United States Court of Appeals for the Federal Circuit

HOSPIRA, INC.,
Plaintiff-Appellant

v.

FRESENIUS KABI USA, LLC,
Defendant-Appellee

2019-1329, 2019-1367

Appeals from the United States District Court for the Northern District of Illinois in Nos. 1:16-cv-00651, 1:17-cv-07903, Judge Rebecca R. Pallmeyer.

Decided: January 9, 2020

ADAM G. UNIKOWSKY, Jenner & Block LLP, Washington, DC, argued for plaintiff-appellant. Also represented by BRADFORD PETER LYERLA, AARON A. BARLOW, YUSUF ESAT, REN-HOW HARN, SARA TONNIES HORTON, Chicago, IL.

IMRON T. ALY, Schiff Hardin LLP, Chicago, IL, argued for defendant-appellee. Also represented by KEVIN MICHAEL NELSON, JOEL M. WALLACE; AHMED M.T. RIAZ, New York, NY.

Before LOURIE, DYK, and MOORE, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Hospira Inc. ("Hospira") appeals from the judgment of the United States District Court for the Northern District of Illinois that claim 6 of U.S. Patent 8,648,106 ("the '106 patent") is invalid as obvious. *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 343 F. Supp. 3d 823 (N.D. Ill. 2018) ("*Opinion*"). Because we find that the district court's factual findings were not clearly erroneous and that those findings support a conclusion of obviousness, we affirm.

BACKGROUND

Hospira makes and sells dexmedetomidine products under the brand name Precedex, including a ready-to-use product known as Precedex Premix. Hospira owns a number of patents that cover its Precedex Premix product. Fresenius Kabi USA LLC ("Fresenius") filed an Abbreviated New Drug Application ("ANDA") seeking approval to enter the market with a generic ready-to-use dexmedetomidine product. Hospira sued for infringement of five patents and eventually dropped all but two claims, one of which was claim 6 of the '106 patent.[1] Fresenius stipulated to infringement of claim 6, and the district court held a bench trial on its validity.

I. Prior Art Dexmedetomidine

Dexmedetomidine is a chemical compound that is effective as a sedative. '106 patent col. 1 ll. 36–37. Dexmedetomidine was first developed and patented by Farmos Yhtyma Oy ("Farmos") in the 1980s. Farmos was issued U.S. Patent 4,910,214, which disclosed the dexmedetomidine compound and its use as a sedative.

---

[1] The other asserted claim was claim 8 of U.S. Patent 9,616,049, which the district court held would have been obvious and is not at issue in this appeal.

In 1989, Farmos submitted an Investigational New Drug application ("the Farmos IND") to the U.S. Food and Drug Administration ("FDA") seeking approval to begin safety testing dexmedetomidine formulations in humans. Farmos conducted at least two human safety studies using intravenous administration of 20 μg/mL dexmedetomidine hydrochloride but subsequently abandoned its safety testing after the studies showed adverse effects.

In 1994, Farmos's successor granted Abbott Laboratories (Hospira's predecessor-in-interest) an exclusive license to make, use, and sell dexmedetomidine for human use in the United States. In 1999, Abbott Laboratories received FDA approval to market a 100 μg/mL dexmedetomidine hydrochloride formulation known as "Precedex Concentrate." Precedex Concentrate is supplied in 2 mL clear glass vials and 2 mL clear glass ampoules made from Type IA sulfur-treated glass sealed with coated rubber stoppers. The 100 μg/mL concentration of Precedex Concentrate is too strong to be directly administered to patients, and thus the label provides instructions for diluting the drug to a concentration of 4 μg/mL before intravenous administration.

Dexmedetomidine is also available as a sedative for commercial veterinary use. In 2002, the European Medicines Evaluation Agency authorized use of a product called Dexdomitor, which is a ready-to-use 500 μg/mL formulation of dexmedetomidine hydrochloride. Dexdomitor is stored in a 10 mL glass vial sealed with a coated rubber stopper and has a two-year shelf life.

II. The '106 Patent

The '106 patent is entitled "Dexmedetomidine Premix Formulation" and is directed to pharmaceutical compositions comprising dexmedetomidine (or a pharmaceutically acceptable salt of dexmedetomidine) formulated as a liquid for parenteral administration to a patient, "wherein the composition is disposed within a sealed container as a premixture." '106 patent at Abstract; *see also* '106 patent col.

1 ll. 19–20 ("The present invention relates to patient-ready, premixed formulations of dexmedetomidine, or a pharmaceutically acceptable salt thereof . . . ."). The '106 patent describes the alleged problems associated with prior art dexmedetomidine formulations that the patented invention was intended to solve:

> To date, dexmedetomidine has been provided as a concentrate that must be diluted prior to administration to a patient. The requirement of a dilution step in the preparation of the dexmedetomidine formulation is associated with additional costs and inconvenience, as well as the risk of possible contamination or overdose due to human error. Thus, a dexmedetomidine formulation that avoids the expense, inconvenience, delay and risk of contamination or overdose would provide significant advantages over currently available concentrated formulations.

Id. col. 1 l. 61–col. 2 l. 3.

To address the perceived shortcomings of the prior art, the '106 patent states that its invention relates to "premixed pharmaceutical compositions of dexmedetomidine, or a pharmaceutically acceptable salt thereof, that are formulated for administration to a patient, without the need to reconstitute or dilute the composition prior to administration." *Id.* col. 2 ll. 7–11. The patent specifies that the invention can be formulated as a "ready to use" composition, which is a premixed dexmedetomidine composition that is "suitable for administration to a patient without dilution." *Id.* col. 3 l. 66–col. 4 l. 2.

Importantly, the '106 patent states that "[t]he present invention is based in part on the discovery that dexmedetomidine prepared in a premixed formulation that does not require reconstitution or dilution prior to administration to a patient, *remains stable and active after prolonged storage*." *Id.* col. 3 ll. 6–10 (emphasis added). The patent

describes "stability studies" that were conducted to measure the loss in potency of the drug over time. *Id.* col. 13–col. 25 (Examples 1, 2, 4, and 6, which describe studies of dexmedetomidine potency over time under different conditions). For instance, Example 1 describes a study of potency of a 4 μg/mL dexmedetomidine hydrochloride formulation over time when stored in different storage containers, and Example 4 describes testing under different stresses and concludes that "[u]nder oxidative conditions, the sample showed highest amount of degradation." *Id.* col. 17 ll. 25–26.

In Example 5, the patent describes a process by which a 4 μg/mL dexmedetomidine hydrochloride formulation "can be manufactured." *Id.* col. 17 ll. 57–58. That example manufacturing process includes "[n]itrogen sparging . . . throughout the manufacturing process." *Id.* col. 17 ll. 60–62. At the conclusion of the process, "[a]n atmosphere of filtered nitrogen gas is maintained in the headspace of the surge bottle," and "the headspace of the container is gassed with nitrogen to achieve not more than 5% of oxygen in the headspace." *Id.* col. 18 ll. 58–62.

Claim 1 is the only independent claim in the '106 patent:

> 1. A ready to use liquid pharmaceutical composition for parenteral administration to a subject, comprising dexmedetomidine or a pharmaceutically acceptable salt thereof disposed within a sealed glass container, wherein the liquid pharmaceutical composition when stored in the glass container for at least five months exhibits no more than about 2% decrease in the concentration of dexmedetomidine.

Id. col. 26 ll. 18–24. Claim 6, which depends from claim 1, is the only claim at issue in this appeal:

> 6. The ready to use liquid pharmaceutical composition of claim 1, wherein the dexmedetomidine or pharmaceutically acceptable salt thereof is at a concentration of about 4 μg/mL.

Id. col. 26 ll. 41–43.

III. District Court Proceedings

The district court held a five-day bench trial on Fresenius's defense that claim 6 of the '106 patent is invalid as obvious over the prior art combinations of Precedex Concentrate in combination with the knowledge of a person of ordinary skill in the art and Precedex Concentrate in combination with Dexdomitor. After the parties submitted their post-trial briefs, the court issued its findings of fact and conclusions of law, holding that Fresenius had proven by clear and convincing evidence that claim 6 would have been obvious over the prior art.

The district court determined that "to prove that a claim covering multiple alternative embodiments is invalid, a defendant need only prove that one of the embodiments is invalid." *Opinion*, 343 F. Supp. 3d at 845–46 (citing *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1281 (Fed. Cir. 2015)). Thus, the court focused on one allegedly obvious embodiment of claim 6, namely, "a ready-to-use, sealed glass container—made from Type I glass and a coated rubber stopper—with 4 μg/mL dexmedetomidine HCl," which the court referred to as the "4 μg/mL preferred embodiment."[2] The court found that the 4 μg/mL preferred embodiment was expressly taught by the prior art, and the

---

[2] For consistency, we will similarly refer to this embodiment as the "4 μg/mL preferred embodiment" herein.

only dispute between the parties concerned the "about 2%" limitation in claim 6.[3] *Id.* at 846.

Based on the evidence in the trial record, the district court found that Fresenius had proven the following facts by clear and convincing evidence:

> All stability data in the record for 4 μg/mL dexmedetomidine HCl formulations stored in Type I glass vials, sealed with coated rubber stoppers, and stored at room temperature shows that there was "no more than about 2%" loss in concentration at five months.
>
> The "about 2%" limitation of the '106 Patent is inherent in a 4 μg/mL dexmedetomidine HCl formulation, stored in a Type I glass vial sealed with a coated rubber stopper, and stored at room temperature for five months.

Opinion, 343 F. Supp. 3d at 841. To reach those findings, the district court relied on fact and expert testimony regarding the stability data for more than 20 tested samples of 4 μg/mL dexmedetomidine hydrochloride in the record,[4] all of which met the about 2% limitation. *Id.* at 846-47. The court also relied on the conclusion of Fresenius's expert that the concentration of dexmedetomidine does not have an effect on its stability. The court rejected Hospira's

---

[3] The "about 2%" limitation refers to the claim limitation that reads "wherein the liquid pharmaceutical composition when stored in the glass container for at least five months exhibits no more than about 2% decrease in the concentration of dexmedetomidine."

[4] The samples included 18 batch configurations in the Precedex Premix New Drug Application (three vial sizes, each of which was analyzed in three upright and three inverted configurations) and three samples in Fresenius's ANDA. *Opinion*, 343 F. Supp. 3d at 833, 836.

arguments regarding stability data from 20 μg/mL samples in the Farmos IND, finding that Fresenius's expert's analysis of that data was more reliable than that of Hospira's expert. *Id.* at 849–50. Furthermore, the court noted that, although a district judge in Delaware had previously found (in a separate litigation brought by Hospira against a different defendant) that the about 2% limitation had not been proven to be inherent, that decision was based on a different record and was not binding in this case. *Id.* at 850–51 (citing *Hospira, Inc. v. Amneal Pharm. LLC*, 285 F. Supp. 3d. 776, 800 (D. Del. 2018), *aff'd*, 748 F. App'x 1024 (Fed. Cir. 2019)).

The district court then considered whether a person of ordinary skill would have had a reasonable expectation of success in achieving the about 2% limitation from combining the other limitations disclosed in the prior art. On that issue, the court found:

> A [person of ordinary skill in the art] would have a considerable understanding of organic chemistry. Based on his or her understanding of the chemical properties of dexmedetomidine, a [person of ordinary skill in the art] would have expected it to be stable in room-temperature storage conditions for at least five months.

Opinion, 343 F. Supp. 3d at 841. To reach that finding, the court relied on expert testimony that the chemical structure of dexmedetomidine would be "a rock stable molecule" under normal conditions based on its aromatic ring structure and lack of hydrolyzable and oxidizable groups. *Id.* at 852. The court also relied on information in the Precedex Concentrate and Dexdomitor labels, which do not contain chemical stabilizers despite their low concentrations. And the court credited expert testimony that the about 2% limitation is consistent with standard industry expectations for drug stability. Moreover, the court rejected each of Hospira's arguments, finding that Hospira had failed to show

that a person of skill would have expected a lower concentration to reduce stability or that a person of skill would have expected oxidation to occur in the absence of nitrogen sparging. *Id.* at 854–57.

Based on its factual findings, the district court concluded that claim 6 of the '106 patent is invalid as obvious and entered judgment in favor of Fresenius. Hospira appealed the court's judgment. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

On appeal from a bench trial, we review a district court's conclusions of law *de novo* and its findings of fact for clear error. *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1358 (Fed. Cir. 2014) (citing *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1123 (Fed. Cir. 2000)). "A factual finding is clearly erroneous when, despite some supporting evidence, we are left with a definite and firm conviction that the district court was in error." *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1186 (Fed. Cir. 2014) (citing *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006)). "The burden of overcoming the district court's factual findings is, as it should be, a heavy one." *Polaroid Corp. v. Eastman Kodak Co.*, 789 F.2d 1556, 1559 (Fed. Cir. 1986). "Where there are two permissible views of the evidence, the fact-finder's choice between them cannot be clearly erroneous." *Anderson v. Bessemer City,* 470 U.S. 564, 574 (1985) (citing *United States v. Yellow Cab Co.*, 338 U.S. 338, 342 (1949)).

Obviousness is a question of law based on underlying facts, including the scope and content of the prior art. *See Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012). "The inherent teaching of a prior art reference is a question of fact." *Par Pharm. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1194 (Fed. Cir. 2014) (citation omitted). When the prior art does not expressly disclose a claim limitation, "inherency may supply a missing claim

limitation in an obviousness analysis." *Id*. at 1194–95 (collecting cases). Inherency is established in the context of obviousness when "the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art." *Id.* at 1195–96.

In this appeal, Hospira challenges the district court's conclusion that claim 6 of the '106 patent is invalid as obvious based on the inherency of the "about 2%" limitation. First, Hospira argues that the district court incorrectly considered the inherency of the about 2% limitation in non-prior art embodiments rather than the allegedly obvious prior art combination. Second, Hospira argues that the court applied a lower "reasonable expectation of success standard" rather than the higher "necessarily present" standard to the inherency question. We address each of these arguments in turn.

I

We first consider Hospira's argument that the district court erred in its application of the inherency doctrine by considering the inherent properties of non-prior art embodiments. Hospira argues that every tested sample of the 4 μg/mL preferred embodiment in the record was either from Hospira's NDA for Precedex Premix or from Fresenius's ANDA for its ready-to-use product, none of which were in the prior art. Hospira's primary contention is that each of those samples was manufactured using the particular manufacturing process described in Example 5 of the '106 patent, and thus the stability data from those samples cannot suffice to prove that all samples of the allegedly obvious combination—a formulation of the 4 μg/mL preferred embodiment which may or may not have been prepared using the manufacturing process of Example 5—would "necessarily" meet the about 2% limitation.

Fresenius responds that the district court did not err in relying on the tested samples of the 4 μg/mL preferred embodiment in the record, and it is irrelevant for the

inherency analysis whether or not those samples were prior art. Fresenius contends that Hospira's argument that unclaimed manufacturing variables from Example 5 distinguish the tested samples from the prior art is a new argument raised for the first time on appeal and is therefore improper, and in any event is unfounded.

As a threshold matter, we agree with Fresenius that the district court did not err in relying on data obtained after the priority date of the '106 patent in its inherency analysis. Extrinsic evidence can be used to demonstrate what is "necessarily present" in a prior art embodiment even if the extrinsic evidence is not itself prior art. *See Monsanto Tech. LLC v. E.I. DuPont de Nemours & Co.*, 878 F.3d 1336, 1345 (Fed. Cir. 2018) (allowing "non-prior art data" to be used to support inherency); *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (finding that the prior art need not recognize the inherent property). Moreover, the work of the inventor or the patentee can be used as the evidence of inherency. *See, e.g.*, *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1369 (Fed. Cir. 2012) (analyzing inherency based on the disclosure of the "patent itself"); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327–28 (Fed. Cir. 2001) (finding that features were inherent "as evidenced by [the patentee]'s own documents"). The later evidence is not itself prior art; it only helps to elucidate what the prior art consisted of. Therefore, it was not legally incorrect for the district court to rely on non-prior art data from Hospira's NDA and Fresenius's ANDA as evidence of the inherent stability of the 4 μg/mL preferred embodiment.

Furthermore, we agree with Fresenius that the unclaimed manufacturing variables in Example 5 do not, as a matter of law, preclude a finding of inherency in this case. First, although Hospira faults the district court for looking only at samples prepared by the manufacturing process of Example 5, it is not entirely clear that Hospira actually argued below that the inherency analysis required stability

data from samples prepared by manufacturing processes other than Example 5. But even assuming that Hospira preserved that argument by raising it to the district court, it is without merit. Claim 6 is directed to a composition of 4 μg/mL dexmedetomidine disposed in a sealed glass container. '106 patent col. 26 ll. 18–24, 41–43. Claim 6 is not a method claim, it is not a product-by-process claim, and there are no limitations in claim 6 regarding the manufacturing process by which the recited 4 μg/mL dexmedetomidine composition must be prepared. Importing such limitations from Example 5 into the claim, as Hospira seeks to do, would be improper. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005). Thus, the district court did not misapply the law of inherency by considering the samples in the record without regard to the process by which those samples were prepared.

Because the district court did not legally err in applying the inherency doctrine, what remains for our review is the court's factual finding that the about 2% limitation was necessarily present in the 4 μg/mL preferred embodiment. At trial, Fresenius presented evidence in support of its inherency contention. That evidence included data from more than 20 samples of the 4 μg/mL preferred embodiment, every one of which met the about 2% limitation. The evidence also included expert testimony that concentration does not affect the stability of dexmedetomidine, which demonstrates that dexmedetomidine is a very stable drug. The district court relied on that evidence to find that the about 2% limitation was necessarily present in the 4 μg/mL preferred embodiment in the prior art.

Hospira disagrees with the factual findings of the district court. For example, Hospira asks us to find that the samples in the record are not representative of every possible formulation of the 4 μg/mL preferred embodiment. But Hospira did not present evidence of even a single sample of the 4 μg/mL preferred embodiment that failed to meet the about 2% limitation. Additionally, Hospira did

not present evidence sufficient to persuade the district court that the manufacturing process of Example 5 was the reason why all tested samples met the about 2% limitation, or that samples prepared by a different process might not meet that limitation. *See Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310, 1335–36 (Fed. Cir. 2018) (noting that the patent owner "cites no support" for the assumption that inherent properties would differ between the prior art and the claim).

Hospira also insists that the district court erred by not requiring Fresenius to present a quantitative drug loss model. But Hospira presented that factual contention at trial, and the court rejected it. The court instead credited the testimony of Fresenius's expert that there was not enough drug loss to be able to discern one drug loss model from another. The court found that, "[i]f anything, the inability to assign a loss model to dexmedetomidine underscores Fresenius Kabi's position that the 4 μg/mL preferred embodiment will necessarily experience no more than two percent loss in concentration at five months." *Opinion*, 343 F. Supp. 3d at 849.

Hospira's arguments on appeal cannot change the trial record, which included more than 20 samples that all met the about 2% limitation. The trial record also included testimonial and statistical evidence that dexmedetomidine is a very stable drug at any concentration; thus, simply adding solvent to dilute it by a factor of 25—from 100 μg/mL, which was known to be stable, to 4 μg/mL—does not affect its inherent stability. On that record, it was not clearly erroneous for the district court to find that the about 2% limitation was necessarily present in the prior art.

II

We turn to Hospira's argument that the district court applied the wrong standard to the inherency question. Hospira argues that the district court applied the "reasonable expectation of success" standard in its inherency

analysis of the chemical structure of dexmedetomidine. Thus, Hospira argues, the district court did not conduct a complete inherency analysis under the correct "necessarily present" standard.

Fresenius responds that the district court completed its inherency analysis when it found that the about 2% limitation was necessarily present in the prior art based on the evidence of the tested samples in the record. Fresenius argues that, after completing that correct analysis of inherency, the court then separately found that a person of ordinary skill would have had a reasonable expectation of success in achieving the about 2% limitation.

"An obviousness determination requires that a skilled artisan would have perceived a reasonable expectation of success in making the invention in light of the prior art." *Amgen Inc. v. F. Hoffman-La Roche, Ltd.*, 580 F.3d 1340, 1362 (Fed. Cir. 2009). In this appeal, the parties do not dispute that Fresenius met its burden of proof on that issue. *See* Appellant's Br. 37 ("[T]he District Court found a reasonable expectation of success; although Hospira respectfully disagrees with the District Court's conclusion on this issue, it acknowledges the deferential standard of review and does not contend that this finding is clearly erroneous."). Thus, the only dispute is whether the district court's inherency analysis was correct. We agree with Fresenius that it was.

As explained above, the district court engaged in a thorough and extensive analysis of the stability data in the record to reach its factual finding that the about 2% limitation was necessarily present in the prior art. *Opinion*, 343 F. Supp. 3d at 841, 845–51. But the district court then engaged in unnecessary analysis in evaluating whether the chemical properties of the dexmedetomidine molecule, the information in the Precedex Concentrate and Dexdomitor labels, and the industry guidance for stability testing would enable a person of ordinary skill to have had a

reasonable expectation of successfully achieving the about 2% limitation. *Id.* at 851–57. The court thus conflated the standards for inherency and reasonable expectation of success. However, that was harmless error that did not infect its inherency analysis and findings. *See Vanderbilt Univ. v. ICOS Corp.*, 601 F.3d 1297, 1308 (Fed. Cir. 2010) ("The district court's findings demonstrate that under the correct legal test, [the plaintiff] did not carry its burden. Thus, any erroneous interpretations of our case law were harmless error."); *see also Environ Prods. v. Furon Co.*, 215 F.3d 1261, 1266 (Fed. Cir. 2000) ("When the error as to the weight of proof could not have changed the result, the erroneous instruction is harmless." (citing 11 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2886 (2d ed. 1995))). If a property of a composition is in fact inherent, there is no question of a reasonable expectation of success in achieving it. The claimed dexmedetomidine formulation already is, as the evidence in this case shows, possessed of the about 2% limitation.

III

Having concluded that the district court's factual findings were not clearly erroneous, we finally turn to the legal question of whether those findings support a conclusion that claim 6 would have been obvious. We conclude that they do.

It is well-settled that the inclusion of an inherent, but undisclosed, property of a composition does not render a claim to the composition nonobvious. *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999) ("[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." (citing *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985))). A patent can be invalid based on inherency when the patent itself makes clear that a limitation is "not an additional requirement

imposed by the claims . . . , but rather a property necessarily present." *In re Kubin*, 561 F.3d 1351, 1357 (Fed. Cir. 2009); *see also Persion Pharm. LLC v. Alvogen Malta Operations Ltd.*, Case No. 18-2361, slip op. at 13 (Fed. Cir. Dec. 27, 2019) ("[T]he district court did not err by finding that the pharmacokinetic limitations of the asserted claims were inherent and added no patentable weight to the pharmacokinetic claims."); *Alcon Research*, 687 F.3d at 1369 ("[T]his claim language does not impose any additional requirement because the '805 patent itself defines mast cell stabilization as a property that is necessarily present at those concentrations."); *In re Kao*, 639 F.3d 1057, 1070 (Fed. Cir. 2011) ("Substantial evidence supports the Board's finding, based upon the specification, which confirms that the claimed 'food effect' is an inherent property of oxymorphone itself . . . .").

Here, the '106 patent itself states that the invention was based on "the *discovery* that dexmedetomidine prepared in a premixed formulation . . . *remains stable and active after prolonged storage*." '106 patent, col. 3 ll. 6–10 (emphasis added). Claim 6 does not recite any manufacturing limitations that are related to stability or an added component that enhances stability; it simply recites a composition, with a "wherein" clause that describes the stability of that recited composition, a result that was inherent in the prior art.

In sum, the district court did not clearly err in finding as a factual matter that the about 2% limitation was necessarily present in the prior art, and as a legal matter the inclusion of the inherent about 2% limitation does not make claim 6 nonobvious. We therefore agree with the district court's conclusion that claim 6 of the '106 patent would have been obvious over the prior art.

CONCLUSION

We have considered Hospira's remaining arguments, but we find them unpersuasive. Accordingly, the judgment of the district court is affirmed.

AFFIRMED