 of U.S. Patent No. 9,763,933 is declared to be invalid on the ground of obviousness, under 35 U.S.C. § 103;

(2) that claim 3 of U.S. Patent No. 9,775,808 is declared to be invalid on the ground of obviousness, under 35 U.S.C. § 103;

(3) that claim 6 of U.S. Patent No. 9,763,886 is declared to be invalid on the ground of obviousness, under 35 U.S.C. § 103;

(4) that claims 3 and 11 of U.S. Patent No. 9,073,933 is declared to be invalid on the ground of obviousness, under 35 U.S.C. § 103;

(5) that claim 21 of U.S. Patent No. 9,522,919 is declared to be invalid on the ground of obviousness, under 35 U.S.C. § 103;

(6) that in view of the Court's rulings that the asserted claims of the Mannion '933 patent, the '808 patent, the '886 patent, the '933 patent, and the '919 patent are invalid, judgment is granted in favor of Defendant on each of Plaintiffs' claims of patent infringement with respect to those patents;

(7) Pursuant to entry of this Final Judgment, all other claims and counterclaims shall be dismissed with prejudice.

SIGNED this 26th day of April 2023.

/s/ Richard G. Andrew
United States District Court Judge

U.S. Const. art. I, § 8, cl. 8

* * *

Section 8. The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

* * *

35 U.S.C. § 103

§ 103. Conditions for patentability; non-obvious subject matter

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, 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 to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 282

§ 282. Presumption of validity; defenses

(a) IN GENERAL.—A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

* * *