# United States Court of Appeals for the Federal Circuit

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**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*

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2023-1603, 2023-1604

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

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Decided: April 15, 2025

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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.

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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 $1 \times 10^{-6}$." 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 $1 \times 10^{-6}$.").

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**