Appeal Nos. 2023-1603, 2023-1604

United States Court of Appeals for the Federal Circuit

SAGE PRODUCTS, LLC,

Appellant,

– v. –

COKE MORGAN STEWART, Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office,

Intervenor.

On Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2021-01201 and IPR2021-01202

APPELLANT'S PETITION FOR REHEARING *EN BANC*

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May 29, 2025

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2023-1603

Short Case Caption Sage Products, LLC v. Becton, Dickinson and Company

Filing Party/Entity Sage Products, LLC

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
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I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 03/31/2023

Signature: /s/ Sandra A. Frantzen

Name: Sandra A. Frantzen

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
Sage Products, LLC	Stryker Corporation	Stryker Corporation

☐ 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).

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5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☑ Yes (file separate notice; see below) ☐ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

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 FEDERAL CIRCUIT RULE 40

Based on my professional judgment, I believe the panel decision is contrary to the following decisions of the Supreme Court of the United States or the precedents of this Court: *SAS Inst., Inc. v. Iancu*, 584 U.S. 357 (2018); *In re IPR Licensing, Inc.*, 942 F.3d 1363 (Fed. Cir. 2019); *EmeraChem Holdings, LLC v. Volkswagen Grp. of Am., Inc.*, 859 F.3d 1341 (Fed. Cir. 2017); *In re NuVasive, Inc.*, 841 F.3d 966 (Fed. Cir. 2016); and *Nike, Inc. v. Adidas AG*, 955 F.3d 45 (Fed. Cir. 2020). The full Court's consideration is necessary to secure or maintain uniformity of the Court's decisions.

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

1. Does this Court apply a *de novo* or abuse of discretion standard of review for the question of whether the Patent Trial and Appeal Board violated the Administrative Procedure Act ("APA") by basing its judgment on grounds not raised in a petition for *inter partes* review ("IPR")?

Dated: May 29, 2025

/s/ Sandra A. Frantzen
Sandra A. Frantzen

INTRODUCTION

In this appeal from two IPR proceedings, Appellant Sage Products, LLC alleged that the Patent Trial and Appeal Board ("the Board") exceeded its statutory authority and violated the Administrative Procedure Act ("APA") by finding all challenged claims of Appellant's patents unpatentable based on theories not presented by the petitioner in its petitions. *See, e.g.,* Opening Br. 29-31, 17-19, 24-27, 33-34, 36, 40, 53-54, 56-58, 61-63; Reply 2-3, 5, 7-8, 21-23, 27. Citing this Court's precedent, Appellant contended that this was *legal* error subject to *de novo* review. Opening Br. 28-29; Reply 2-3,15.

Appellant's contention—whether a governmental agency (the Board) exceeded its statutory authority and violated the APA—should have been subject to *de novo* review by this Court. It was not. Instead, the precedential Panel Opinion held that "[i]t is for *the Board* to determine what grounds are being articulated in a petition," applying an "abuse of discretion" standard in affirming the Board's off-petition analysis. Panel Op. 14.[1] The standard of review portion of the Panel Opinion stated:

> We review the Board's interpretation of 'what has been put before it' in a petition, and what arguments it presents and does not present, for an abuse of discretion. *See Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th

[1] Unless otherwise noted, all emphases herein have been added and quotations and citations are omitted.

990, 1002-03 (Fed. Cir. 2023); *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1330 (Fed. Cir. 2019).

Id., 7.

However, as the Supreme Court recognized in *SAS Inst. Inc. v. Iancu*, 584 U.S. 357 (2018), the Board is not the arbiter of the scope of its own authority and does not have the statutory authority to deviate from petitioned arguments in an IPR. Specifically, the Court held that the statutes governing IPR do not "contemplate a petition that asks the Director to initiate whatever kind of inter partes review he might choose." *Id.* at 364. Indeed, nothing in the IPR statutes "suggests the Director enjoys a license to depart from the petition and institute a *different* inter partes review of his own design." *Id.* at 365 (original emphasis). Rather, "Congress chose to structure a process in which it's the petitioner, *not the Director*, who gets to define the contours of the proceeding." *Id.* at 364. "[T]he petitioner's petition, *not the Director's discretion*, is supposed to guide the life of the litigation." *Id.* at 366. The Court accepted the argument that the Director "exceeded his statutory authority" and confirmed that it was in *the Court's authority* "to ensure that an [IPR] proceeds in accordance with the law's demands." *Id.* at 371.

Consistent with *SAS*, this Court has repeatedly held that whether the Board violated the APA by relying on new arguments is subject to *de novo* review. *In re IPR Licensing, Inc.*, 942 F.3d 1363, 1369 (Fed. Cir. 2019) ("Whether the Board improperly relied on new arguments is reviewed *de novo*."); *Nike, Inc. v. Adidas AG*,

955 F.3d 45, 50 (Fed. Cir. 2020) (same); *EmeraChem Holdings, LLC v. Volkswagen Grp. of Am., Inc.*, 859 F.3d 1341, 1345 (Fed. Cir. 2017) ("We review the Board's procedures for compliance with the [APA] de novo…."); *In re NuVasive, Inc.*, 841 F.3d 966, 970 (Fed. Cir. 2016) (whether a ground the Board relied on was new is "subject to de novo review"). And this Court has repeatedly found Board error when its judgments relied upon new theories not raised in the IPR petitions. *See, e.g., Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1335-37 (Fed. Cir. 2020) (Board erred in relying on new prior art combination); *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (Board is not "free to adopt arguments on behalf of petitioners that could have been, but were not, raised by the petitioner during an IPR"); *EmeraChem*, 859 F.3d at 1350-52 (Board violated APA by relying on prior art in a different ground); *IPR Licensing*, 942 F.3d at 1369-70 (Board erroneously relied on standards cited in ground three that were not cited in ground one); *M&K Holdings v. Samsung Elecs. Co.*, 985 F.3d 1376, 1385 (Fed. Cir. 2021) (Board "deviated impermissibly" from obviousness theory when finding anticipation).

Patent owners hailed before the Board are entitled—by statute—to understand the scope of the case against them and fairly defend their government-granted property rights. The Board is limited—by statute—to deciding the cases presented in the petitions before it and violates the APA when it goes beyond those petitions.

The correct *de novo* review standard should be applied in this case. The precedential Panel Opinion never purported to review what was in the petitions and instead affirmed the Board's conclusion under the "abuse of discretion" standard. Rehearing *en banc* is warranted to ensure uniformity in this Court's decisions regarding the Board's compliance with the APA when the Board deviates from the petitioned grounds. The Board's judgments should be reversed.

ARGUMENT

I. THE BOARD'S AUTHORITY IS LIMITED BY THE IPR STATUTES AND THE APA

This Court's "review of final written decisions by the Board is rooted in 'basic principles of administrative law,'" which "impose important limits on the Board's authority during" IPR proceedings. *IPR Licensing*, 942 F.3d at 1368; *see also M&K*, 985 F.3d at 1385. Indeed, "[i]n a formal adjudication, like an IPR, the APA imposes particular procedural requirements on the USPTO." *EmeraChem*, 859 F.3d at 1348. Specifically, "IPR proceedings are creations of the America Invents Act (AIA), 35 U.S.C. §311, and must also proceed according to the requirements set out by that statute." *Corephotonics*, 84 F.4th at 1001. Thus, the Board is constrained by the statutes and regulations governing IPRs (e.g., 35 U.S.C. §311(a), 312(a)(3), 314(b), 37 C.F.R. §42.23(b)) and the APA (e.g., 5 U.S.C. §554(b)-(c)).

"35 U.S.C. §314(b) states that '[t]he Director shall determine whether to institute an [IPR]…*pursuant to a petition*.'" *Koninklijke*, 948 F.3d at 1335 (original

ellipses). "[A]s explained by the Supreme Court, §314(b) informs us that the Director 'is given only the choice 'whether' to institute an [IPR]…. Congress told the Director what he must say yes or no to: an [IPR] that proceeds *'[i]n accordance with' or 'in conformance to' the petition*." *Id.*, quoting *SAS*, 584 U.S. at 364-65.

As the Supreme Court held in *SAS*, "[t]he statutory provisions before us deliver unmistakable commands…The statute…makes the petition *the centerpiece* of the proceeding both before and after institution…." 584 U.S. at 369. As discussed above, the Board does not "enjoy[] a license to depart from the petition and institute a *different* [IPR] of his own design." *Id.* at 365 (emphasis original). Rather, "the petitioner's contentions…define the scope of the litigation all the way from institution through to conclusion…." *Id.* at 367. Thus, the Board is not "free to adopt arguments on behalf of petitioners that could have been, but were not, raised by the petitioner during an IPR." *Magnum*, 829 F.3d at 1381. "Instead, the Board must base its decision on arguments that were advanced by a party, and to which the opposing party was given a chance to respond." *Id*.

For these reasons, "[i]t is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify 'with particularity' the 'evidence that supports the grounds for the challenge to each claim.'" *Intelligent Bio-Systems Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016). That is because "[a]ny marked departure from the grounds

identified with particularity in the petition would impose 'unfair surprise' on the patent owner and, consequently, violate both the APA and the IPR statute." *Corephotonics*, 84 F.4th at 1002. Moreover, "[t]he Board must 'timely inform the patent owner of 'the matters of fact and law asserted'' and 'give all interested parties the opportunity to submit and consider facts and arguments,' among other requirements." *M&K*, 985 F.3d at 1383, *quoting EmeraChem*, 859 F.3d at 1348.

II. THE PRIOR PROCEEDINGS AND THE BOARD'S NEW UNPATENTABILITY GROUNDS THAT WERE REVIEWED UNDER THE ABUSE-OF-DISCRETION STANDARD

Appellant owns the two patents-at-issue, which relate to "sterilized" chlorhexidine products used as topical antiseptics to prepare patients before surgery. *See generally* Opening Br. 13-16; Appx208-249.[2] The "sterilized" products themselves comprise "sterilized" components including "sterilized" chlorhexidine gluconate, which is an antiseptic that was once (wrongly) believed to be inherently "sterile" and was known to be difficult to sterilize without compromising efficacy. *Id.*; Opening Br. 6-7.

As explained below, during the course of the IPR proceedings, the Board adopted *Appellant's* claim construction and construed the claim term "sterilized" to

[2] The Final Written Decisions in the two IPR proceedings are substantively similar, and Appellant presently cites to the record in IPR2021-01201.

mean that the "sterilized" product or component "has been subjected to a suitable sterilization process such that sterility can be validated." Appx12.

A. The Petitions

The petitions presented three grounds of unpatentability. The primary reference for all three grounds was a 2010 UK "Public Assessment Report" ("PAR") for one of the petitioner's UK products. Appx6007-6008.

In ***Ground 1***, the petitions alleged anticipation by PAR. Appx6043-6046. Notably, in arguing that the challenged independent claims were anticipated, the petitions *never referenced any "UK regulatory standards,"* but instead presented a claim construction argument contending that the term "sterilized" simply meant being "in a sterile condition." Appx6043-6046; Appx6431-6432; Appx3155-3156. Notably, this construction differed from Appellant's construction (presented to the district court) that "sterilized" required validated sterilization processing. Appx6350-6356; Appx6506-6508; Appx3163. According to Ground 1, PAR anticipated simply because it used the word "sterile," which was all that the petition contended was required by the independent claims. Appx6043-6046.[3]

In ***Ground 2***, the petitions alleged obviousness over PAR *alone,* now utilizing *Appellant's* claim construction (the construction that required validated sterility

[3] It is undisputed that the petitioners labeled their unsterilized *U.S.* antiseptic product "sterile" though the antiseptic did not undergo sterility processing. Opening Br. 7-9.

processing).[4] Appx6069. In its single-paragraph obviousness argument for the challenged independent claims, the petitions referenced "UK regulatory standards" but *never argued obviousness based upon any prior art combinations*. Appx6069.

In ***Ground 3*****,** the petitions alleged obviousness based upon PAR and a prior art reference called Degala, arguing that skilled artisans would understand that Degala taught that the PAR was "sterilized" under Appellant's construction. Appx6074-6075.

B. The Board's Final Written Decisions

For all three IPR grounds, the Board either disregarded or *even outright rejected* the grounds articulated in the petitions and instead, in contravention of *SAS*, found the claims unpatentable under the Board's *own* new theories.

For ***Ground 1***, the Board *rejected* the petitions' argument that "sterile" and "sterilized" were the same and adopted *Appellant's* claim construction. Appx12.[5] But instead of denying Ground 1 based on the only petitioned ground that was offered, the Board instead forged its own theory: that skilled artisans would know UK regulatory standards and would understand the word "sterile" in PAR to mean "sterilized" under Appellant's claim construction. Appx41-42; Appx28. The Board

[4] Thus, even the petitions implicitly acknowledged that PAR did not anticipate under Appellant's claim construction.

[5] The Board came to the same conclusion in its Institution Decisions. Appx6193.

drew this conclusion even though the petitions (1) *never argued* that any UK standards were relevant to anticipation of the independent claims but simply argued "sterile" and "sterilized" were the same and (2) *never purported* to apply Appellant's claim construction in that ground. Appx6043-6046.[6] Tellingly, the Board openly acknowledged its new theory was not in the petitions. Appx28, n.7 (admitting that Board argument originated from dependent—not independent—claims[7]). The Board's new ground in its Final Written Decisions was particularly surprising given that the Board had preliminarily ruled in favor of *Appellant* in Ground 1 in its Institution Decisions after finding in favor of Appellant on the claim construction issue. Appx6201, Appx6205-6206.

For ***Ground 2***, though the petitions never advanced *any* prior art combinations for the independent claims, the Board concluded that it would have been obvious to modify PAR based on numerous *prior art references* (e.g., Degala, Scholz, and Chiang (a reference never mentioned in the petitions)) and "sterilize the things labeled 'sterile.'" Appx71-74, Appx76-77. The Board spent pages discussing these

[6] Moreover, there was never an explanation regarding how the Board could require skilled artisans ("POSAs") to understand UK regulations governing the petitioner's product when neither party suggested it and neither expert purported to have that knowledge. Opening Br. 33-34; Appx6031, Appx6348-6349, Appx3954, Appx3990, Appx3993. The Appellee never disputed that no party advocated for this POSA requirement. Resp. 37.

[7] In Ground 1, the petitions only referenced UK standards for achieving particular *sterility assurance levels* recited in two *dependent* claims. Appx6062-6063.

prior art references including the one never even submitted with the petitions. Appx73-74, Appx76-77. The Board again acknowledged that its prior art-based theories were not previously presented in Ground 2 but then excused its new ground by contending that skilled artisans were "presumed to know the relevant prior art." Appx76 (admitting newly-cited prior art references were "not argued explicitly in the Petition as part of petitioner's first obviousness challenge").

For ***Ground 3***, the Board likewise ignored the petitioned arguments and instead decided it would have been obvious to modify PAR and "sterilize the things identified as 'sterile'" (Appx92-94)—even though the petitions never made that argument (Appx6073-6075).

C. The Panel Opinion

On appeal, Appellant alleged that the Board violated the APA by relying on new grounds for unpatentability including by citing prior art, POSA "knowledge," and other evidence that was never presented in the petitions. *See, e.g.,* Opening Br. 29-31, 17-19, 24-27, 33-34, 36, 40, 53-54, 56-58, 61-63; Reply 2-3, 5, 7-8, 21-22, 27. Appellant contended that "[w]hether the Board improperly relied on new arguments is reviewed *de novo*" and further explained that this Court reviews "compliance with the [APA] *de novo.*" Opening Br. 28-29, quoting *IPR Licensing*, 942 F.3d at 1369 and *EmeraChem*, 859 F.3d at 1345. On Reply, Appellant further clarified that *de novo* review was appropriate after the Appellee (now withdrawn

from this appeal) argued that "abuse of discretion" was the applicable standard. Reply 2-3.

The Panel Opinion affirmed the Board's judgments, finding that the Board's anticipation conclusions (Ground 1) were supported by substantial evidence. Panel Op. 8-12, 17. Specifically, the Panel Opinion endorsed the Board's new theory that skilled artisans "would know about the differing regulatory requirements in the United States and the UK" and thus know that the word "sterile" in PAR meant "sterilized"—even though the petitions never referenced any UK regulatory standards for anticipation of the independent claims in Ground 1.[8] *Id.* at 9; Appx6043-6046.

Notwithstanding Appellant's allegation that the Board violated the APA, the Panel Opinion never made any *de novo* determination regarding whether the Board's decisions improperly raised new theories or whether the Board complied with the APA. Instead, the Panel Opinion stated: "[w]e review the Board's interpretation of 'what has been put before it' in a petition, and what arguments it presents and does not present, for an abuse of discretion." Panel Op. 7. The Panel Opinion ultimately concluded that there was "no abuse of discretion in the Board's reading of the petition" to include what Appellant had alleged to be improper new grounds. *Id.*, 14.

[8] It was undisputed that the FDA did not require sterilization of chlorhexidine gluconate antiseptics in the U.S. and that the petitioners had labeled their unsterilized U.S. product "sterile." Opening Br. 7-9.

III. THIS COURT SHOULD REVIEW THE BOARD'S APA VIOLATIONS *DE NOVO* AND REVERSE THE BOARD'S JUDGMENTS

"An agency may not finally decide the limits of its statutory power. That is a judicial function." *Soc. Sec. Bd. v. Nierotko*, 327 U.S. 358, 369 (1946). Indeed, the Supreme Court recently reaffirmed that "[c]ourts *must* exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412 (2024). The Board's compliance with the legal requirements of the IPR statutes—including whether the Board observed its mandate to institute an IPR "pursuant to a petition"—must be reviewed without deference to the Board.

The Panel Opinion erred by employing an "abuse of discretion" standard to review Appellant's allegations about the Board's APA violations. As explained above, "the requirement that the initial petition identify...the 'evidence that supports the grounds for the challenge…'" is important because the Board does not "enjoy[] a license to depart from the petition and institute a *different* [IPR] of [its] own design.'" *Intelligent Bio-Systems*, 821 F.3d at 1369; *SAS*, 584 U.S. at 365 (emphasis original). "[T]he petitioner's petition, *not the Director's discretion*, is supposed to guide the life of the litigation." *SAS*, 584 U.S. at 366.

This Court has repeatedly recognized that "[w]hether the Board improperly relied on new arguments is reviewed *de novo*." *IPR Licensing*, 942 F.3d at 1369; *EmeraChem*, 859 F.3d at 1345. And this Court "review[s] the Board's procedures

for compliance with the [APA] de novo, under which we must 'hold unlawful and set aside agency action...not in accordance with the law [or]…without observance of procedure required by law.'" *EmeraChem*, 859 F.3d at 1345 (brackets and ellipses original); *see also NuVasive*, 841 F.3d at 970 (whether Board relied on new ground is "subject to de novo review").

This Court has repeatedly found the Board erred when it advanced new theories and arguments never presented in the petition. *See, e.g., EmeraChem*, 859 F.3d at 1348 (vacating Board where it "denied [patentee] its procedural rights guaranteed by the APA" by citing prior art petitioner relied upon elsewhere in petition but not for dependent claims at issue); *IPR Licensing*, 942 F.3d at 1370 (reversing Board where it "cited…arguments under ground three" for unpatentability under ground one); *Koninklijke*, 948 F.3d at 1336-37 (Board erred in instituting on an obviousness combination not articulated in the petition though the art itself was in the petition); *Magnum*, 829 F.3d at 1381 (reversing Board where it relied on new obviousness theory based on combination with art that was only cited as motivation for obviousness); *M&K*, 985 F.3d at 1385 (Board "deviated impermissibly from the invalidity theory set forth in…petition"); *Oren Tech., LLC v. Proppant Express Investments LLC*, No. 2019-1778, 2021 WL 3120819, *5 (Fed. Cir. July 23, 2021) (reversing Board where it "repurpose[ed]" a theory advocated for a different limitation).

The Panel Opinion relied on *Corephotonics* and *Henny Penny* to support the "abuse of discretion" standard of review. Panel Op. 7. However, neither case purported to upend (or should be read to upend) established Federal Circuit precedent mandating *de novo* review in cases such as this one. In both cases, the Court did not address the *legal* issue of whether *the Board itself* relied on new arguments or violated the APA (the issue here); rather, the Court reviewed the Board's findings regarding whether the *petitioner* improperly raised new theories in its reply briefs. *Corephotonics*, 84 F.4th at 1010 (Board did not err by allowing consideration of petitioner's reply arguments where there was "adequate opportunity to respond"); *Henny Penny*, 938 F.3d at 1331 (Board did not err in rejecting petitioner's attempt to raise new reply arguments). Indeed, *Corephotonics* acknowledged that "'whether a ground the Board relied on is 'new'…is a question of law' we review de novo." 84 F.4th at 1008, quoting *NuVasive*, 841 F.2d at 970 (brackets removed).

En banc review and clarification of the law is warranted because other panels of this Court have also employed abuse-of-discretion review under various circumstances, raising questions regarding the appropriate standard. Unlike the present case, these cases focus on whether the *petitioner*—not the Board—raised new theories on reply and/or whether the Board adequately considered a petitioned argument (and thus did not raise the issue of whether the Board violated the APA by

itself raising new arguments). *See, e.g., Netflix, Inc. v. DivX, LLC*, 84 F.4th 1371, 1376, 1380-81 (Fed. Cir. 2023) (Board did not abuse its discretion by not considering argument that was not developed in petition or by rejecting new reply arguments); *Rembrandt Diag., LP v. Alere, Inc.*, 76 F.4th 1376, 1385 (Fed. Cir. 2023) (Board did not abuse discretion when determining *petitioner* reply theories were not new); *Ericsson Inc. v. Intellectual Ventures I LLC*, 901 F.3d 1374, 1380 (Fed. Cir. 2018) (Board erred in rejecting petitioner's reply arguments); *Uniloc 2017 LLC v. Facebook, Inc.,* Nos. 19-2162, 19-2159, 2021 WL 5370480, *7-8 (Fed. Cir. Nov. 18, 2021) (Board abused its discretion by neglecting argument presented in petition); *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 2023-1805, 2023 WL 8794633, *2 (Fed. Cir. Dec. 20, 2023) ("we review the Board's determination whether, under the Board's own regulations, a party exceeded the scope of a proper reply for abuse of discretion").

Here, the question is whether *the Board*—not the petitioner—improperly relied on new arguments. The Board acknowledged its theories were new and not in the petitions. Appx28, n.7; Appx76. The Board thus erred as a matter of law in relying on "argument[s] that the Board itself raised, addressed, and decided." *Nike*, 955 F.3d at 54. "[R]eversal is appropriate when a new rationale for unpatentability is adopted by the Board in its final written decision." *EmeraChem*, 859 F.3d at 1352.

The Board's repeated deviations from the petitions were reversible *legal* error that violated the APA and should have been reviewed *de novo*.[9,10]

CONCLUSION

The Board exceeded its authority and violated the APA when it found that Appellant's patents should be cancelled based on its own new grounds that were never raised in the petitions. The Panel Opinion should be vacated and the Board's judgments finding the claims unpatentable should be reversed.

Respectfully submitted,

Dated: May 29, 2025

/s/ Sandra A. Frantzen

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[9] Other circuit courts apply *de novo* review in assessing allegations that an agency violated the APA. *See, e.g., Kirk v. Comm'r of Soc. Sec. Admin.*, 987 F.3d 314, 320 (4th Cir. 2021) ("We review legal issues, including claims of APA or due process violations, *de novo*"); *Firearms Regul. Accountability Coal., Inc. v. Garland*, 112 F.4th 507, 519 (8th Cir. 2024) ("We 'review de novo…whether an agency action violates the APA'…"); *Comite' De Apoyo A Los Trabajadores Agricolas v. Perez*, 774 F.3d 173, 182 (3d Cir. 2014). ("We [] review APA-based challenges on a *de novo* basis…").

[10] Even under an abuse-of-discretion review standard, this Court should consider the challenged basis and undertake meaningful review of the decision below. *EcoFactor, Inc. v. Google LLC*, No. 2023-1101, Slip Op. at 6 (Fed. Cir. May 21, 2025) (en banc). Here, the Panel Opinion concluded that the Board did not abuse its discretion in relying on allegedly new grounds in the Final Written Decisions, yet the Board itself never considered the issue of whether it raised new grounds.

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Addendum

United States Court of Appeals for the Federal Circuit

SAGE PRODUCTS, LLC,
Appellant

v.

COKE MORGAN STEWART, ACTING UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND ACTING DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2023-1603, 2023-1604

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2021-01201, IPR2021-01202.

Decided: April 15, 2025

SANDRA A. FRANTZEN, McAndrews, Held & Malloy, Ltd., Chicago, IL, argued for appellant. Also represented by DEBORAH LAUGHTON, BEN MAHON, ROBERT ANTHONY SURRETTE.

SHEHLA WYNNE, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for

intervenor. Also represented by PETER J. AYERS, SARAH E. CRAVEN, AMY J. NELSON.

Before REYNA, CUNNINGHAM, and STARK, *Circuit Judges*.

STARK, *Circuit Judge*.

Sage Products, LLC ("Sage") challenges the final written decisions ("FWD") of the Patent Trial and Appeal Board ("Board") finding all challenged claims of two of its patents unpatentable. Becton, Dickinson and Co. ("BD"), the original appellee in this appeal, withdrew after filing its brief. The Director of the U.S. Patent and Trademark Office ("PTO") then exercised her right to intervene, under 35 U.S.C. § 143, and continued the appeal by relying on the briefing already filed by BD.[1] We affirm the judgment of the Board.

I

A

Sage's U.S. Patent Nos. 10,398,642 ("'642 patent") and 10,688,067 ("'067 patent"), are both entitled "Sterilized Chlorhexidine Article and Method of Sterilizing a Chlorhexidine Article." The '067 patent is a continuation of the '642 patent. They share a common specification and a common effective filing date of November 25, 2015.[2]

The patented invention relates to a sterilized chlorhexidine product in a package, such as an applicator filled with an antiseptic composition for disinfecting skin. At issue in

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[1] Because the PTO relies on BD's briefing, we refer to arguments advanced in BD's briefing as those of the PTO.

[2] Like the parties, we cite the specification of the '642 patent.

this appeal are claims 1-3, 5-8, 10-18, and 20 of the '642 patent and claims 1-3, 5-8, and 10-19 of the '067 patent. Challenged claims 1, 7, and 10 of the '642 patent, reproduced below, illustrate the limitations at issue in this appeal:

> 1. A *sterilized chlorhexidine product* for topical disinfection, said sterilized chlorhexidine product comprising:
>
> > a *sterilized chlorhexidine gluconate composition*;
> >
> > an applicator for facilitating application of the sterilized chlorhexidine composition; and
> >
> > a receptacle containing the sterilized chlorhexidine gluconate composition to provide the sterilized chlorhexidine gluconate composition to impregnate the applicator when the receptacle is compromised;
> >
> > wherein the sterilized chlorhexidine gluconate composition comprises chlorhexidine gluconate and alcohol.
>
> 7. The sterilized chlorhexidine product of claim 1, wherein the sterilized chlorhexidine gluconate composition further comprises one or more additives selected from the group consisting of a sterilized surfactant, a sterilized pH adjuster, a sterilized odorant, *a sterilized colorant*, a sterilized stabilizer, a sterilized skin protectant, a sterilized preservative, or combinations thereof.
>
> 10. The sterilized chlorhexidine product of claim 1, wherein said sterilized chlorhexidine article has *a sterility assurance level [SAL]* of from 10-3 to 10-9.

J.A. 228 (emphasis added).

The specification recites that a product may be referred to as "sterilized" "where such sterility can be validated." J.A. 216 at col. 3 ll. 56-61. Sterilization methods mentioned in the patents include heat and radiation treatments.

B

The Board relied on four key pieces of prior art in finding Sage's claims unpatentable. The first is the ChloraPrep Public Assessment Report ("PAR"), a publication of the United Kingdom's ("UK's") Medicine and Healthcare Products Regulatory Agency ("MHRA"). The PAR sets out the MHRA's grant of a marketing license for a specific medical product, ChloraPrep, and includes approved packaging information for that product. In particular, the PAR describes the ChloraPrep composition as comprising 20 mg/ml of chlorhexidine gluconate "for disinfection of the skin prior to invasive medical procedures," and depicts an applicator that a user squeezes to break an interior ampoule of the solution for application. J.A. 1524. Notably, the PAR includes required labeling stating that "ChloraPrep with Tint is a *sterile* alcoholic antiseptic solution containing chlorhexidine gluconate and isopropyl alcohol in an applicator" and that the "applicator is *sterile* until the packaging is opened." J.A. 1529 (emphasis added).

The Board additionally looked to the British Standard EN 556-1 ("BS EN-556-1"), which establishes the UK's requirements for labeling a medical device as being sterile. J.A. 1951 ("Sterilization of medical devices – Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilized medical devices"). BS EN-556-1 specifies that, in order to designate a terminally sterilized device as "sterile," the "probability of there being a viable micro-organism on/in the device shall be equal to or less than 1×10^{-6}." J.A. 1958. BS EN-556-1 goes on to explain that the term "terminally sterilized" refers to the "condition of a medical device which has been exposed to a sterilization process in a packaged or

assembled form that maintains the sterility of the medical device or a defined portion thereof." J.A. 1957.

Another prior art reference the Board relied on is U.S. Patent Application Publication 2015/0190535, "Systems, Methods, and Devices for Sterilizing Antiseptic Solutions" ("Degala"). J.A. 1568. Degala discloses sterilizing antiseptic solutions by exposing them to a sterilizing temperature from "about 85° C[] to about 135° C" for "from about 1 minute to about 19 hours." J.A. 1568. Degala explains that the European Union ("EU"), unlike the United States, requires topical antiseptics to have some degree of sterilization, adding that one "known antiseptic solution containing 2% w/v chlorhexidine gluconate in 70% v/v isopropanol in water, manufactured by CareFusion Corp., is sterilized for EU countries using a known sterilization method" involving heat treatment. J.A. 1570 ¶ 2.

The final prior art reference pertinent to the issues before us is U.S. Patent Publication No. 2014/0371695, "Skin Antiseptic Applicator and Methods of Making and Using the Same" ("Chiang"). J.A. 3318. Chiang is "directed to skin antiseptic composition applicators, particularly to skin antiseptic composition applicators that include one or more antimicrobial (e.g., antiseptic) materials in a single use applicator." J.A. 3330 ¶ 3. Chiang states:

> [T]he ChloraPrep® applicator, provided by CareFusion, has the active skin antiseptic composition, containing chlorhexidine gluconate (CHG), stored in a breakable glass ampule inside the applicator device. In the ChloraPrep® applicator, the sealed glass ampule protects the CHG composition during the sterilization process from ethylene oxide penetration which could otherwise compromise the efficacy of the antiseptic composition.

J.A. 3330 ¶ 10. Sage's expert, Dr. William Rutala, cited Chiang as demonstrating the state of the art at the time of the '067 invention, including that, in his opinion, "the

prevailing knowledge [was] that the [chlorhexidine gluconate] composition within ChloraPrep was *not* sterilized." J.A. 3802-03 ¶ 331 (emphasis added).

C

During the *inter partes* review ("IPR") proceedings, BD advanced three grounds for finding the challenged claims of the '642 patent and '067 patent unpatentable: (1) the claims are anticipated by the PAR; (2) the claims are obvious over the PAR, given the knowledge of a person of ordinary skill in the art ("skilled artisan"); and (3) the claims are obvious over the PAR in view of Degala. In instituting the IPR and evaluating the petition, the Board construed the term "sterilized" to mean "the component or composition has been subjected to a suitable sterilization process such that sterility can be validated." J.A. 6193. Then, in its FWD, the Board found that a skilled artisan at the time of the invention would have known, through education and experience, that the term "sterile," as used in the PAR in the UK, is equivalent to the term "sterilized," as used in the United States and, particularly, in the Sage patents. Reviewing the totality of the evidence before it, including both parties' experts' reports and testimony, the Board determined each of the challenged claims was unpatentable on all three of the petition's grounds.

Sage timely appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

II

"A claim is anticipated if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference." *Arbutus Biopharma Corp. v. ModernaTX, Inc.*, 65 F.4th 656, 662 (Fed. Cir. 2023). "Anticipation is a question of fact subject to substantial evidence review." *IOENGINE, LLC v. Ingenico Inc.*, 100 F.4th 1395, 1402 (Fed. Cir. 2024) (cleaned up). "Substantial evidence is such relevant evidence as a reasonable

mind might accept as adequate to support a conclusion." *Id.* (internal quotation marks and citation omitted). "[T]he possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence." *Consolo v. Fed. Mar. Comm'n*, 383 U.S. 607, 620 (1966). Moreover, we "defer to the Board's findings concerning the credibility of expert witnesses." *Incept LLC v. Palette Life Scis.*, 77 F.4th 1366, 1377 (Fed. Cir. 2023).

"What the prior art discloses . . . [is a] fact question[] that we review for substantial evidence." *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1378 (Fed. Cir. 2023); *see also PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1196-97 (Fed. Cir. 2014) ("What a reference teaches and whether it teaches toward or away from the claimed invention are questions of fact.").

The Board's finding regarding the level of skill in the art a person of ordinary skill would possess is a question of fact that we review for substantial evidence. *See Best Med. Int'l, Inc. v. Elekta Inc.*, 46 F.4th 1346, 1353 (Fed. Cir. 2022); *see also Innovention Toys, LLC v. MGA Entertainment, Inc.*, 637 F.3d 1314, 1324 (Fed. Cir. 2013).

We review the Board's interpretation of "what has been put before it" in a petition, and what arguments it presents and does not present, for an abuse of discretion. *See Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1002-03 (Fed. Cir. 2023); *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1330 (Fed. Cir. 2019).

III

Resolution of this appeal requires us to decide three principal issues: (1) whether substantial evidence supports the Board's finding that a skilled artisan would have understood the PAR to describe a "sterilized" composition and "sterilized" product; (2) whether substantial evidence supports the Board's additional findings that all elements of

each of the challenged claims were also disclosed in the PAR; and (3) whether the Board committed procedural errors. As we explain below, Sage has not persuaded us there is any reversible error on any of these points.

A

The PAR states that "ChloraPrep with Tint is a *sterile* alcoholic antiseptic solution," "[t]he *sterile* applicators are individually packaged in an ethyl vinyl acetate film," and "the applicator is *sterile* unless seal is broken." J.A. 1526, 1529 (emphasis added). Each of the challenged claims in Sage's patents requires a "*sterilized* chlorhexidine product" or a "*sterilized* chlorhexidine article" comprising a "*sterilized* chlorhexidine gluconate composition" (emphasis added). Sage argued to the Board, and reiterates to us, that the PAR's use of the term "sterile" stemmed from a mistaken belief – widely shared in the pertinent community of skilled artisans – that the antiseptic composition in ChloraPrep was sterile when, in fact, it was not. The Board took account of this contention and found that a skilled artisan would have understood the PAR's references to "sterile" meets the Board's construction of "sterilized," which is "the article/component/composition recited as 'sterilized' has been subjected to a suitable sterilization process such that sterility can be validated." J.A. 12.[3] Substantial evidence supports the Board's finding.

The Board identified the skilled artisan as "possess[ing] at least an undergraduate bachelor's degree in the pharmaceutical sciences, pharmacy, biochemistry, microbiology, or a related field, with at least four years of experience with sterilization processes for medical products and their components, as well as familiarity with antiseptics such as chlorhexidine." J.A. 17. Sage did not object to

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[3] Sage does not challenge the Board's construction of "sterilized."

the Board's definition and did not offer its own description of the qualifications of the skilled artisan. Sage's expert, Dr. Rutala, "agree[d] with this definition;" indeed, the Board's requirement of "at least four years of experience with sterilization processes" was adopted by the Board on the recommendation of Dr. Rutala. J.A. 6348; *see also* J.A. 16-17, 3468.

On appeal, Sage now insists that this definition was erroneous because it did not require the skilled artisan to be familiar with the challenges involved in the sterilization of chlorhexidine gluconate, and also because the Board read into its definition a familiarity with UK regulations that Sage asserts the skilled artisan would lack. These are challenges to the Board's factual findings and they lack merit – because the Board's findings are supported by substantial evidence.

Given the party's positions, the Board confronted a factual dispute as to whether the skilled artisan would read the PAR as disclosing "sterilized" products and compositions, as that term is used in the Sage patents. To resolve this dispute, the Board found it necessary not only to make a finding as to the definition of the skilled artisan but also to make additional findings as to the knowledge of such a person. Specifically, the Board found that the skilled artisan – who had, as Sage's expert opined, "at least four years of experience" – would know about the differing regulatory requirements in the United States and the UK. That knowledge would include recognizing that the PAR, an MHRA publication about a UK medical product, would have to satisfy UK regulatory standards, including the BS EN-556-1 standard, to be labeled "sterile." J.A. 28-29 (finding skilled artisan "would have understood the term 'sterile' in a regulatory document to unequivocally disclose[] a SAL [sterility assurance level] from 10^{-3} to 10^{-9}") (internal quotation marks omitted); *see also* J.A. 1958 (BS EN-556-1: "For a terminally-sterilized medical device to be designated 'STERILE', the theoretical probability of there being

a viable micro-organism present on/in the device shall be equal to or less than 1×10^{-6}.").

The Board found "it implausible that someone with four years of experience with sterilization processes for medical products and their components would lack familiarity with the regulatory regimes that set the conditions under which the products or processes they work with may be used." J.A. 42. Substantial evidence, including the testimony of BD's expert, Dr. Dabbah, supports this finding. J.A. 1381-83, 1387. Dr. Dabbah explained that a skilled artisan having the education and experience required by the Board's definition would know the differences between the United States and UK regulatory standards for "sterile" and would know, therefore, that the PAR's references to "*sterile*" items would satisfy the challenged claims' requirement for "*sterilized*" items. J.A. 1355.

Relatedly, the Board found that (i) even though BS EN-556-1 does not expressly apply to "medical products" such as ChloraPrep, but instead to medical devices, and it is a voluntary "standard," a skilled artisan would nonetheless understand that a medical product like ChloraPrep would comply with those standards in order to be labeled "sterile" in the UK; and (ii) the same skilled artisan would not have viewed sterilization of chlorhexidine gluconate at the pertinent time as being impossible or any more difficult than "routine."[4] Substantial evidence, including the testimony of BD's expert, Dr. Dabbah, whom the Board repeatedly credited over Dr. Rutala, *see, e.g.*, J.A. 37-38, supports each

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[4] The Board acknowledged the "evidence identified by Patent Owner regarding the challenges of developing sterilized" chlorhexidine gluconate and observed that "[i]n the absence of a disclosed method for sterilizing [chlorhexidine gluconate], these concerns might be persuasive. But here, methods for sterilizing [chlorhexidine gluconate] were known and disclosed in the Degala patent." J.A. 65.

of these findings. J.A. 1348, 1355, 1372-73, 1381-83. Therefore, Sage's contention that the Board allegedly erred by requiring a skilled artisan to know UK regulatory requirements while not needing to know the supposed challenges in sterilizing chlorhexidine products is meritless, as it relies on rejection of the Board's actual, supported findings.

Contrary to Sage's contentions, the Board did not "ignore" or "disregard" evidence. Instead, the Board surveyed all of the competing evidence – including, for example, the history of mislabeling of the United States-version of ChloraPrep as "sterile," and found, as it is permitted to do, that BD's evidence outweighed Sage's. *See* J.A. 38-43.

Additionally, since a skilled artisan would understand "sterile," as used in the PAR, to satisfy the "sterilized" claim limitation of the challenged claims, the Board's conclusion that the PAR teaches a sterilized chlorhexidine product or article – that is, a sterilized chlorhexidine composition and an applicator – is also supported by substantial evidence. As the Board noted, the PAR explicitly discloses that the whole product "'is sterile until the packaging is opened,'" indicating that the composition and applicator are both sterile. J.A. 25 (quoting J.A. 1529). The Board cited as support for this finding the evidence we have already identified above, including testimony from both parties' experts, as well as Chiang, which the Board found "reflects the knowledge of" the skilled artisan that the ChloraPrep product – the subject of the PAR – was known to use a sealed glass container to protect the solution. J.A. 25-27. This disclosure in Chiang , the Board found, "reinforces" its finding that the ChloraPrep PAR discloses sterilization of the entire ChloraPrep product. J.A. 26-27. The Board cited substantial evidence for each of these determinations.

Applying its definition of the skilled artisan, the Board also evaluated, and rejected, Sage's criticisms of BD's

expert, Dr. Dabbah. The Board found that Dr. Dabbah met the education and experience requirements of its definition, qualifying him to opine from the perspective of such a person. The Board also correctly observed that Sage did not move to exclude Dr. Dabbah's testimony. In the course of its analysis, then, the Board was free to, and did, credit Dr. Dabbah's opinions and decide how much weight to give them. *See, e.g.*, J.A. 25, 29, 37. Sage has identified no reversible error.

B

While the bulk of the parties' briefing relates to the issues of "sterilization" and the knowledge of the skilled artisan, which we have addressed above, Sage also challenges the Board's findings regarding certain limitations in the dependent claims. In particular, Sage contends that the PAR does not disclose the "sterilized colorant" limitation of the colorant claims and does not disclose the "sterilized chlorhexidine article has a [SAL] of from 10^{-3} to 10^{-9}" of the SAL claims. We conclude that the record contains substantial evidence for the Board's findings with respect to these limitations.

With respect to the colorant claims, Sage observes that the colorant described in the PAR is in a container distinct from the glass ampoule of chlorhexidine gluconate, and argues that the PAR lacks any explicit disclosure that the colorant container is itself sterilized. The Board disagreed, relying instead on the testimony of Dr. Rutala and Dr. Dabbah to find that any inactive ingredients – including a colorant – would have to be sterilized in order for the PAR to accurately describe the composition as sterile. The Board also pointed to the PAR's statement that "ChloraPrep with Tint is a sterile alcoholic antiseptic solution." J.A. 61-62 (citing J.A. 1526). Thus, substantial evidence supports the Board's conclusion that the dependent colorant claims are anticipated by the PAR.

Substantial evidence also supports the Board's finding that the PAR teaches that the sterilized chlorhexidine gluconate of ChloraPrep has a SAL falling within the range of 10^{-3} to 10^{-9}, thereby meeting the SAL limitation. After the Board determined that "sterile" as used in the PAR means "sterilized" as construed in the challenged claims, the Board evaluated Dr. Dabbah's testimony that the applicable regulatory standard (BS EN-556-1) requires a SAL of 10^{-6} or less. Crediting Dr. Dabbah, the Board concluded that the person of ordinary skill would have "understood the product disclosed in the ChloraPrep PAR to have a sterility assurance level" within the scope of the claims. J.A. 63. Thus, substantial evidence supports the Board's conclusion that the dependent SAL claims are anticipated by the PAR.[5]

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[5] Contrary to Sage's suggestion, the Board's reference to BS EN-556-1 is not improper in the context of analyzing whether the PAR anticipates Sage's claims. Open. Br. at 39 ("The Board's anticipation analysis, based on materials outside of PAR, was flawed as a matter of law."). An anticipation analysis is undertaken from the perspective of the person of ordinary skill in the art and, therefore, must take account of the knowledge of such a person. *See Arthrocare Corp. v. Smith & Nephew, Inc.,* 406 F.3d 1365, 1373-74 (Fed. Cir. 2005) ("[E]ven if a piece of prior art does not expressly disclose a limitation, it anticipates if a person of ordinary skill in the art would understand the prior art to disclose the limitation and could combine the prior art description with his own knowledge to make the claimed invention."). As we have already held, the Board had substantial evidence for its finding that a skilled artisan would have known of UK regulatory standards for sterility, as embodied in BS EN-556-1. Such a person would have carried that knowledge with her when examining each of the challenged claims.

C

Sage additionally faults the Board for committing what it contends are numerous procedural errors in its anticipation analysis. We do not agree.

Sage argues that the Board exceeded its proper role in an IPR, which is limited to evaluating whether the grounds asserted in a petition have been proven, and improperly created its own grounds and supporting arguments that BD never raised. "It is for the Board to determine what grounds are being articulated in a petition and what arguments and evidence are being referred to in the responses and any replies." *Corephotonics*, 84 F.4th at 1002. We find no abuse of discretion in the Board's reading of the petition as contending that "sterile," as used in the PAR, would be understood by the skilled artisan to mean "sterilized" as recited in the claims.

Much of what Sage complains about simply repeats, in procedural garb, the same factual challenge we have already discussed relating the knowledge of the person of ordinary skill in the art. *See supra* III.A. As we have held, the Board had substantial evidence for its finding that such a person (as defined by the Board, without objection from Sage) would understand "sterile" as used in the PAR to teach the same thing as is meant by the "sterilization" limitations of the challenged claims. This contention was always a component of BD's theory that the PAR anticipates Sage's claims, as an anticipatory reference must disclose all limitations of those claims. J.A. 6029-30, 6043-44. Then, after Sage disputed this factual assertion in its patent owner response, *see, e.g.*, J.A. 6354-55 ("Petitioner conflates the terms 'sterile' and 'sterilized' when assessing the PAR's disclosure."); *id.* ("[A skilled artisan] would not have understood the bare use of the word 'sterile' in a 2010 document describing an antiseptic product – especially ChloraPrep – to mean that it had been sterilized."), BD, in reply, responded with further argument and evidence

directly responsive to Sage's disagreements, *see, e.g.*, J.A. 6434, 6436-37 (arguing that Sage "blurs two distinct products . . . the ChloraPrep UK product and the ChloraPrep US product" and that "a [skilled artisan] would have properly understood that the ChloraPrep UK product was subject to different regulations than the US product"). There was no abuse of discretion in the Board permitting BD to do so. *See Corephotonics*, 84 F.4th at 1002.

All of this, as we have said, put before the Board the question of how a skilled artisan would have understood "sterile" as used in the PAR. To do so, the Board decided it had to delve into not just the undisputed identification of *who* is the pertinent skilled artisan, but also had to assess *what* that skilled artisan would know. In the FWD, the Board considered all the evidence and argument before it and, necessarily and properly, resolved the factual dispute. In doing so, the Board did not exceed its role, but rather fulfilled it.

There was likewise nothing improper in the Board relying on evidence outside of the PAR to make findings as to what the skilled artisan would understand the PAR to be disclosing. It is true, as Sage emphasizes, that the Board considered the opinion of BD's expert, Dr. Dabbah, in its anticipation analysis. *See, e.g.*, J.A. 37, 42. Our precedents establish that expert opinion "may be used to interpret [an] allegedly anticipating reference and to shed light on what it would have meant to" a person having ordinary skill in the art. *Monsanto Tech. LLC v. E.I. DuPont de Nemours & Co.*, 878 F.3d 1336, 1345 (Fed. Cir. 2018); *see also Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1328 (Fed. Cir. 2001) ("[R]ecourse to extrinsic evidence is proper to determine whether a feature, while not explicitly discussed, is necessarily present in a reference.").

Sage also argues that the Board erred by relying on declarations from BD employees and confidential quality assurance protocol documents about BD's UK-marketed

version of ChloraPrep. In the FWD, after laying out Dr. Dabbah's expert testimony as well as the teachings of Degala, the Board added that "two of Petitioner's employees confirm that the version of C[h]loraPrep product sold in the U.K. had sterilized chlorhexidine gluconate." J.A. 40. The employee-witnesses merely confirmed what Dr. Dabbah had already made clear to the Board's satisfaction: that the regulatory standard, BS EN-556-1, applied to the UK ChloraPrep product, and that this fact would have been known to a skilled artisan. J.A. 29 ("We credit Dr. Dabbah's testimony . . . and find that a [skilled artisan] would have understood that the product described in the ChloraPrep PAR was required to comply with applicable standards, including BS EN-556-1."). Hence, even if the Board's confirmatory reference to the non-prior-art confidential employee declarations, including their incorporation of confidential quality assurance protocol information, *see, e.g.*, J.A. 2279, was error, it was harmless because it did not prejudice Sage. *See In re Chapman*, 595 F.3d 1330, 1338 (Fed. Cir. 2010) ("The judicial review provision of the APA includes a harmless error rule.").

In sum, none of the supposed procedural errors Sage accused the Board of committing provides a meritorious basis to reverse or vacate the Board decision.

IV

Sage raises numerous other arguments, only one of which requires additional, brief comment. This is Sage's contention that the Board erred in its determination that the PAR is enabled. We have held that enablement of an anticipatory reference may be demonstrated by another reference when that additional reference shows that the claimed subject matter was in the public's possession. *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001). Here, the Board found that the PAR was enabled by relying on: (i) Dr. Dabbah's testimony that a skilled artisan would be familiar with terminal

sterilization procedures, (ii) Chiang's teachings that ChloraPrep was sterilized using ethylene oxide, (iii) Dr. Rutala's testimony discussing sterilization using ethylene oxide gas, and (iv) Degala's disclosure regarding known methods to sterilize a chlorhexidine gluconate solution. Contrary to Sage's accusation, the Board did not consider Degala to fill in gaps in the PAR but, instead, to assess the state of the prior art at the time the patent application was filed, which the Board is permitted to do. *See, e.g., In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Hence, once again, we find no merit to Sage's criticism.

V

We have considered the parties' remaining arguments relating to anticipation and find them unpersuasive. Our disposition of this case solely on anticipation grounds renders it unnecessary to consider the Board's obviousness determinations. Hence, for the foregoing reasons, we affirm the decision of the Board.

AFFIRMED

FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2023-1603, 2023-1604

Short Case Caption: Sage Products, LLC v. Stewart

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Name: Sandra A. Frantzen