

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

**KNOA PHARMA LLC, KNOA PHARMACEUTICALS
LLC, FKA PURDUE PHARMACEUTICALS L.P.,**
Plaintiffs-Appellants

v.

ACCORD HEALTHCARE, INC.,
Defendant-Appellee

2025-1060

Appeal from the United States District Court for the
District of Delaware in No. 1:22-cv-00913-WCB, Circuit
Judge William C. Bryson.

Decided: June 8, 2026

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Before HUGHES and STOLL, *Circuit Judges*, and SEEBORG,
Chief District Judge.[†]

SEEBORG, *Chief District Judge*.

In this patent case, appellants¹ challenge the trial court’s finding of invalidity on grounds of obviousness. The focus of the litigation is the inventors’ claim to have developed a non-obvious product-by-process for an “abuse-deterrent” pill containing oxycodone hydrochloride, often known simply as “oxycodone.”

Oxycodone is a synthetic opioid, developed in 1916, in an effort to find a less addictive alternative to heroin and morphine for soldiers in World War I. At lower doses, opioids have analgesic (pain relieving) effects. At higher doses,

[†] Honorable Richard Seeborg, Chief District Judge, United States District Court for the Northern District of California, sitting by designation.

¹ The original appellants in this action were Purdue Pharma L.P. and Purdue Pharmaceuticals L.P. (collectively, “Purdue”). After oral argument, and as a result of developments in Purdue’s bankruptcy proceedings, we have granted a motion by Knoa Pharma LLC (“Knoa”) to be substituted for Purdue Pharma L.P. and to recognize that the name of Purdue Pharmaceuticals L.P. has been changed to Knoa Pharmaceuticals LLC. Knoa asserts it now holds the rights to the patent at issue in this appeal, and there is no evidence to the contrary. For convenience, we will continue to refer to the appellants and patent holder as “Purdue,” in the singular.

they have euphoric effects, which can lead to abuse. J.A. 2471.

Following a bench trial, the trial court held all the asserted claims of U.S. Patent No. 11,304,908 (“the ’908 patent”) invalid on obviousness grounds. *Purdue Pharma L.P. v. Accord Healthcare Inc.*, No. CV 22-913-WCB, 2024 WL 4120717, at *23 (D. Del. Sept. 9, 2024) (“*Purdue*”). One independent claim and several dependent claims were in dispute. The patent holder appeals as to only one dependent claim, claim 18. That claim incorporates a limitation set out in the claim from which it depends, claim 17, that the abuse-deterrent oxycodone pills be heated “in a coating pan” for a specified approximate minimum time period and at an approximate minimum temperature. ’908 patent 164:47–48.

The relevant prior art taught heating the pills in a tablet press, which cannot readily produce pills in large quantities. The trial court found that use of coating pans to heat the tablets would have been an obvious alternative, as coating pans can treat large numbers of tablets at a time, and were known devices already employed in the production of pharmaceutical tablets, albeit for other purposes.

Purdue timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1). The trial court’s factual determinations are free from clear error. On *de novo* review of the trial court’s legal conclusion of obviousness, we affirm.

BACKGROUND

In 1995, Purdue developed and obtained FDA approval for OxyContin, a pill with oxycodone as the active ingredient. The oxycodone in the pill was contained within a chemical matrix of an inert material that breaks down slowly over time in the body, allowing the release of the oxycodone over an extended period—*e.g.*, 12 hours.

Not long after the original OxyContin was available on the market, it became apparent that some people were

abusing the tablets by crushing them and snorting the residue, or by mixing the crushed tablets with liquid and injecting the solution. Through these methods, abusers were able to experience the effects of an entire dose of oxycodone in a short period of time, leading to a more pronounced euphoric effect than if the pill released the drug over several hours, as designed.

Purdue began investigating whether it could produce a form of OxyContin less susceptible to abuse. Purdue considered two main approaches, either adding an “antagonist” to the formulation that would render the drug unusable for abuse or making the tablets tamper-resistant so that abusers could not readily crush the tablets to release the drug inside.

In February of 2005, the United States Patent and Trademark Office published United States Patent Application 2005/0031546 A1 (“Bartholomäus”), filed by Johannes Bartholomäus and Heinrich Kugelmann, which was directed to drug-containing tablet formulations made tamper-resistant by hardening the tablets. The application was later assigned to Grunenthal GmbH, a German pharmaceutical company. Bartholomäus teaches using an opioid drug formulation containing polyethylene oxide (“PEO”) having a specified molecular range, press-forming the formulation, and heating it to the melting point of the PEO through preceding, simultaneous, or subsequent exposure to heat.

Bartholomäus reports that the resulting tablets were extremely hard. The tablets did not break, even when exposed to a force of 500 Newtons. In addition, while the tablets could be cut into pieces having an edge length as small as about 2 millimeters, they could not be pulverized. When the pieces were combined with water, a highly viscous gel was formed that could not easily be pressed through an injection needle. J.A. 8132.

In April of 2005, one of the inventors on Purdue's '908 patent, Dr. Richard Mannion, reviewed the Bartholomäus application. Mannion and other Purdue employees then visited the Grunenthal facilities to learn more about Bartholomäus's approach. Although Purdue argues Dr. Mannion initially rejected pursuing a PEO-based formulation, within months thereafter, Purdue had successfully produced a crush-resistant product by curing PEO tablets in a manner generally similar to that described in Bartholomäus.

As noted, the method described in Bartholomäus cured the tablets in a tablet press, a device that was not readily scalable for the purpose of producing commercial quantities of tablets. In contrast, Purdue used a different heating mechanism to cure its tablets: a device known as a coating pan, which could process hundreds of tablets at a time.

Coating pans, as suggested by their name, had traditionally been used to apply coatings to tablets, presumably as the final step in production. Although the coating process includes applying heat to dry the sprayed-on coating, generally the goal was to *avoid* heating the tablets to the point that it would cause any change in their properties. As Purdue puts it, coating pans had only ever been used to coat tablets, not to cure them. Appellants' Br. 2.

In August 2006, Purdue filed a provisional patent application. The '908 patent, entitled "tamper resistant dosage forms," claims priority to that provisional patent application.

Purdue later sought FDA approval for its abuse-resistant oxycodone formulation, asserting it was bioequivalent to the original OxyContin. In 2010, the FDA approved the new formulation. Eventually, the FDA also approved Purdue's application to have the OxyContin label revised to reflect that the new tablets were abuse-deterrent. At that time, the FDA required Purdue to remove the original formulation of OxyContin from the market.

Subsequently, defendant-appellee Accord Health Care, Inc. (Accord) filed an Abbreviated New Drug Application (ANDA) seeking the FDA's approval to market a generic version of Purdue's tamper-resistant OxyContin product. In response, Purdue filed an action in the District of Delaware seeking a declaration that Accord's proposed generic would infringe the '908 patent. Accord responded by stipulating to infringement but asserted that the '908 patent was invalid as obvious.

The district court held a bench trial in February of 2024. The court found the asserted claims of the '908 patent invalid as obvious, in light of Bartholomäus.²

As noted, the only claim in dispute in this appeal is dependent claim 18, which, of course, must be read in conjunction with the claims from which it depends, specifically

² Prior to this case, Purdue brought a separate action against Accord, asserting patents from the same family as the '908 patent. *See Purdue Pharma L.P. v. Accord Healthcare Inc.*, 669 F. Supp. 3d 286 (D. Del. 2023) ("*Accord I*"). That case involved three patents directed to tamper-resistant tablet formulations, together with two other unrelated patents. The patents related to tamper-resistant tablets were all found invalid as obvious, largely in light of Bartholomäus.

At the time of the trial court decision in this case, *Accord I* was still on appeal. The district court's decision has now been affirmed. *See Purdue Pharma L.P. v. Accord Healthcare, Inc.*, No. 2023-1953, 2024 WL 5244764, at *1 (Fed. Cir. Dec. 30, 2024). Although the trial court found additional support in *Accord I* for certain of its findings in this matter, neither the trial court decision nor the appellate opinion in that case are directly relevant to the specific issues raised by Purdue in this appeal and neither party argues otherwise.

independent claim 1 and dependent claim 17. The relevant claims are as follows, with the disputed language emphasized:

1. A solid oral extended release pharmaceutical dosage form, comprising a shaped, convection heated, and cooled extended release matrix, said matrix comprising at least one polyethylene oxide (PEO) having, based on rheological measurements, an approximate molecular weight of at least 800,000, and at least one opioid analgesic, wherein (a) the shaped matrix is convection heated to an elevated temperature that is at least the softening temperature of said PEO for a time period of at least about 1 minute and thereafter cooled; and (b) a plurality of convection heated particles of PEO adhere to or fuse with each other within the matrix.

17. The dosage form of claim 1, wherein the extended release matrix is shaped to form a tablet *and heated in a coating pan*; said time period is at least about 5 minutes; and said elevated temperature is at least about 60° C.

18. The dosage form of claim 17, wherein the opioid analgesic is oxycodone or a pharmaceutically acceptable salt thereof.

The judgment under appeal finds claim 18 invalid because the element “heated in a coating pan” set out in claim 17, from which 18 depends, would have been an obvious modification to the teachings of Bartholomäus that a person of ordinary skill in the art would have been motivated to make. The central issue on appeal is whether the district court erred in holding claim 18 obvious.

LEGAL STANDARDS

“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) (first citing *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007); and then citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)).

DISCUSSION

I.

To establish obviousness, Accord was required to prove by clear and convincing evidence that a person of ordinary skill in the art “would have been motivated to combine or modify the teachings in the prior art” to arrive at the claimed invention. *Regents of the Univ. of Cal. v. Broad Inst., Inc.*, 903 F.3d 1286, 1291 (Fed. Cir. 2018). The ultimate touchstone of the “motivation to combine” inquiry is not whether “one of ordinary skill in the art *could* combine” a number of prior art references, but whether “they *would*

have been motivated to do so.” *InTouch Techs., Inc. v. VGO Commc’ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014). The party seeking to invalidate a patent must provide “reasoning with some rational underpinning” for combining the prior art, in order to avoid “the pitfalls of hindsight that belie a determination of obviousness.” *Innogenetics, N.V. v. Abbott Laboratories*, 512 F.3d 1363, 1373 (Fed. Cir. 2008) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

At trial, Accord presented evidence through its expert, Dr. Leah Appel. She testified that while Bartholomäus teaches an abuse-proofed PEO oxycodone formulation, the actual heating device (a manual tablet press heated inside of a heating cabinet) was not a scalable or commercial solution. Bartholomäus teaches using *conductive* heating (direct application of heat to the tablets) rather than *convection* heating, where heat is transferred through hot air or another fluid.

Dr. Appel explained how ovens, fluid beds, and coating pans were capable of handling hundreds of kilograms of tablets at a time and were also common pieces of equipment found in drug manufacturing facilities. Dr. Appel further explained why a coating pan would have been an especially attractive piece of heating equipment, as it allowed large scale curing, followed by coating, and thus a person of ordinary skill in the art would have been especially motivated to use a coating pan to cure Bartholomäus’s PEO tablets at scale to maximize manufacturing efficiency.

The trial court expressly found Dr. Appel’s testimony to be credible and convincing. Based thereon, the court made the factual finding that a person of ordinary skill in the art would have been motivated to modify Bartholomäus by replacing the tablet press and “curing the tablets in a convection heating device such as a coating pan.” *Purdue*, 2024 WL 4120717, at *11.

Purdue first contends the court committed legal error when it allegedly “collapsed” dependent claim 18 into claim 1 by repeatedly referring to the convection heating limitation of claim 1 in conjunction with the “heated in a coating pan” limitation of claim 18. Appellants’ Br. 4. For example, the district court observed Dr. Appel had testified that “convection heating devices *such as* coating pans, ovens, or fluid bed dryers, are commonly found in facilities where pharmaceutical tablets are manufactured, and that there would be a strong motivation to substitute *such* devices” *Purdue*, 2024 WL 4120717, at *8 (emphasis added). Purdue appears to be saying it would not be enough for the court to have concluded that use of a coating pan was obvious merely because use of *some* form of convection heating might have been obvious.

The district court, however, was addressing the validity both of claim 18 and dependents of claim 21. The dependents of claim 21 did *not* include a coating pan limitation, only a convection heating limitation. It was entirely appropriate for the district court to discuss the issues together, and it always made clear that it was keeping in mind the coating pan limitation applicable to claim 18.

For example, in summarizing its factual findings, the court stated, “Bartholomäus expressly discloses all the limitations found in the asserted claims of the ’908 patent except for the limitations requiring that the formulation be cured by convection heating (all asserted claims), *that the heating be performed in a coating pan (claim 18)*” *Purdue*, 2024 WL 4120717, at *11 (emphasis added). The court did not commit legal error by “collapsing” the relevant claim limitations.

The remainder of Purdue’s argument consists of listing the evidence it believes undermines the court’s factual finding of a motivation to use coating pans and complaining that the court did not address the points it advanced at trial in what it contends is the requisite detail.

“Determining the weight and credibility of the evidence is the special province of the trier of fact.” *Inwood Lab’s, Inc. v. Ives Lab’s, Inc.*, 456 U.S. 844, 856 (1982). Here, the district court found Dr. Appel’s testimony credible and convincing. “[C]redibility determinations by the trial judge can virtually never be clear error.” *JVW Enters., Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1334 (Fed. Cir. 2005) (citations omitted).

Furthermore, Federal Rule of Civil Procedure 52(a) does not require “elaborate, detailed findings on every factual issue raised.” *Atlantic Thermoplastics Co. v. Faytex Corp.*, 5 F.3d 1477, 1479 (Fed. Cir. 1993). A district court’s findings of fact are adequate if they are “sufficiently comprehensive and pertinent to the issue to form a basis for the decision.” *Medtronic, Inc. v. Daig Corp.*, 789 F.2d 903, 906 (Fed. Cir. 1986) (quoting *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 873 (Fed. Cir. 1985)). The trial court’s decision easily meets that standard.

II.

Purdue’s attack on the trial court’s finding that a person of ordinary skill in the art would have had a reasonable expectation of success with respect to using coating pans parallels its arguments regarding motivation to combine. Again, the trial court relied on Dr. Appel’s testimony that it found credible and convincing, and again Purdue insists that testimony was too conclusory, and that the court failed to give sufficient weight to contrary evidence or to engage sufficiently with all of Purdue’s specific contentions.

As with the motivation to combine issue, Purdue’s insistence that the evidence could have supported a different result on the issue of reasonable expectation of success is insufficient to overturn the trial court’s factual findings. That a contrary conclusion could have been reached does not meet the “clear error” standard.

III.

Purdue also asserts that the district court erred in finding that the claimed invention did not meet a long-felt but unmet need. Before reaching a conclusion on obviousness, courts analyze “the objective indicia of nonobviousness.” *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1357–58 (Fed. Cir. 2013). Such indicia “play a critical role in the obviousness analysis,” as their consideration is “crucial in avoiding the trap of hindsight when reviewing, what otherwise seems like, a combination of known elements.” *Id.* at 1358. Among those objective indicia is evidence that the claimed invention solved “a long felt but unresolved need.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1332 (Fed. Cir. 2016). This “tends to show non-obviousness because it is reasonable to infer that the need would have not persisted had the solution been obvious.” *Id.*; *see also, e.g., Amgen*, 66 F.4th at 964.

Here, Purdue contended at trial that there was “a long felt but unresolved need” for an abuse-deterrent oxycodone tablet. Addressing Purdue’s arguments at length, the trial court found this alleged need had already been met by Bartholomäus, which disclosed an extended-release opioid with abuse-deterrent properties. Given Bartholomäus’s undisputed teachings as set forth above, the district court did not clearly err in so finding. *See, e.g., BTG Int’l Ltd. v. Amneal Pharms. LLC*, 923 F.3d 1063, 1076 (Fed. Cir. 2019) (where the “Asserted Claims only require an effective treatment for prostate cancer” and other treatments were available and effective, evidence did not establish long-felt unmet need).

On appeal, Purdue shifts focus to argue the long-unmet need was for scalable, commercially practical abuse-deterrent tablets. Accord contends this is a new theory, forfeited by Purdue’s failure to present it to the trial court. We agree. Even assuming the argument was not forfeited, claim 18 is directed to a “solid oral extended release pharmaceutical

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dosage form” and does not recite a scalable process. As such, any long-felt need for a scalable process is not commensurate in scope with the claim. *See, e.g., ABT Sys., LLC v. Emerson Elec. Co.*, 797 F.3d 1350, 1362 (Fed. Cir. 2015) (rejecting long-felt need argument that “ignores the scope of [the] claim”).

CONCLUSION

We have considered Purdue’s remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm the district court’s final judgment, finding claim 18 of the ’908 patent invalid as obvious under 35 U.S.C. § 103.

AFFIRMED