

Appeal Nos. 19-1329, 19-1367

---

UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT

---

---

HOSPIRA, INC.,

*Plaintiff-Appellant,*

v.

FRESENIUS KABI USA, LLC,

*Defendant-Appellee.*

---

Appeal from the United States District Court for the  
Northern District of Illinois in Case No. 1:16-cv-00651

---

**PETITION FOR REHEARING *EN BANC***

---

Sara T. Horton  
Aaron A. Barlow  
Yusuf Esat  
Ren-How H. Harn  
Jenner & Block LLP  
353 N. Clark Street  
Chicago, IL 60654-3456  
Telephone: (312) 222-9350  
Facsimile: (312) 527-0484

Adam G. Unikowsky  
Jenner & Block LLP  
1099 New York Ave. NW, Suite 900  
Washington, DC 20001  
Telephone: (202) 639-6000  
Facsimile: (202) 639-6066

*Attorneys for Plaintiff-Appellant  
Hospira, Inc.*

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

Hospira, Inc. v. Fresenius Kabi USA, LLC

Case No. 19-1329, 19-1367

**CERTIFICATE OF INTEREST**

Counsel for the:

(petitioner)  (appellant)  (respondent)  (appellee)  (amicus)  (name of party)

**Hospira, Inc.**

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Hospira, Inc.	Not applicable	Pfizer Inc.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (**and who have not or will not enter an appearance in this case**) are:

Jenner & Block LLP: Chad J. Ray

FORM 9. Certificate of Interest

Form 9  
Rev. 10/17

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

The following cases involve one or more of the patents-at-issue:

- Hospira, Inc. v. Amneal Pharmaceuticals, 18-1522 (Fed. Cir.)
- Hospira, Inc. v. Fresenius Kabi USA, LLC, 17-cv-7903 (N.D. Ill.)
- Hospira, Inc. v. Par Sterile Products, LLC, 16-cv-879-RGA (D. Del.)
- Hospira, Inc. v. Gland Pharma Ltd., 18-cv-190-RGA (D. Del.)
- Hospira, Inc. v. Jiangsu Hengrui Medicine Co., Ltd., 18-cv-191-RGA (D. Del.)

2/10/2020

Date

/s/ Sara T. Horton

Signature of counsel

Sara T. Horton

Printed name of counsel

Please Note: All questions must be answered

cc: All Parties

Reset Fields

## TABLE OF CONTENTS

CERTIFICATE OF INTEREST .....	i
TABLE OF AUTHORITIES .....	iv
RULE 35(b)(2) STATEMENT .....	1
INTRODUCTION .....	2
BACKGROUND .....	5
A.    The Claim-in-Suit.....	5
B. <i>Amneal</i> .....	6
C. <i>Fresenius Kabi</i> .....	8
ARGUMENT .....	10
I.    The Court’s Decision Is Wrong.....	10
II. <i>En banc</i> Review Is Warranted.....	14
CONCLUSION .....	17

## TABLE OF AUTHORITIES

### CASES

<i>Guangdong Alison Hi-Tech Co. v. ITC</i> , 936 F.3d 1353 (Fed. Cir. 2019) .....	2
<i>Honeywell International Inc. v. Mexichem Amanco Holding S.A. de C.V.</i> , 865 F.3d 1348 (Fed. Cir. 2017) .....	16-17
<i>Hospira, Inc. v. Amneal Pharmaceuticals LLC</i> , 285 F. Supp. 3d 776 (D. Del. 2018), <i>aff'd</i> , 748 F. App'x 1024 (Fed. Cir. 2019) .....	6, 7, 8, 13
<i>Hospira, Inc. v. Amneal Pharmaceuticals LLC</i> , 748 F. App'x 1024 (Fed. Cir. 2019) .....	8
<i>Hospira, Inc. v. Fresenius Kabi USA, LLC</i> , 343 F. Supp. 3d 823 (N.D. Ill. 2018), <i>aff'd</i> , 946 F.3d 1322 (Fed. Cir. 2020) .....	8, 9, 11, 12
<i>PAR Pharmaceuticals, Inc. v. TWI Pharmaceuticals, Inc.</i> , 773 F.3d 1186 (Fed. Cir. 2014) .....	2, 10, 11, 17
<i>Transclean Corp. v. Bridgewood Services, Inc.</i> , 290 F.3d 1364 (Fed. Cir. 2002) .....	2

**RULE 35(b)(2) STATEMENT**

Based on my professional judgment, I believe this appeal requires an answer to a precedent-setting question of exceptional importance:

Whether a party seeking to show that a property is inherent in a combination of prior art disclosures must affirmatively prove that the property is necessarily present in that combination, regardless of how that combination is prepared.

/s/ Sara T. Horton

*Attorney of Record for Plaintiff-Appellant Hospira, Inc.*

## INTRODUCTION

This case presents a fundamental question of patent law that the *en banc* court has never addressed—the burden a patent challenger must meet to establish inherency in an obviousness case.

In the context of anticipation, the law of inherency is well-settled. “An element may be inherently disclosed only if it is necessarily present, not merely possibly present, in the prior art.” *Guangdong Alison Hi-Tech Co. v. ITC*, 936 F.3d 1353, 1364 (Fed. Cir. 2019) (internal quotation marks omitted). Thus, when a prior art embodiment sometimes, but not always, possesses a property, that property is not inherent. *See, e.g., Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002) (affirming summary judgment of no inherency because “[a]lthough it is possible that the [prior art] detection means could under some circumstance...effectively equalize the flow rates as well, it is also possible for that not to be the case.”).

In the context of obviousness, however, the doctrine of inherency is less typically applied—and the case law on the requirements for its proof is less well-developed. *PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1194-95 (Fed. Cir. 2014) (“[T]he use of inherency, a doctrine originally rooted in anticipation, must be carefully circumscribed in the context of obviousness.”). Inherency in the obviousness context is easy to apply where the question is whether *a specific first*

*prior art reference* inherently possesses a claimed property, and then this prior art reference is combined with a second prior art reference to arrive at the claimed invention. In that context, the inherency analysis is the same as in the anticipation context: in order to be inherent, the property must be necessarily present in the first prior art reference.

More complex questions arise when the inherency analysis turns on whether a *combination* of prior art elements inherently discloses a property. In that scenario, the patent challenger must prove that a particular property is inherent not in a particular embodiment described in prior art, but in a combination of prior art elements. The inherency analysis differs in this context because there may be multiple ways of preparing that hypothetical combination. For instance, combining those prior art elements may have required design or manufacturing choices—choices that may be unspecified in the prior art. The question then becomes: how does a patent challenger prove that a hypothetical combination of prior art disclosures that can be combined in multiple ways, necessarily possesses a particular property?

That question becomes most difficult in the scenario presented here—when the patent challenger proffers *examples* of the allegedly obvious combination that do possess the property, but those examples do not originate in the prior art. In that scenario, the question becomes: what *more* does the patent challenger have to do to



prove inherency? Does the patent challenger bear the affirmative burden of showing that the property exists in the combination, regardless of its manner of preparation? Or, conversely, does the burden shift to the patentee to show that there may be a way of preparing the combination in which the property does not appear?

This case illustrates the difficulty of that question. Two different district courts reached opposite conclusions—the District of Delaware found that inherency was not proved, and the Northern District of Illinois found that inherency was proved—and this Court affirmed both decisions as not clearly erroneous. Of course, in view of the deferential clear-error standard of review, there is no logical inconsistency between this Court’s affirmances of both judgments. But the divergent outcomes do not merely reflect differences in the factual records before the two courts; rather, they reflect a conceptual disagreement on what it means to prove that a property is inherently present in a hypothetical combination of elements.

This Court should rehear this case *en banc* to resolve that disagreement and set a clear standard for inherency in obviousness law. On the merits, the Court should hold that, as a matter of law, non-prior art examples are not enough to sustain a patent challenger’s burden of proving inherency. Rather, the patentee bears the affirmative burden to extrapolate the inherent properties of the allegedly obvious combination, no matter how it is prepared. Because Fresenius Kabi did not meet that burden, the judgment should be reversed.

## BACKGROUND

### A. The Claim-in-Suit

This case relates to a pharmaceutical known as dexmedetomidine. The patent-in-suit, U.S. Patent No. 8,648,106 (“the ’106 patent”) is directed to a premixed, ready-to-use dexmedetomidine product, which Hospira markets as a sedative under the brand name Precedex Premix.

Claim 6, the claim-in-suit, recites a premixed version of dexmedetomidine that has a certain property: that, at a particular concentration (4  $\mu\text{g}/\text{mL}$ ), over a particular time period (five months), it meets a particular stability threshold (no more than 2% concentration decrease). Specifically, independent claim 1, on which the claim-in-suit depends, recites:

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.

The claim-in-suit recites:

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  $\mu\text{g}/\text{mL}$ .

Hospira has now litigated the validity of this patent twice. In both cases, the district courts concluded that every claim limitation *except* the “2% decrease” limitation is expressly disclosed in the prior art, and that a skilled artisan would have combined those disclosures. In other words, both courts concluded that a skilled artisan would have combined prior art elements in order to prepare 4 µg/mL premixed dexmedetomidine solution in a sealed glass container. Hospira does not dispute that conclusion on appeal.

But it was undisputed in both cases that the prior art contains no *express* disclosure of such a product that satisfies the “2% decrease” limitation. Thus, in both cases, the patent challengers relied on the inherency doctrine. In both cases, the question then became: if a skilled artisan combined every *other* claim limitation (and hence prepared a 4 µg/mL premixed dexmedetomidine solution in a sealed glass container), would the “2% decrease” stability property be inherently present in that combination of elements?

As explained below, the two courts reached opposite conclusions, and both were affirmed.

### ***B. Amneal***

In one case, Hospira sued Amneal Pharmaceuticals for infringing claim 6 of the ‘106 patent, and Amneal counterclaimed that the claim was invalid for obviousness. *See Hospira, Inc. v. Amneal Pharm. LLC*, 285 F. Supp. 3d 776 (D.

Del. 2018), *aff'd*, 748 F. App'x 1024 (Fed. Cir. 2019). Amneal argued that a skilled artisan would have combined prior art elements to create a 4 µg/mL dexmedetomidine solution in a sealed glass container, and that the “2% decrease” property was inherent in that combination. To prove inherency, Amneal pointed to non-prior art testing data, primarily the inventor’s own testing data, in which batches of 4 µg/mL dexmedetomidine solution in sealed glass containers were found to meet the stability limitation described in the claim. *Id.* at 789. “Characterizing its evidence as ‘unrebutted experimental evidence,’” Amneal claimed that its “examples alone are sufficient under the law to prove inherency.” *Id.* at 799. Amneal also argued that “the lack of evidence of degradants or oxidation of dexmedetomidine formulations stored in sealed glass containers at room temperature further support the inherency of the claimed stability.” *Id.*

The district court held that Amneal had not proven inherency. It held that “Plaintiff’s internal testing documents related to the development of Plaintiff’s Precedex premix products”—even “unrebutted”—could not show inherency absent additional scientific evidence. *Id.* at 800. “The lack of evidence” of degradation “increase[d] the weight of Defendant’s affirmative examples,” but was not “affirmative evidence” sufficient to establish inherency. *Id.*

On appeal, Amneal challenged the district court’s inherency finding, but this Court affirmed in a Rule 36 judgment. *Hospira, Inc. v. Amneal Pharm., LLC*, 748 F. App’x 1024 (Fed. Cir. 2019).

### ***C. Fresenius Kabi***

Hospira also sued Fresenius Kabi for infringing claim 6 of the ‘106 patent, and Fresenius Kabi counterclaimed, alleging the claim was invalid. *See Hospira, Inc. v. Fresenius Kabi USA, LLC*, 343 F. Supp. 3d 823 (N.D. Ill. 2018), *aff’d*, 946 F. 3d 1322 (Fed. Cir. 2020).

As in *Amneal*, the issue that ultimately proved dispositive in the district court’s decision was whether the “about 2% decrease” stability property was inherent in the allegedly obvious combination. As in *Amneal*, Fresenius Kabi’s inherency case focused heavily on Hospira’s internal testing data, *id.* at 832-33—the same data that Amneal relied on.<sup>1</sup> Fresenius Kabi also proffered “expert testimony regarding the chemical properties of dexmedetomidine,” which, in the district court’s view, “support[ed] a conclusion that a POSA would have had a reasonable

---

<sup>1</sup> The *Amneal* district court referred to “two examples” of Hospira’s testing data, 285 F. Supp. 3d at 800, while the *Fresenius* court referred to “18 batch configurations.” App. 7 n.4. These “two examples” and “18 batch configurations” correspond to the same data. The “two examples of stability data” in *Amneal* were (a) data for 20 mL glass vials, and (b) data for 50 mL and 100 mL glass vials. *Amneal*, 285 F. Supp. 3d at 798-800. The “eighteen batch configurations” reflect the same data—the aggregate data from the 20, 50, and 100 mL glass vials. *Fresenius*, 343 F. Supp. 3d at 833.

expectation of success from combining the other limitations disclosed in the prior art.” *Id.* at 851. But Fresenius Kabi did not proffer a quantitative model of the inherent stability properties of dexmedetomidine—because, based on the *non-prior art* examples, its expert found that degradation of the dexmedetomidine in the examples was too slight for a quantitative model to be determined. *Id.* at 849. Nonetheless, the district court found that Fresenius Kabi had proven inherency based on clear and convincing evidence, emphasizing that “all stability data in the record”—even though it was non-prior art data—supported Fresenius Kabi’s inherency argument. *Id.* at 846.

This Court affirmed. The Court first pointed to evidence that all of the non-prior art data in the record—the inventor’s data, Hospira’s commercial product, and Fresenius Kabi’s copies of Hospira’s product—met the requisite stability limitations. App. 12. The Court also pointed to the expert testimony regarding dexmedetomidine’s stability. *Id.*

The Court then rejected Hospira’s argument that Fresenius Kabi had not shown that the property was inherent in the allegedly obvious combination, regardless of the manner of its preparation. It reasoned that Hospira had not provided evidence that the stability property would *not* have been satisfied:

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.

App. 12-13.

## **ARGUMENT**

The Court's decision is incorrect, and this case is sufficiently important to warrant *en banc* review. While couched as a narrow affirmance of the district court's factual findings, the Court's decision actually shifts the legal standard for establishing inherency in a fundamental and misguided way. *En banc* review is warranted to clarify the legal standard for inherency in the obviousness context and ensure that the standard for invalidity is not unfairly skewed in favor of patent challengers.

### **I. The Court's Decision Is Wrong.**

The Court erred in upholding the district court's determination that Fresenius Kabi had proved inherency by clear and convincing evidence. The Court incorrectly relieved Fresenius Kabi of the burden of affirmatively proving that the "2% decrease" property is inherent in the allegedly obvious combination, no matter how it is prepared.

"Inherency[] may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *PAR*, 773 F.3d at 1194-95 (quotation marks omitted). Rather, a party

must “meet a high standard in order to rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis—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. Like any factual finding in an invalidity case, inherency must be proved by clear and convincing evidence. *Id.* at 1196. In this case, Fresenius Kabi bore the burden of proving that the *allegedly obvious combination*—the 4 µg/mL premixed dexmedetomidine solution in a sealed glass container—inherently possessed the “2% decrease” stability property. Thus, under *PAR*, it bore the burden of proving that the allegedly obvious combination *necessarily* meets that stability property—no matter how it is prepared.

Fresenius Kabi’s inherency case largely boiled down to its reliance on non-prior art examples of the allegedly obvious combination. Those examples consisted of Hospira’s own testing work—which, unsurprisingly, embodied the invention—and Fresenius Kabi’s own product—which infringed the patent. Fresenius Kabi also pointed to scientific testimony regarding dexmedetomidine’s stability—but that testimony is subject to two caveats. First, the district court concluded that the scientific testimony supports not a conclusion of *inherency*, but a conclusion that “a POSA would have had a reasonable expectation of success from combining the other limitations disclosed in the prior art,” 343 F. Supp. 3d at 851—a holding this Court said was “unnecessary” and “conflated the standards for inherency and reasonable



expectation of success.” App. 14-15. Second, although Fresenius’s expert testified in *qualitative* terms that dexmedetomidine is a stable molecule, he did not proffer a *quantitative* model showing that the molecule would meet a particular stability threshold at a particular time at a particular concentration, as required by the claim. Instead, he testified—based on his analysis of the *non-prior art examples*—that, dexmedetomidine was too stable to develop such a model. The district court was persuaded by this testimony, 343 F. Supp. 3d at 849, and this Court upheld the district court’s conclusion. App. 13.

Thus, Fresenius Kabi’s inherency case—including its expert’s theory that the molecule was too stable to develop a quantitative model—hinged on data from non-prior art examples. Nonetheless, the district court found that Fresenius Kabi had proven inherency by clear and convincing evidence, and this Court affirmed. This Court emphasized that Hospira had not identified counter-examples: “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.” App. 12. Nor had Hospira offered a scientific theory demonstrating that other manufacturing methods *would not* yield the same stability property: “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.” App. 12-13. In the absence of

such contrary evidence by Hospira, this Court held that Fresenius Kabi's *examples* of embodiments disclosing the "2% decrease" property were sufficient to prove that the allegedly obvious combination *inherently* disclosed that property.

The Court's reasoning inverted the burden of proof. Fresenius Kabi bore the burden of proving that the allegedly obvious combination, no matter how it was prepared, *inherently* disclosed the "2% decrease" property. Thus, it was not Hospira's burden to prove that other manufacturing processes would have yielded a *less* stable product. Rather, it was Fresenius Kabi's burden to prove the opposite: that other manufacturing processes *would not* have yielded a less stable product, because the product *necessarily* discloses the "2% decrease" property no matter how it is prepared. There are many ways Fresenius Kabi might have proved that. It might have presented evidence about the different ways a skilled artisan might have prepared the allegedly obvious combination, and shown that the stability property would not change. It could have proffered a quantitative model. It could have done its own testing. But Fresenius Kabi cannot meet its burden of proving inherency merely by relying on non-prior art examples and the absence of counter-examples.

The *Amneal* district court got the analysis right. In *Amneal*, as here, the patent challenger provided "unrebutted" evidence from "internal testing documents related to the development of Plaintiff's Precedex premix products," and also relied on the "lack of evidence" of degradation. 285 F. Supp. 3d at 800. As the district court

correctly held, however, more is required to prove inherency. A patent challenger must present “affirmative evidence” that a property is inherent in a combination, no matter how it is prepared. Neither *Amneal* nor *Fresenius Kabi* did so.

## **II. *En banc* Review Is Warranted.**

This case warrants *en banc* review for three reasons. First, the question of how to apply inherency in the obviousness context is fundamentally important and has never been explored by the *en banc* court. Second, the Court’s resolution of that question, although couched as a mere affirmance of factual findings on clear-error review, in fact will alter the burden of proof in a broad swath of cases. Third, the Court’s decision will skew obviousness analysis by weakening the legal standard for proving inherency.

1. The question in this case is important. The inherency doctrine is powerful because it allows patent challengers to prove obviousness even when a claim limitation is not expressly disclosed in the prior art. But the *en banc* court has yet to explore how inherency and obviousness fit together. In the context of anticipation, it is straightforward to apply inherency law—a court must assess whether a property is necessarily present in a particular prior art disclosure. In the context of obviousness, the question is more subtle. A court must determine whether a property is inherent in a *hypothetical* construct that a skilled artisan would have made. Because a skilled artisan could prepare that hypothetical construct in many

ways, a plaintiff must show that the property is present regardless of the skilled artisan's method of preparation. How a patent challenger goes about proving that proposition is an important question of patent law that the *en banc* court has never considered.

2. The Court upheld the district court's burden-shifting approach—once the patent challenger proffered examples of the property being present, the burden shifted to the patentee to explain why those examples did not cover the waterfront of all ways of preparing the allegedly obvious combination. That holding cannot be confined to the facts of this case—it could applied in *any* obviousness case involving inherency. The Court relied on (1) the inventor's own work, and (2) Fresenius Kabi's infringing product, as evidence that *some* embodiments disclose the “2% decrease” limitation. But such non-prior art examples will exist in *every case* in which there is infringement and obviousness analysis turns on whether a property is inherent in an allegedly obvious combination. There will *always* be non-prior art work by the inventor disclosing all limitations in the claim-in-suit—otherwise, the inventor could not have gotten the patent in the first place. And there will *always* be post-patent embodiments by the defendant disclosing all limitations in the claim-in-suit—otherwise, there is no infringement and the question of inherency is irrelevant. In every case, therefore, the Court's burden-shifting approach to inherency will apply. The patent challenger need only point to the inventor's own

non-prior art products, and its own infringing products, to show that a particular property is *in some cases* present in an allegedly obvious combination of structural limitations. And under the Court's reasoning, that will be enough to prove that the property is *necessarily* present in that allegedly obvious combination unless the patentee can come forward with contrary evidence.

Of course, the Court applied a deferential standard of review—and as its *Amneal* affirmance makes clear, a contrary conclusion would also be upheld under a deferential standard of review. But that makes the case for *en banc* review stronger, not weaker. Under current law, a district court gets to choose whether to apply a burden-shifting approach (as the *Fresenius Kabi* court did) or to require the patent challenger to provide affirmative evidence that the property is inherent regardless of how the combination is prepared (as the *Amneal* court did). Thus, district courts will have the authority to decide how the burden of proof is allocated—a classic legal question—and their judgments will be upheld no matter what they do. *En banc* review is warranted to adopt a unitary approach for inherency analysis in the obviousness context.

3. The Court's decision will unfairly skew invalidity analysis in favor of patent challengers. Inherency is a powerful doctrine: it allows a patent challenger to establish that a claim limitation was present in the prior art, even if no one was aware of it. *See, e.g., Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A. de C.V.*, 865

F.3d 1348, 1355 (Fed. Cir. 2017) (“We have previously stated that the use of inherency in the context of obviousness must be carefully circumscribed because that which may be inherent is not necessarily known and that which is unknown cannot be obvious” (internal quotation marks omitted)). To guard against overuse of the inherency doctrine in the obviousness context, the Court has made clear that inherency should be hard to prove: “Inherency[] may not be established by probabilities or possibilities.” *PAR*, 773 F.3d at 1195 (quotation marks omitted).

By upholding the district court’s burden-shifting approach, the Court weakened the requirement that a patent challenger prove that a property is *necessarily* present, and instead effectively allowed inherency to be shown with evidence that it was reasonably probable that the limitation was present. Armed with that weakened burden of proof, patent challengers will be able to use the inherency doctrine to prove obviousness even in cases where they cannot show that a skilled artisan would have had a reasonable expectation of success. That holding will unfairly skew the patent playing field in favor of patent challengers.

### **CONCLUSION**

The petition for rehearing en banc should be granted.

Respectfully submitted,

Dated: February 10, 2020

/s/ Sara T. Horton

Sara T. Horton  
Aaron A. Barlow  
Yusuf Esat  
Ren-How H. Harn  
JENNER & BLOCK LLP  
353 N. Clark Street  
Chicago, IL 60654-3456  
Telephone: (312) 222-9350  
Facsimile: (312) 527-0484  
shorton@jenner.com  
abarlow@jenner.com  
yesat@jenner.com  
rharn@jenner.com

Adam G. Unikowsky  
JENNER & BLOCK LLP  
1099 New York Ave. NW, Suite 900  
Washington, DC 20001  
Telephone: (202) 639-6000  
Facsimile: (202) 639-6066  
aunikowsky@jenner.com

*Attorneys for Plaintiff-Appellant  
Hospira, Inc.*

APPENDIX



**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.<sup>1</sup> 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 Farnos Yhtyma Oy (“Farnos”) in the 1980s. Farnos was issued U.S. Patent 4,910,214, which disclosed the dexmedetomidine compound and its use as a sedative.

---

<sup>1</sup> 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, Farnos submitted an Investigational New Drug application (“the Farnos IND”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to begin safety testing dexmedetomidine formulations in humans. Farnos 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, Farnos’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 pre-mixture.” ’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  $\mu\text{g}/\text{mL}$ .

*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  $\mu\text{g}/\text{mL}$  dexmedetomidine HCl,” which the court referred to as the “4  $\mu\text{g}/\text{mL}$  preferred embodiment.”<sup>2</sup> The court found that the 4  $\mu\text{g}/\text{mL}$  preferred embodiment was expressly taught by the prior art, and the

---

<sup>2</sup> For consistency, we will similarly refer to this embodiment as the “4  $\mu\text{g}/\text{mL}$  preferred embodiment” herein.

only dispute between the parties concerned the “about 2%” limitation in claim 6.<sup>3</sup> *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,<sup>4</sup> 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

---

<sup>3</sup> 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.”

<sup>4</sup> 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 factfinder'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  $\mu\text{g}/\text{mL}$  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  $\mu\text{g}/\text{mL}$ , which was known to be stable, to 4  $\mu\text{g}/\text{mL}$ —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.



HOSPIRA, INC. v. FRESENIUS KABI USA, LLC

17

CONCLUSION

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

**AFFIRMED**

## CERTIFICATE OF COMPLIANCE

Counsel for Plaintiff-Appellant Hospira, Inc. certifies the following:

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 35(b)(2)(A). The brief contains 3783 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(c)(2).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2013 in 14-point New Times Roman font.

Respectfully submitted,

Date: February 10, 2020

By: /s/ Sara T. Horton

**CERTIFICATE OF SERVICE**

I hereby certify that on February 10, 2020, I caused the foregoing Petition for Rehearing En Banc to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system, which caused a copy of the foregoing to be delivered by electronic means to counsel of record.

Respectfully submitted,

Date: February 10, 2020

By: /s/ Sara T. Horton