Nos. 2020-2334, -2335, -2337, -2338, -2339, -2340

In the United States Court of Appeals
For the Federal Circuit

CORNELL RESEARCH FOUNDATION, INC.,
Appellant

v.

KATHERINE K. VIDAL, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

Appeals from the United States Patent and Trademark Office Patent Trial and Appeal Board, Inter Partes Review Nos. IPR2019-00577, IPR2019-00578, IPR2019-00579, IPR2019-00580, IPR2019-00581, and IPR2019-00582

CORRECTED COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 20-2334-KH

Short Case Caption Cornell Research Foundation v. Vidal

Filing Party/Entity Cornell Research Foundation

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 7/8/2022

Signature: /s/ Ajit J. Vaidya

Name: Ajit J. Vaidya

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☐ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☑ None/Not Applicable
Cornell Research Foundation, Inc.	Huvepharma EOOD	
	Huvepharma, Inc.	

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☒ None/Not Applicable ☐ Additional pages attached

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☐ None/Not Applicable ☐ Additional pages attached

Huvepharma EOOD, et. al. v. E.I DuPont De Nemours and Co., et. al., C.A. No. 1:18-cv-914-RGA (D. Del. 2018)	Huvepharma EOOD, et. al. v. BASF Corp., et. al., C.A. No. 1:20-cv-00513-RGA (D. Del. 2020)	Huvepharma EOOD, et. al. v.KONINKLIJKE DSM N.V., et. al., C.A. No. 1-20-cv-00514-RGA (D. Del. 2020)

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

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STATEMENT OF COUNSEL UNDER FED. CIR. R. 35(B)

This Petition is limited to reconsideration of the Court's holding regarding the 8,993,300 ("the '300 patent") patent's dependent claims 10-12 and 21-23, which were subject to IPR2019-00577.

Based on my professional judgment, I believe the Panel's decision is contrary to the following precedents of this court: *PAR Pharm., Inc. v. TWI Pharm., Inc*., 773 F.3d 1186, 1195-96 (Fed. Cir. 2014); *Millennium Pharm., Inc. v. Sandoz Inc*., 862 F.3d 1356, 1367 (Fed. Cir. 2017); *Continental Can Co. v. Monsanto Co*., 948 F.2d 1264, 1269 (Fed. Cir. 1991); *Hospira, Inc. v. Fresenius Kabi USA, LLC, 946 F.3d 1322 (Fed. Cir. 2020)*.

Based on my professional judgment, I believe this appeal requires an answer to one or more precedent-setting questions of exceptional importance:

1. Does absence of inherency data in the prior art and only general conclusory expert opinion qualify to meet the "high standard" required for obviousness based inherency of claim limitations that require specific data of temperature and time constraints, when there is evidence in the prior art of unpredictability of the alleged inherency?

2. Can inventor's data of unexpected results in the patent specification be used as evidence of *prior art* obviousness based inherency of claims that require specific data of temperature and time constraints?

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POINTS OF FACT OR LAW OVERLOOKED OR MISAPPREHENDED BY THE COURT

The Panel misapprehended the doctrine of inherency and this Court's precedent in *PAR Pharm*, *Millennium Pharm, Continental Can, and Hospira,* in holding that silence in the prior art of inherency data is satisfactory to find inherency of claims requiring specific time and temperature constraints, when the prior art did state that there can be significant variations in conditions and results. Op. 9

In the absence of actual prior art data and inherency evidence, the Panel cited to *inventor's data* of unexpected results in the patent specification as satisfactory evidence of *prior art* obviousness based inherency of the claims. Op. 9.

These holdings were clear error under *Par Pharm*, *Millenium Pharm, Continental Can, and Hospira*.

INTRODUCTION

"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 Pharm*., 773 F.3d at 1196. Until May, 2022 this Court's own jurisprudence has consistently held that the prior art must show a claim limitation was *necessarily present in the prior art* to invoke the doctrine of inherency. The reasoning is plain – a district court, or the Board, could simply ignore claim limitations at issue and hold that any claim could be inherent without having evidence of the inherency data in the prior art and relying merely upon an opposing expert's conclusory opinion. The Panel and the Board jettisoned foundation jurisprudence of this doctrine and held just that – no evidentiary data of inherency is required to hold a claim invalid that requires specific data results, and claim limitations that are *not necessarily present* in the prior art can be invalid for inherency.

This opinion is fundamental legal error and conflicts with the Court's doctrine of inherency, which, without en banc review, would be condoned by this Court.

BACKGROUND

I. THE CLAIMS ISSUED DUE TO THE UNEXPECTED RESULTS EMBODIED IN THE LIMITATIONS OF DEPENDENT CLAIMS 10-12 AND 21-23

At the time of the invention, Dr. Lei's successful phytase expression was unexpected because bacterial phytases, such as E. coli, were thought to have an unpredictable impact on an enzyme's activity. Appx4043-4044, ¶212. Likewise, using a fungal host was known to result in unpredictable heterologous expression. Appx4035, ¶199. And introducing heat into the equation further complicated the search for a commercially acceptable phytase and host combination, as "heat can affect certain factors that contribute to a protein's stability. . . . [W]hat stabilizes one protein may not be predictive of what would stabilize another unrelated protein." Appx3929, ¶33; see generally Appx3951-3952 (describing further unpredictability in the art); Appx8268 (Petitioner ABF's expert Dr. Robertson describing the E. coli phytases as unpredictable when subjected to heat).

Dr. Lei also found that his genetically engineered fungal cells expressing heterologous E. coli phytases experienced dramatically better thermostability, making them suitable for use with commercial feeds. Appx4145, ¶382. And Dr. Lei's genetically engineered fungal cells expressing E. coli phytases demonstrated additional unexpected results: they worked effectively over a broad pH range and expressed much faster than other phytases previously used in releasing phosphate from phytate. Appx967-968, 6:66-7:11; see also Appx978, 28:25-26 ("Compared with [the prior art], the phytase expression system in Pichia is a very efficient expression system.").

Dependent claims 10-12 and 21-23 of the '300 Patent are directed to—in a specific and particularized manner—the unexpected results of superior thermostability. Claims 10-12 are reproduced below:

> 10. The method of claim 1 wherein the *Escherichia coli* phytase has an optimum activity at a temperature range of 57 degrees C. to 65 degrees C.
>
> 11. The method of claim 1 wherein the *Escherichia coli* phytase retains at least 40% of its activity after heating the phytase for 15 minutes at 80 degrees C.
>
> 12. The method of claim 1 wherein the *Escherichia coli* phytase retains at least 60% of its activity after heating the phytase for 15 minutes at 60 degrees C.

The Board issued the six final written decisions on July 23, 2020, holding all challenged claims unpatentable in view of the prior art, alone or in combination. Appx1-900. All of the prior art references the Board relied upon except one, Romanos, were considered by the examiner during prosecution. Appx9. In allowing the claims, the examiner afforded weight to the unexpected results of improved thermostability, a factor that did not persuade the Board. Appx9, Appx11716.

II. THE PANEL'S DECISION

The Panel, in affirming the Board's decision regarding claims 10-12 and 21-23 held that although Cornell faulted the Board for citing no data to support its

inherency findings, but the data in the specification of the ’300 patent could be used to find prior art obviousness inherency since the specification data is consistent with the language of the claims. Op. at 9.

The Panel also affirmed the Board’s decision regarding inherency finding for the Dassa/Greiner prior art combinations, quoting Cornell’s expert testimony that the same enzyme is needed for the thermostability characteristics of an enzyme produced by a particular enzyme-host combination to be inherent. Op. at 9.

The Board, and the Panel’s, decisions missed the point of Cornell’s expert opinion and the determination by the examiners of patentability – that no *E. Coli* AppA enzyme had been expressed before in a fungal host, and the expressions in fungal and yeast hosts were agreed by both experts to be unpredictable. The inventor claimed unexpected results of thermostability for being the first person to express the *E. Coli AppA* in a fungal host, and multiple examiners over a 17 year time period of prosecution of six patents agreed. Dr. Lei was the only source of thermostability data for such a combination, which was unfairly, and without precedent, used against his patent claims by the Board and the Panel.

ARGUMENT

Silence in the prior art of inherency data of thermostability cannot equate to evidence of inherency limitations in the claims. The Board erred in cancelling, and the Panel erred in affirming, the dependent claims that relate to superior thermostability (i.e., claims 10-12 and 21-23 of the '300 Patent). Substantial evidence does not support a finding that the thermostability limitations are inherent results that necessarily flow from combining the prior art.

"When the prior art does not expressly disclose a claim limitation, inherency may supply a missing claim limitation in an obviousness analysis." *Hospira*, 946 F.3d at 1329. However, "[i]nherency 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. (emphasis added). "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." *Continental Can*, 948 F.2d at 1269.

Dependent claims 10-12 and 21-23 of the '300 Patent require specific temperature ranges and characteristics. See Appx982 (claims 10 and 21 require that "the Escherichia coli phytase has an optimum activity at a temperature range of 57 degrees C. to 65 degrees C"; claims 11 and 22 require that "the Escherichia coli phytase retains at least 40% of its activity after heating the phytase for 15 minutes at

80 degrees C"; claims 12 and 23 require that "the Escherichia coli phytase retains at least 60% of its activity after heating the phytase for 15 minutes at 60 degrees C.").

The Board correctly acknowledged when analyzing Kretz as an anticipatory reference that there is "no data in the record establishing that the claimed thermostability properties will necessarily be the same as the properties recited in claims 10-12 and 21-23 of the '300 Patent." Appx56 (emphasis in original). In view of this failure of proof, the Board and the Panel declined to cancel the claims due to anticipation by Kretz. Appx58 ("Thus, although it is possible that Kretz's E. coli B sequence and Dr. Lei's appA sequence have the same or very similar thermostability characteristics, again, such speculation is not sufficient to meet the inherent anticipation standard. *See Continental Can Co*., 948 F.2d at 1269.").

However, the Board, which the Panel adopted, nonetheless found claims 10-12 and 21-23 of the '300 Patent to be inherently disclosed in view of the asserted prior art obviousness combinations—including combinations with Kretz. See Appx78-79, Appx130, Appx140-141. This contradictory finding was erroneous. There is no data or other record evidence sufficient to meet this Court's strict inherency standard. The Panel adopted the Board's decision stating,

> The Board explained that it did not find the thermostability limitations inherent under Kretz because ABF was relying on Kretz's teachings using the E. coli B phytase whereas the thermostability data from the '300 patent resulted from using the E. coli appA phytase. Final Written Decision, at 58. Op. 9.

But the Board, and the Panel, misapprehended the claim scope and the inherency doctrine. The claims, copied above, state an "Escherichia coli phytase" produced using the claimed method has the limitations of the temperature and time before degradation. There is no difference between Kretz's E. coli B enzyme or the Greiner/Dassa enzyme for this matter – none of references expressed an *E. coli* enzyme in a fungal host and no reference provided any data that could be used for inherency doctrine cancellation of the above claims. The Board's and the Panel's conclusions were based merely on speculation, not inherency. Silence in, and speculation of, the prior art is the very antitheses of the inherency doctrine, and Panel's holding should be reversed.

In *Hospira*, this Court affirmed a district court's finding of inherency in the obviousness context, it did so after praising the district court's "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." 946 F.3d at 1331. Such data, evidence, and analysis is noticeably absent here. Instead, the Board relied on a page of Dr. Benedik's testimony, but Dr. Benedik merely testified that the claimed invention works. See Appx7694-7695 (Dr. Benedik's testimony); see also Appx78-79, Appx92-93 (Board's opinion). The Board also relied on a paragraph from Dr. Robertson's declaration, but Dr. Robertson just cited the aforementioned

testimony from Dr. Benedik without further analysis. Appx5820, ¶59 (citing Appx7694-7695, Appx9212).

The Board and Panel cited to statements from the specification that, again, merely provide the requisite evidence the invention works. Appx78-79; Op. 9. This alone is not sufficient evidence of inherency. *See Millennium Pharm*., 862 F.3d at 1367 (in the section of the opinion discussing inherency, stating "making weight of the method [patentee] used in finding the invention is beside the point.") (citation omitted).

To the extent the Board relied on this evidence to find inherent obviousness, the Board's decision is internally inconsistent. And in any event, under this Court's inherency jurisprudence, similarities are not enough. *See, e.g., Continental Can Co*., 948 F.2d at 1269.

The Board's findings that the limitations of dependent claims 10-12 and 21-23 of the '300 Patent would have been inherent in the prior art combinations are erroneous. There is insufficient record evidence—indeed, no data—to show that these very specific numerical limitations of these claims necessarily must be present or are the natural result of the combination of elements allegedly disclosed by the prior art. The Panel's cancellation of the thermostability dependent claims must be reversed.

The Board, and now the Panel, fails to demonstrate the "high standard" required for obviousness by inherency is met. *See PAR Pharm.,* 773 F.3d at 1195-96. Like the Board, the Director cites to **no data** supporting an assertion that the properties naturally flow from the combination, only conclusory expert testimony. That is legally insufficient to prove obviousness-based inherency. *Cf. Hospira, Inc.* 946 F.3d at 1331 (praising the district court's "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"). Unpredictability of glycosylation also undermines the Board's obviousness-based inherency finding. *See Honeywell Int'l Inc. v. Mexichem Amanco Holding* S.A. DE C.V., 865 F.3d 1348, 1354 (Fed. Cir. 2017) ("[T]he Board erred in relying on inherency to dismiss evidence showing unpredictability in the art[.]").

The Panel also makes the same mistake as the Board, relying on statements from the specification that prove the invention works as alleged evidence of inherency. *Millennium Pharm., Inc.* 862 F.3d at 1367 (in the section of the opinion discussing inherency, stating "making weight of the method [patentee] used in finding the invention is beside the point.").

Finally, the Panel has no explanation of how the Board could find no inherency in an anticipation analysis when considering Kretz but inherency in its obviousness analyses, which is a stricter standard. *Compare* Appx58 (no inherent

anticipation) *with* Appx87 (inherent obviousness). The Panel merely guessed that the enzymes used in the prior art were different, but as stated above the enzymes are the same under the claim scope. The lack of data for the Kretz enzyme is the same lack of data for the Greiner/Dassa enzyme.

PAR Pharmaceuticals teaches that "the use of inherency, a doctrine originally rooted in anticipation, must be carefully circumscribed in the context of obviousness. . . . [a] party must, therefore, 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." 773 F.3d at 1195-96. The Board found the lower standard of anticipation-based inherency in view of Kretz was not met, but the "high standard" of inherency in an obviousness analysis was. The Board's Kretz finding is inconsistent and demonstrates error in its inherent obviousness analysis.

The Panel erred in finding the thermostability claims of the '300 Patent obvious due to inherency.

CONCLUSION

Rehearing or en banc review should be granted.

Dated: July 8, 2022

Respectfully submitted,

/s/ Ajit Vaidya

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2020-2334, -2335, -2337, -2338, -2339, -2340

Short Case Caption: *Cornell Research Foundation v. Vidal*

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it meets one of the following:

- ☑ the filing has been prepared using a proportionally-spaced typeface and includes 2532 words.
- ☐ the filing has been prepared using a monospaced typeface and includes _____ lines of text.
- ☐ the filing contains _____ pages / _____ words / _____ lines of text, which does not exceed the maximum authorized by this court's order (ECF No. _____).

Dated: 07/08/2022

Respectfully submitted,

/s/ Ajit Vaidya
Ajit Vaidya

Counsel for Appellant
Cornell Research Foundation, Inc.

ADDENDUM

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

CORNELL RESEARCH FOUNDATION, INC.,
Appellant

v.

KATHERINE K. VIDAL, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2020-2334, 2020-2335, 2020-2337, 2020-2338, 2020-2339, 2020-2340

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2019-00577, IPR2019-00578, IPR2019-00579, IPR2019-00580, IPR2019-00581, IPR2019-00582.

Decided: May 24, 2022

JULIE S. GOLDEMBERG, Morgan, Lewis & Bockius LLP, Philadelphia, PA, argued for appellant. Also represented by ROBERT CHRISTIAN BERTIN, ROBERT JOHN SMYTH, Washington, DC; AJIT VAIDYA, Kenealy Vaidya LLP, Washington, DC.

MAUREEN DONOVAN QUELER, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor. Also represented by MICHAEL S. FORMAN, THOMAS W. KRAUSE, AMY J. NELSON, FARHEENA YASMEEN RASHEED.

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

PROST, *Circuit Judge*.

Cornell Research Foundation, Inc. ("Cornell") appeals from six inter partes reviews ("IPR"), each regarding a different Cornell patent, in which the Patent Trial and Appeal Board ("Board") concluded that the challenged claims were unpatentable as anticipated or obvious. *E.g.*, *Associated British Foods PLC v. Cornell Rsch. Found., Inc.*, No. IPR2019-00577, Paper 117 (P.T.A.B. July 23, 2020) ("*Final Written Decision*"). Because substantial evidence supports the Board's determinations that the claims were obvious, we affirm.

BACKGROUND

I

The patents at issue relate to phytases in livestock feed. Phytases are enzymes that help certain animals absorb phosphate, an important nutrient. Skilled artisans can produce phytase enzymes by taking a phytase gene from one organism and incorporating it into a host; the host then replicates and expresses the phytase protein, which can then be added to the feed.

U.S. Patent No. 8,993,300 ("the '300 patent"), representative in this appeal, describes a heterologous method of producing phytase: it uses a phytase gene derived from *Escherichia coli*, a species of bacteria, and a fungal host. There are different strains of *E. coli*, and different strains express different phytases. Two are relevant here: *E. coli*

appA phytase and *E. coli* B phytase. There are also a variety of fungal species. As is relevant here, the fungal kingdom includes yeast, of which *Saccharomyces cerevisiae* and *Pichia pastoris* are species.

Independent claim 1 and dependent claims 10–12 of the '300 patent are representative for the purposes of this consolidated appeal. They recite:

> 1. A method of producing a phytase in fungal cells, the method comprising:
>
> providing a polynucleotide encoding an *Escherichia coli* phytase;
>
> expressing the polynucleotide in the fungal cells; and
>
> isolating the expressed *Escherichia coli* phytase wherein the *Escherichia coli* phytase catalyzes the release of phosphate from phytate.
>
> 10. The method of claim 1 wherein the *Escherichia coli* phytase has an optimum activity at a temperature range of 57 degrees C. to 65 degrees C.
>
> 11. The method of claim 1 wherein the *Escherichia coli* phytase retains at least 40% of its activity after heating the phytase for 15 minutes at 80 degrees C.
>
> 12. The method of claim 1 wherein the *Escherichia coli* phytase retains at least 60% of its activity after heating the phytase for 15 minutes at 60 degrees C.

Dependent claims 10–12 add so-called "thermostability limitations" to the phytases produced by the heterologous method described in independent claim 1.

II

We recount only the relevant procedural history below. Associated British Foods PLC ("ABF") filed six IPR petitions, each challenging a different Cornell patent. The Board instituted review for all six and found all challenged claims unpatentable.

ABF asserted two varieties of prior-art combinations in its petitions—those involving Kretz[1] and those not involving Kretz. The Kretz-based challenges apply only to the '300 patent. But the parties agree that all six Board decisions "stand and fall" with the Board's non-Kretz obviousness analysis for the '300 patent. Reply Br. 26–27. We accordingly focus our discussion on the Board's Final Written Decision for the '300 patent.

Beginning with the non-Kretz grounds, ABF asserted that all challenged claims of the '300 patent would have been obvious over two combinations: (1) Dassa,[2] Greiner,[3] and Cheng[4] and (2) Dassa, Greiner, Romanos,[5] and Van Gorcom[6] (collectively, "the Dassa/Greiner

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[1] U.S. Patent No. 5,876,997 ("Kretz").

[2] Janie Dassa, Christian Marck, & Paul L. Boquet, *The Complete Nucleotide Sequence of the* Escherichia coli *Gene* appA *Reveals Significant Homology Between pH 2.5 Acid Phosphatase and Glucose-1-Phosphatase*, 172 J. BACTERIOLOGY 5497 (1990) ("Dassa").

[3] R. Greiner, U. Konietzny, & Kl.-D. Jany, *Purification and Characterization of Two Phytases from* Escherichia coli, 303 ARCHIVES BIOCHEMISTRY & BIOPHYSICS 107 (1993) ("Greiner").

[4] U.S. Patent No. 5,985,605 ("Cheng").

[5] Michael A. Romanos, Carol A. Scorer, & Jeffrey J. Clare, *Foreign Gene Expression in Yeast: A Review*, 8 YEAST 423 (1992) ("Romanos").

[6] U.S. Patent No. 5,436,156 ("Van Gorcom").

combinations"). ABF argued that the thermostability claims of the '300 patent would have been obvious for two independent reasons: (1) they were inherent properties of the Dassa/Greiner combinations, and (2) they were disclosed by Olsen.[7] In its Final Written Decision, the Board concluded that there was a motivation to combine and reasonable expectation of success for the Dassa/Greiner combinations and that the thermostability dependent claims of the '300 patent were obvious due to inherency. *See Final Written Decision*, at 127–31, 141, 172–73.

For the Kretz-based invalidity arguments, ABF asserted that Kretz (1) anticipated certain challenged claims of the '300 patent as § 102(e) prior art[8] and (2) rendered all challenged claims obvious in combination with other references. *See id.* at 10–11. The Board determined that Cornell failed to antedate Kretz, *id.* at 34, and that Kretz anticipated certain claims and rendered obvious the rest in light of those other references, *see id.* at 172–73.

Cornell appeals from all six final written decisions in this consolidated appeal. The Patent and Trademark Office Director intervened to defend the Board's decisions after ABF filed a notice of non-participation. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

Cornell asserts primarily that three Board conclusions lack substantial evidence: (1) that there was a motivation to combine and reasonable expectation of success for the Dassa/Greiner combinations; (2) that the thermostability properties of the phytases produced by the claimed heterologous method are inherent; and (3) that Cornell failed to

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[7] Ole Olsen & Karl Kristian Thomsen, *Improvement of Bacterial* ß*-Glucanase Thermostability by Glycosylation*, 137 J. GEN. MICROBIOLOGY 579 (1991) ("Olsen").

[8] 35 U.S.C. § 102(e) (2010).

antedate Kretz. We affirm the Board on the first two issues and accordingly do not reach the third.

I

Putting aside the thermostability limitations of the '300 patent's dependent claims (discussed below), Cornell does not dispute that the Dassa/Greiner combinations disclose all limitations of the relevant claims. Cornell disputes only the Board's findings of motivation to combine and reasonable expectation of success for an *E. coli* phytase with a fungal host. Those are both fact questions that we review for substantial evidence, which is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012); *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014).

In finding a motivation to combine, the Board credited ABF's expert testimony that *P. pastoris* yeast was known to "produce high yields of heterologous protein [e.g., bacterial protein] and, thus, reduce industrial costs—an important factor in producing phytases for livestock feed" on an industrial level. *Final Written Decision*, at 128. The Board found this to be "persuasive evidence setting forth reasons why [a] skilled artisan would have been motivated to express an *E. coli* appA [enzyme] in a fungal cell." *Id.* This constitutes substantial evidence for a motivation to combine. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007) ("[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.").

Cornell's two main arguments to the contrary are unpersuasive. First, Cornell asserts that the Board's motivation-to-combine conclusion is contrary to ABF's expert

testimony that the Wodzinski reference[9] taught away from using a bacterial phytase in animal feed. We note that Wodzinski is not a part of the Dassa/Greiner combinations; additionally, the Board did not make any determination as to whether Wodzinski does or does not teach away. *Final Written Decision*, at 84. And even if the Board concluded that Wodzinski's suggestions about bacterial phytases in animal feed, generally, were outweighed by the rest of the record evidence about producing *E. coli* appA phytase via a fungal host for use in animal feed, specifically, we would see no error. *See In re Young*, 927 F.2d 588, 591 (Fed. Cir. 1991).

Second, Cornell contends that the art suggested that pairing a bacterial phytase with a bacterial host was more advantageous than pairing such a phytase with a fungal host. Even if that's true, as the Board correctly noted, "the law 'does not require that the motivation be the best option, only that it be a suitable option.'" *Final Written Decision*, at 81–82 (emphasis omitted in original) (quoting *PAR Pharm.*, 773 F.3d at 1197–98).

Cornell's challenge to the substantial evidence of the Board's reasonable-expectation-of-success finding is similarly flawed. Cornell asserts a skilled artisan would have "had no reason to expect 'that expressing the *E. coli* phytase in a fungal host would have produced an active enzyme'" due to increased glycosylation, as its expert testified. Appellant's Br. 33 (quoting J.A. 4084–89). Cornell's expert provided two examples of unsuccessful heterologous systems "where one of ordinary skill . . . may have attributed the lack of enzyme activity to glycosylation." *Final Written Decision*, at 90. But the Board was free to weigh ABF's expert testimony more heavily, and that's what it did. The Board credited ABF's expert testimony providing "nine or ten" contrary examples of systems that

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[9] *See* J.A. 22462–63; *see also* J.A. 15187–89.

produced active bacterial enzymes in yeast hosts. *Id.* at 90–91. In addition, the Board pointed to Cornell's expert testimony that, "in the majority of cases[,] glycosylation did not have an effect on the activity of the enzyme." *Id.* at 91–92.

We accordingly affirm the Board's determination that there was a motivation to combine and reasonable expectation of success for the Dassa/Greiner combinations.[10]

II

Cornell also challenges the Board's finding that the thermostability limitations in the '300 patent's dependent claims are inherent results of the Dassa/Greiner combinations. Whether prior art inherently discloses a claim limitation is a question of fact that we review for substantial evidence. *PAR Pharm.*, 773 F.3d at 1194.

The Board found the thermostability limitations inherent to a heterologous system expressing the Dassa/Greiner *E. coli* appA phytase in a fungal host disclosed by Cheng, Romanos, or Van Gorcom, including *P. pastoris* and *S. cerevisiae*. The Board cited Cornell's expert testimony, ABF's expert testimony, the '300 patent, and prosecution history as support. *Final Written Decision*, at 78–79. Indeed, the Board credited Cornell's expert, who confirmed that "express[ing] the *same enzyme* in the *same host* under the *same conditions*" produces "inherent results," like thermostability characteristics. J.A. 7694–95 (emphasis added); *Final Written Decision*, at 78 (citing J.A. 7695). This constitutes substantial evidence supporting the Board's determination.

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[10] We are not persuaded by Cornell's contention that the Board's analysis of the non-Kretz combinations is infected by analysis of Kretz.

Cornell's two arguments to the contrary are not persuasive. First, Cornell faults the Board for citing no data outside of the '300 patent to support its inherency finding. But the Board permissibly cited the '300 patent's disclosure that an *E. coli* appA phytase expressed in a *P. pastoris* host has optimum activity at 60 degrees Celsius as well as the patent's teaching that an *E. coli* appA phytase expressed in a *S. cerevisiae* host retained 69 percent of its activity after heating it for 15 minutes at 80 degrees Celsius. *Final Written Decision*, at 78–79; *see Hospira, Inc. v. Fresenius Kabi USA, LLC*, 946 F.3d 1322, 1329–30 (Fed. Cir. 2020). That data is consistent with the thermostability limitations of claims 10–12. Although it may be possible that the conditions of the Dassa/Greiner combinations were not the same as those described in the '300 patent, Cornell did not make that argument and offered no evidence to that effect. Oral Arg. at 26:27–27:10, No. 20-2334, https://oralarguments.cafc.uscourts.gov/default.aspx?fl=20-2334_05032022.mp3.

Second, Cornell asserts that the Board's inherency finding for the Dassa/Greiner combinations is at odds with its finding of no inherency with respect to Kretz as anticipatory art. Cornell argues that this is especially concerning because the standard for inherency under § 103 is higher than that under § 102. In this case, we find no error. The Board explained that it did not find the thermostability limitations inherent under Kretz because ABF was relying on Kretz's teachings using the *E. coli* B phytase whereas the thermostability data from the '300 patent resulted from using the *E. coli* appA phytase. *Final Written Decision*, at 58. This is consistent with the Board's reliance on Cornell's expert testimony that the same enzyme is needed for the thermostability characteristics of an enzyme produced by a particular enzyme-host combination to be inherent.

We thus also affirm the Board's inherency finding as supported by substantial evidence. Since that resolves this

appeal as to all patents and all claims, we do not reach Cornell's other arguments, including those about antedating Kretz.

CONCLUSION

We have considered the parties' remaining arguments but find them unpersuasive. For the foregoing reasons, we affirm the Board's obviousness conclusions.

AFFIRMED

COSTS

Costs to Intervenor.