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Paper 41
Date: January 9, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON DICKINSON AND COMPANY,
Petitioner,

v.

SAGE PRODUCTS, LLC,
Patent Owner.

IPR2021-01201
Patent 10,398,642 B1

Before JAMES A. TARTAL, GEORGIANNA W. BRADEN, and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)
Granting Patent Owner's Motion for Entry of Protective Order and to Seal
37 C.F.R. §§ 42.14, 42.54

We have jurisdiction to hear this *inter partes* review under 35 U.S.C. § 6, and this Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). For the reasons that follow, we determine Becton Dickinson and Company ("Petitioner") has shown by a preponderance of the evidence that claims 1–3, 5–8, 10–18, and 20 of U.S. Patent No. 10,398,642 B1 (Ex. 1001, "the '642 patent") are unpatentable.

I. INTRODUCTION AND BACKGROUND

A. Procedural History

Petitioner filed a Petition requesting an *inter partes* review of claims 1–3, 5–8, 10–18 and 20 (the "challenged claims") of the '642 patent. Paper 2 ("Pet."). Sage Products, LLC ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp."). Pursuant to 35 U.S.C. § 314(a), we instituted an *inter partes* review of all challenged claims on all proposed grounds of unpatentability. *See* Paper 7 ("Dec. to Inst."), 46.

After institution of trial, Patent Owner filed a Patent Owner Response (Paper 23, "PO Resp."), to which Petitioner filed a Reply (Paper 28, "Pet. Reply"). Patent Owner then filed a Sur-Reply (Paper 35, "PO Sur-Reply").

An oral argument was held on October 13, 2022. A transcript of the oral argument is included in the record. Paper 40 ("Tr.").

B. Real Parties in Interest

Petitioner states "[t]he real party-in-interest for Petitioner is Becton, Dickinson and Company." Pet. 3. Patent Owner states that "Sage is a wholly-owned subsidiary of Stryker Corporation." Paper 4 (Patent Owner's Mandatory Notice), 2. The parties do not raise any issue or provide arguments regarding real parties in interest in this proceeding.

C. Related Proceedings

The parties identify the following district court case involving the '642 patent: *Sage Products, LLC v. Becton, Dickinson and Company,* Case No. 2:20-cv-08000-KMJBC (D. N.J. filed June 30, 2020). Pet. 4; Paper 4, 2. The parties also identify IPR2021-01202 asserted against U.S. Patent No. 10,688,067, which is related to the '642 patent. Pet. 4; Paper 4, 2.

D. The '642 Patent (Ex. 1001)

The '642 patent is titled "Sterilized Chlorhexidine Article and Method of Sterilizing a Chlorhexidine Article," and issued on September 3, 2019. Ex. 1001, codes (45), (54). It is a continuation of U.S. Patent Application No. 15/360,037, which issued as U.S. Patent No. 10,188,598, and relies on a provisional application filed on Nov. 25, 2015. *Id.* at codes (60), (63).

1. Written Description

The '642 patent relates to a sterilized chlorhexidine gluconate ("CHG") product that includes (1) a sterilized composition of chlorhexidine gluconate and alcohol, (2) an applicator, and (3) a receptacle to impregnate the applicator with the sterilized chlorhexidine gluconate composition when the receptacle is compromised. *Id.* at code (57). One embodiment of the invention is shown in Figures 3 and 4, reproduced below:

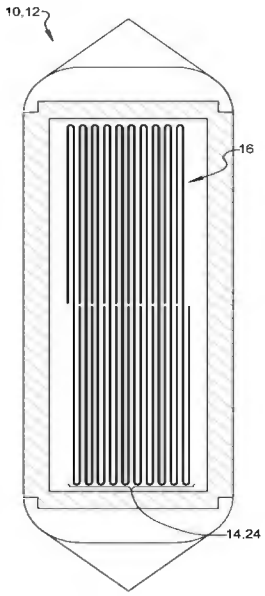

FIG. 3

FIG. 4

As shown above in Figures 3 and 4, sterilized chlorhexidine product 10 comprises package 12 and chlorhexidine article 14. Ex. 1001, 2:35–37. Package 12 defines interior volume 16, and chlorhexidine article 14 is removably disposed in interior volume 16 of package 12. *Id.* at 2:37–39. The '642 patent discloses that package 12 is particularly suitable for terminal sterilization processes. *Id.* at 2:53–55. The '642 patent explains that "when the chlorhexidine product 10 is subjected to a sterilization process, such as a terminal sterilization process, it will be appreciated that the package 12 is also subjected to the sterilization process in addition to the chlorhexidine article 14 disposed therein." *Id.* at 16:66–17:3.

In certain embodiments, the sterilized chlorhexidine article is intended to be used by a patient care provider for disinfecting skin or mucous membranes of a patient. *Id.* at 3:64:4:2. As shown above in Figure 4, chlorhexidine article 14 comprises applicator 24 and an antiseptic composition. *Id.* at 4:5–6. Applicator 24 facilitates topical application of the antiseptic composition to the skin or mucous membranes of a patient. *Id.*

at 4:6–9. The '642 patent discloses that "[t]he antiseptic composition comprises one or more antibacterial agents and one or more solvents." *Id.* at 7:23–24.

The '642 patent provides ranges for each of the components of the antiseptic compositions explaining that such ranges "may refer to the amounts of those components in the sterilized antiseptic compositions or the unsterilized anti-septic compositions." *Id.* at 14:38–42. The '642 patent discloses that "[b]ecause certain sterilization processes may cause certain components to degrade, the amount of each component in the antiseptic composition may vary from the non-sterile condition to the sterilized condition." *Id.* at 14:42–45; *see also id.* at 17:14–18 ("When the chlorhexidine article is sterilized, the sterilized antiseptic composition may further comprise degradation impurities. The degradation impurities may be a result of exposing the chlorhexidine article to the sterilization process.").

The '642 patent states:

> It should be appreciated that the present disclosure describes a method of sterilizing a chlorhexidine product to form a sterilized chlorhexidine article. As such, throughout this disclosure, description that accompanies the terms the chlorhexidine article, or components and compositions thereof, may be referred to as the 'sterilized' component or composition upon being exposed to suitable processing where such sterility can be validated. By way of nonlimiting example, the sterility of the chlorhexidine article may be validated in accordance with ISO 11137.

Id. at 3:54–63. The '642 patent provides examples of sterilization processes that may be "suitable to sterilize the chlorhexidine article 14 such that the sterility of the chlorhexidine article 14 can be validated." *Id.* at 16:14–17. Such examples include "heat sterilization, radiation sterilization, ethylene

oxide gas sterilization, or combinations thereof." *Id.* at 16:17–20. In one embodiment, "[c]ooling the chlorhexidine product 10 may comprise cooling the chlorhexidine product 10 to a temperature of from -100° C. to 20° C." *Id.* at 19:25–27.

The '642 patent then discloses that

> The method further comprises sterilizing the chlorhexidine product 10 to form the sterilized chlorhexidine article 14. The chlorhexidine product 10 may be sterilized by any sterilization process such that the sterility of the chlorhexidine article 14 can be verified. In some embodiments, sterilizing the chlorhexidine product 10 comprises irradiating the chlorhexidine product 10 to form a sterilized chlorhexidine article 14.

Id. at 20:66–21:11. The '642 patent explains that in certain other embodiments, "sterilizing the chlorhexidine product 10 further comprises heat sterilizing the chlorhexidine product 10." *Id.* at 21:7–9. The '642 patent then provides a reminder that "[o]f course it should be appreciated that the antibacterial agent of the antiseptic composition may not be compatible with heat sterilization." *Id.* at 21:9–11.

In addition to cooling, freezing, and heat sterilization, the '642 patent discloses irradiating "the chlorhexidine product 10 to form the sterilized chlorhexidine article 14." *Id.* at 21:34–36. The '642 patent states that the radiation type can include "gamma radiation, electron- beam radiation, x-ray radiation, or combinations thereof" or "electron beam radiation." *Id.* at 21:37–41. The '642 patent further discloses that "[t]he chlorhexidine product 10 may be irradiated with the radiation type by any suitable radiation unit." *Id.* at 21:43–44.

2. Illustrative Claims

The '642 patent includes twenty claims. Claims 1–3, 5–8, 10–18, and 20 are challenged here. Pet. 6. Claims 1 and 12 are the only independent claims. Claim 1 is illustrative of the claims challenged in this Petition and reads as follows:

> 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.

Ex. 1001, 27:25–35.

E. Asserted Challenges to Patentability and Evidence of Record

Petitioner challenges the patentability of claims 1–3, 5–8, 10–18 and 20 of the '642 patent based on the following references or combination of references:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–3, 5–8, 10–18, and 20	102(a)	ChloraPrep PAR[1]
1–3, 5–8, 10–18, and 20	103[2]	ChloraPrep PAR
1–3, 5–8, 10–18, and 20	103	ChloraPrep PAR, Degala[3]

Patent Owner does not dispute that each reference qualifies as prior art. *See, e.g.*, PO Resp. 20–57.

In support of its patentability challenge, Petitioner relies on, *inter alia*, the following declarations: (1) Roger Dabbah, Ph.D. ("Dr. Dabbah") (Ex. 1003); (2) Simon Noble-Clarke (Ex. 1037); (3) Christopher McGinley (Ex. 1038); and (4) Sean Sheridan, Ph.D. ("Dr. Sheridan") (Ex. 1039). Additionally, Petitioner submits the testimony of William Rutala, Ph.D adduced in the parallel district court proceeding. *See* Exs. 1040, 1042, 1043.

To support its positions, Patent Owner relies on the Declaration of William Rutala, Ph.D. ("Dr. Rutala") (Exhibit 2023).

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[1] Medicines and Healthcare products Regulatory Agency, Public Assessment Report, "ChloraPrep with Tint 2% w/v/70%v/v Cutaneous Solution," archived on November 17, 2010, *available at* https://webarchive.nationalarchives.gov.uk/ukgwa/20101117020428/http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con071263.pdf ("ChloraPrep PAR," Ex. 1005).

[2] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), included revisions to 35 U.S.C. § 103 that became effective as of March 16, 2013. The application for the '642 patent was filed after March 16, 2013, and includes a priority claim to an application filed after this date. Ex. 1001, codes (22), (63). Accordingly, we apply the post-AIA version of 35 U.S.C. § 103.

[3] Degala et al., US 2015/0190535 A1, published Jul. 9, 2015 ("Degala," Ex. 1007).

II. PRELIMINARY MATTERS

Claim Construction

A claim "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.100(b) (2020). Under that standard, "[c]laim terms are given their ordinary and customary meaning, which is the meaning the term would have to a person of ordinary skill in the art at the time of the invention." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 904 F.3d 965, 971 (Fed. Cir. 2018) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc)). The meaning of claim terms may be determined by "look[ing] principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17).

The ordinary and customary meaning of a claim term applies "unless the patentee demonstrated an intent to deviate from [it] . . . by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Teleflex, Inc. v. Ficosa N. America Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002); *see also Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014). Additionally, although we "look to the specification and prosecution history to interpret what a patentee meant by a word or phrase in a claim," we do not read "extraneous limitations . . . into the claims from the specification or prosecution history"

absent an express definition or clear disavowal of claim scope. *Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1348 (Fed. Cir. 2002).

In the Petition, Petitioner asserted that all claim terms should receive their "plain and ordinary meaning" and that an express construction of the challenged claims is unnecessary for resolution of this proceeding. Pet. 16.

In the Institution Decision, we construed the claim term "sterilized" to mean: "the component or composition has been subjected to a suitable sterilization process such that sterility can be validated." Dec. to Inst. 22. Patent Owner agrees with this construction. PO Resp. 17–18 ("The Institution Decision correctly construed 'sterilized' . . . consistent with its ordinary meaning, the description in the patent, and the meaning to a [person of ordinary skill in the art]."); Sur-reply 3–4 (same). In its Reply, Petitioner argues that the construction in the Institution Decision "improperly imports a process limitation into apparatus claims, even though the process by which an apparatus is made is irrelevant." Reply 3. Petitioner also contends that the "use of the word 'suitable' [in the Board's preliminary construction] interjects needless ambiguity into the claims." *Id.* Thus, Petitioner proposes that the term "sterilized" should be construed to mean "in a sterile condition." *Id.* at 2.

We begin by considering the specification of the '642 patent. The specification states:

> It should be appreciated that the present disclosure describes a method of sterilizing a chlorhexidine product to form a sterilized chlorhexidine article. As such, throughout this disclosure, description that accompanies the terms the chlorhexidine article, or components and compositions thereof, may be referred to as the 'sterilized' component or composition upon being exposed to suitable processing where such sterility

> can be validated. By way of non-limiting example, the sterility of the chlorhexidine article may be validated in accordance with ISO 11137.

Ex. 1001, 3:54–63. The specification thus defines the term "sterilized" to mean that the article/component/composition described as sterilized was "exposed to suitable processing where such sterility can be validated." *See also id.* at 16:21–25 ("In the context of this disclosure, when the chlorhexidine article 14 is sterilized, the components of the chlorhexidine article 14 are in a sterile condition, and that sterile condition has been validated, the resultant article is referred to as a sterilized chlorhexidine article 14").

During the prosecution of the parent application to the '642 patent, Patent Owner specifically stated that "for an article or product to have 'a sterility assurance level' as required by claim 1, the article/product must first be subjected to a sterilization process." Ex. 2012, 95. Patent Owner explained:

> the "sterility assurance level" of a product is unrelated to the amount of chlorhexidine gluconate (or for that matter, any antimicrobial agent) present in the product. Instead the "sterility assurance level" of a product results from a sterilization process.

Id. Patent Owner then distinguished the cited prior art on the basis that "[n]one of the cited references disclose, teach, or even suggest subjecting a chlorohexidine product as recited in the claims to a sterilization process." *Id.* Thus, the prosecution history, like the specification, associates the sterility of a product with subjecting that product to a "sterilization process."

Petitioner argues that our preliminary construction "improperly imports a process limitation into apparatus claims." Petitioner's proposed

construction thus avoids reciting a process step by proposing that "sterilized" means "in a sterile condition." The Federal Circuit, however, has explained that "process steps can be treated as part of the product claim if the patentee has made clear that the process steps are an essential part of the claimed invention." *Vectura Ltd. v. Glaxosmithkline LLC*, 981 F.3d 1030, 1038 (Fed. Cir. 2020) (quoting *Continental Circuits LLC v. Intel Corp.*, 915 F.3d 788, 799 (Fed. Cir. 2019)).

Here, as discussed above, the specification and prosecution history make clear that being subjected to a sterilization process is an essential part of the claimed invention. Because the case law makes clear that process steps can be part of a product claim, and because our preliminary claim construction is more closely aligned with the language used in the specification and in the prosecution history than the language proposed by Petitioner, we maintain our preliminary claim construction. Accordingly, we construe "sterilized" to mean that the article/component/ composition recited as "sterilized" has been subjected to a suitable sterilization process such that sterility can be validated.

A. Principles of Law

A claim is unpatentable under 35 U.S.C. § 102 if a prior art reference discloses every limitation of the claimed invention, either explicitly or inherently. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995). Furthermore, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must lead to a composition that falls within the scope of the claim "without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972). Thus, it is not

enough that the prior art reference discloses multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention. *See Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371–72 (Fed. Cir. 2008) (finding a prior art reference is anticipatory only if the reference discloses every limitation of the claimed invention arranged or combined in the same way as in the claim). "However, a reference can anticipate a claim even if it 'd[oes] not expressly spell out' all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination." *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (quoting *In re Petering*, 301 F.2d 676, 681 (CCPA 1962)) (alteration in original). Specifically, a "reference may still anticipate if that reference teaches that the disclosed components or functionalities may be combined and one of skill in the art would be able to implement the combination." *Blue Calypso, LLC., v. Groupon, Inc.*, 815 F.3d 1331, 1341-1344 (Fed. Cir. 2016); *see Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001).

In order to anticipate "a prior art reference must disclose all elements . . . within the four corners of the document." *Microsoft v. Biscotti*, 878 F.3d 1052, 1068 (Fed. Cir. 2017). Nonetheless, "[e]xtrinsic evidence 'may be used to interpret the allegedly anticipating reference and [to] shed light on what it would have meant to a [PHOSITA]." *Monsanto Technology LLC v. EI DuPont de Nemours and Company*, 878 F.3d 1336, 1345 (Fed. Cir. 2018) (quoting *Ciba-Geiby Corp. v. Alza Corp.*, 68 F.3d 487 (Fed. Cir. 1995).

A claim is unpatentable under 35 U.S.C. § 103 if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, objective evidence of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also "determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of prior art elements would have produced a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

B. Burden of Proof

In an *inter partes* review, the petitioner must show with particularity why each challenged claim is unpatentable. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016); 37 C.F.R. § 42.104(b). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

C. Level of Ordinary Skill in the Art

Factors pertinent to determining the level of ordinary skill in the art include (1) the educational level of the inventor; (2) the type of problems encountered in the art; (3) prior-art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the technology; and (6) the educational level of workers active in the field. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696–97 (Fed. Cir. 1983). Not all factors may exist in every case, and one or more of these or other factors may predominate in a particular case. *Id.* These factors are not exhaustive, but merely a guide to determining the level of ordinary skill in the art. *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). Moreover, the prior art itself may reflect an appropriate skill level. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

Petitioner contends that a person of ordinary skill in the art at the critical time would have possessed "at least an undergraduate degree in the pharmaceutical sciences, pharmacy, biochemistry, microbiology, or a related field, and a Masters in a similar field and at least 6 years industry experience or a Ph.D. in a similar field and at least 4 years industry experience in the field developing sterilization processes, sterile medical devices and/or formulations or tests for evaluating sterility." Pet. 15.

Patent Owner does not expressly offer its own definition of a person of ordinary skill in the art, but agrees with the definition we provided in our Institution Decision. Ex. 2023 ¶¶ 141–143 (Dr. Rutala agreeing with the definition provided in our Institution Decision); PO Resp. 15 (citing Dr. Rutala's testimony). The Institution Decision defined the person of ordinary skill as follows:

> [A] person of ordinary skill in the art at the time of the invention would have possessed at least an undergraduate degree in the pharmaceutical sciences, pharmacy, biochemistry, microbiology, or a related field, with experience with sterilization processes for medical products and their components, as well as familiarity with antiseptics such as chlorhexidine.

Inst. Dec. 19. Dr. Rutala adds one caveat – that the person of ordinary skill in the art would have had at least four years of relevant experience. Ex. 2023 ¶ 143.

As to Petitioner's proposed definition, Patent Owner contends that Petitioner's proposal "is disconnected from the disclosure of the 642 Patent as it requires no experience with antiseptics or chlorhexidine, but only a general awareness of 'sterilization processes, sterile medical devices and/or formulations or tests for evaluating sterility.'" PO Resp. 15 (citing Pet. 15). Patent Owner argues that "Petitioner also inflated the educational requirements to a Master's or PhD, but its expert conceded that only a Bachelor's was required." *Id.* (citing Ex. 2024, 42:10–15, 40:10–19). Although Patent Owner asserts that it prevails under either proposed skill level, it nonetheless argues that the definition of a person of ordinary skill in the art is important because a person of ordinary skill in the art "with familiarity with antiseptics and chlorhexidine and would be aware of the challenges facing practitioners." *Id.* at 16.

Patent Owner further contends "Dr. Dabbah is not a [person of ordinary skill in the art] and cannot adequately opine on what was known or obvious to a [person of ordinary skill in the art] about developing sterilized chlorhexidine product/articles." *Id.* at 16. Patent Owner concedes Dr. Dabbah is knowledgeable about sterilization generally, but argues that

Dr. Dabbah has no experience with antiseptics or CHG specifically, and therefore, cannot opine credibly as a person of ordinary skill in the art so his testimony should be disregarded. *Id.* at 17 (citing *Kyocera Senco Indus. Tools Inc. v. ITC*, 22 F.4th 1369, 1377–78 (Fed. Cir. 2022); *Flex-Rest, LLC v. Steelcase, Inc.*, 455 F.3d 1351, 1360-61 (Fed. Cir. 2006); *Schott Gemtron Corp. v. SSW Holding Co.*, IPR2013-00358, 2014 WL 4181969, at *10 (PTAB Aug 20, 2014) (Paper 106) ("[W]e accord the testimony . . . regarding the alleged obviousness of the claims less weight because he was not a [POSA] . . . ."); *see also* Tr. 39:1–13 ("And I'll point out to you the fact that [Dr. Dabbah] had never read any articles about chlorhexidine gluconate prior to this case. He never even heard of ChloraPrep prior to this case. So, how [h]e could opine about how it was so obvious to sterilize chlorhexidine gluconate. You know, I think that testimony is not provided."). According to Patent Owner, its own witness, Dr. Rutala, in contrast is a person of ordinary skill in the art and a "well-recognized expert on antiseptics including CHG and sterilization processing." *Id.* at 17 (citing Ex. 2023 ¶¶ 5–24; Ex. 2005, 4.)

Based on the entirety of the record, we determine that a person of ordinary skill in the art at the time of the invention would have possessed 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. Such level of skill in the art is consistent with the '642 patent and the asserted prior art of record.

Regarding Patent Owner's arguments that Dr. Dabbah is not a person of ordinary skill in the art and cannot adequately opine on what was known or obvious to a person of ordinary skill in the art about developing sterilized chlorhexidine product/articles, we first note Patent Owner did not file a Motion to Exclude Dr. Dabbah's testimony. *See* Tr. 39:19–26. As to Dr. Dabbah's qualifications, there can be no dispute that Dr. Dabbah meets the educational requirements set forth in our definition. Dr. Dabbah received a Bachelor's degree in Microbiology and Chemistry, a Masters in Dairy Microbiology, and a Ph.D. in Food Sciences and Biochemistry. Ex. 1003 ¶ 6. Nor can there be a reasonable dispute that Dr. Dabbah has at least four years of experience with sterilization processes for medical products and their components, as well as familiarity with antiseptics. *See* Ex. 1003, ¶¶ 6–17, 70, Appendix A (Dr. Dabbah's CV); Ex. 2024, 18:18–20:23 (Dr. Dabbah testifying regarding his educational and work experience, specifically that he had experience with "sterilization of . . . infant formula to validation of the process used in sterilization of those Similac products"), 22:22–23:16 (Dr. Dabbah testifying that he was personally involved in the steam and Eto sterilization processes for several products including medical devices); 37:19–38:1 (Dr. Dabbah testimony rejecting assertion that he lacked experience with antiseptics); 53:4–54:12 (Dr. Dabbah testifying regarding his familiarity with antiseptics). Accordingly, on this record as a whole, we do not agree with Patent Owner's position. Rather, we determine Dr. Dabbah qualifies as at least a person of ordinary skill in the art. Thus, we will consider his testimony in this proceeding.

III. ANALYSIS

A. Alleged Anticipation of Claims 1–3, 5–8, 10–18 and 20 by ChloraPrep PAR

Petitioner asserts that claims 1–3, 5–8, 10–18, and 20 are unpatentable as anticipated by the ChloraPrep PAR. Pet. 26–52. Patent Owner disagrees, arguing, *inter alia*, that ChloraPrep PAR does not disclose any of the elements recited in the independent claims. PO Resp. 23–30. Patent Owner also offers arguments with respect to the additional limitations recited in several of the independent claims. *Id.* at 30–36. And Patent Owner argues that the ChloraPrep PAR does not anticipate the challenged claims because it is not enabling. For the reasons discussed below, Petitioner has established by a preponderance of the evidence that the ChloraPrep PAR anticipates claims 1–3, 5–8, and 10–19 of the '642 patent.

1. Overview of ChloraPrep PAR (Exs. 1004, 1005)

ChloraPrep PAR is a Public Assessment Report for "ChloraPrep with Tint 2% w/v/70%v/v Cutaneous Solution," authored by the United Kingdom Medicines and Healthcare products Regulatory Agency ("MHRA").[4] Ex. 1005, 1. ChloraPrep PAR discloses that:

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[4] According to Petitioner:

> The UK MHRA is responsible for, *inter alia*, evaluating marketing authorization applications for drug products, and provides the basis for the authorization of medicines in the United Kingdom. Ex. 1020. In connection with this regulatory function, the MHRA publishes Public Assessment Reports ("PARs"), which include, Summaries of Product Characteristics ("SPCs") and Product Information Leaflets ("PILs"). These regulatory reports are published to memorialize the authorization of pharmaceutical drugs and

> The Medicines and Healthcare products Regulatory Agency (MHRA) granted Enturia Limited a Marketing Authorisation (licence) for the medicinal product ChloraPrep® with Tint 2%w/v/70%v/v Cutaneous Solution (PL 31760/0001. This is a general sales medicine (GSL) and is used to disinfect the skin and help prevent infections before invasive medical procedures such as injections, insertion of catheters and minor or major surgery.

Ex. 1005, 2.

ChloraPrep PAR begins with a "Lay Summary," which states that the ChloraPrep product "contains the active ingredients chlorhexidine gluconate 2%w/v and isopropyl alcohol 70% v/v" and goes on to state that "[t]his is a new combination of two well-known antiseptic agents." Ex. 1005, 2. According to ChloraPrep PAR, "[t]he rationale for development of a fixed combination product containing 2% chlorhexidine gluconate and 70% isopropyl alcohol was to develop an antiseptic with rapid onset and long lasting activity against potential pathogens." *Id.*

ChloraPrep PAR contains a figure within the section titled "Summary of Product Characteristics" ("SPC") (*id.* at 5–8) that depicts three different forms of applicators for the ChloraPrep product each dispensing a different volume of the chlorhexidine gluconate/isopropyl alcohol solution. *Id.* at 5. The figure is reproduced below:

> medical devices and disclose the MHRA's reasoning and approval process.

Pet. 17.

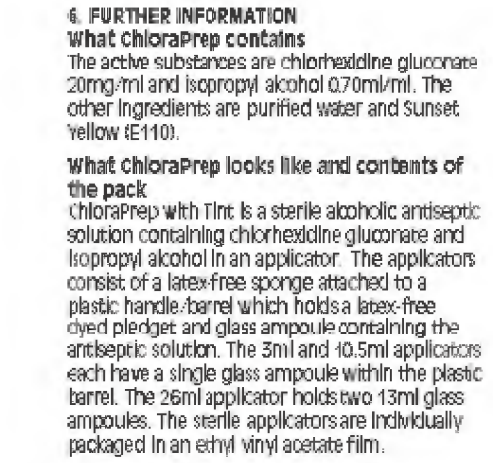
Applicator	Maximum Coverage Area (cm x cm)	For Procedures such as:
3 ml 	15 x 15	- Midline & Central Venous Catheter (CVC) insertion and maintenance - Peritoneal dialysis site cleansing
10.5 ml 	25 x 30	- Minor and major surgical procedures - Implantable device placement - Prosthetic device placement or removal - Midline, Peripheral Intravascular Central Catheter (PICC) & CVC insertion and maintenance - Cardiac catheterisation and Cardiac Cath Lab procedures - Interventional Radiology procedure
26 ml 	50 x 50	

Id. The above figure is a table in which the left column identifies three sizes of applicators, the middle column identifies the "Maximum Coverage Area" for each size of applicator, and the right column identifies procedures in which the differently sized applicators can be used. *Id.* The three sizes of applicator are 3 ml, 10.5 ml, and 26 ml. *Id.* "The 3 ml and 10.5 ml applicators each have a single glass ampoule within the plastic barrel. The 26 ml applicator holds two 13 ml glass ampoules." *Id.* at 7. ChloraPrep PAR states that "[t]he applicator is removed from the wrapper and held with the sponge facing downward. The applicator is squeezed gently to break the ampoule containing the antiseptic solution, which is released onto the sponge in a controlled flow." *Id.* at 5.

ChloraPrep PAR discloses that the pharmaceutical composition contains 20mg/ml of chlorhexidine gluconate and 0.70ml/ml of isopropyl alcohol as well as the excipient, "Sunset Yellow." *Id.* at 5, 7. According to ChloraPrep PAR, "ChloraPrep with Tint is a sterile alcoholic antiseptic

solution" in which "[t]he sterile applicators are individually packaged in an ethyl vinyl acetate film." *Id.* at 7. ChloraPrep PAR instructs users to "[s]tore in the original packaging; applicator is sterile unless seal is broken." *Id.*

ChloraPrep PAR also includes the Product Information Leaflet ("PIL") for the product, which describes the CHG composition as a "sterile alcoholic antiseptic solution containing chlorhexidine gluconate and isopropyl alcohol in an applicator" as shown in the figure reproduced below:



6. FURTHER INFORMATION

What ChloraPrep contains

The active substances are chlorhexidine gluconate 20mg/ml and isopropyl alcohol 0.70ml/ml. The other ingredients are purified water and Sunset Yellow (E110).

What ChloraPrep looks like and contents of the pack

ChloraPrep with Tint is a sterile alcoholic antiseptic solution containing chlorhexidine gluconate and isopropyl alcohol in an applicator. The applicators consist of a latex-free sponge attached to a plastic handle/barrel which holds a latex-free dyed pledget and glass ampoule containing the antiseptic solution. The 3ml and 10.5ml applicators each have a single glass ampoule within the plastic barrel. The 26ml applicator holds two 13ml glass ampoules. The sterile applicators are individually packaged in an ethyl vinyl acetate film.

Ex. 1005, 10. The Figure reproduced above is an excerpt from the product packaging describing "[w]hat ChloraPrep contains," "[w]hat ChlorPrep looks like," and the "contents of the pack." *Id.*

2. *Analysis of Independent Claim 1*

a) preamble "a sterilized chlorhexidine product for topical disinfection, said sterilized chlorhexidine product comprising"

Claim 1 recites as its preamble "a sterilized chlorhexidine product for topical disinfection." Ex. 1001, 27:25–26. Petitioner contends that, to the extent the preamble is limiting, the ChloraPrep PAR discloses the elements of the preamble. Pet. 27. More specifically, Petitioner contends that "[t]he sterile applicators and sterile CHG and isopropyl alcohol solution form a

sterilized chlorhexidine product." *Id.* at 28. As support, Petitioner points to the Product Information Leaflet ("PIL") included in the ChloraPrep PAR, which "states that the '[t]he sterile applicators are individually packaged in an ethyl vinyl acetate film.'" *Id.* According to Petitioner, a skilled artisan would know that ethyl vinyl acetate "is a common material used in medical packaging to ensure that the contents of the packaging remain sterile." *Id.* at 28 (citing Ex. 1005, 10, Ex. 1035 ¶¶ 11–13). Petitioner then argues that the statement in the ChloraPrep PAR that the "applicator is sterile unless seal is broken" confirms that the purpose of the ethyl vinyl acetate is to keep the contents of the packaging sterile. *Id.* (citing Ex. 1005, 7); *see also, id.* at 27 (quoting the statement in ChloraPrep PAR that "ChloraPrep with Tint . . . is sterile until the packaging is opened").

Patent Owner acknowledges the statements in the ChloraPrep PAR teaching that the CHG solution and the applicator are sterile, but argues that these statements "describe the solution (limitation 1.a) and the applicator (limitation 1.b), not the product that comprises them and a [person of ordinary skill in the art] would not understand [them] to teach that the product itself is sterilized." PO Resp. 24. Patent Owner disputes Petitioner's assertion that both "[t]he sterile applicators and sterile CHG . . . solution form a sterilized chlorhexidine product," arguing that "this combination does not establish that the product itself is sterile or sterilized." *Id.* at 24–25. Patent Owner also cites a ChloraPrep Frequently Asked Questions document ("the FAQ") from 2015 addressing questions regarding Petitioner's ChloraPrep label change, which Patent Owner contends "proves" that there is a distinction between a sterilized product and a sterilized component of that product. *Id.* (citing statement in Ex. 2006 that

"though all ChloraPrep applicators are sterilized . . . , the solution inside . . . is not sterile."). Finally, Patent Owner argues that "Petitioner does not explain how the PAR discloses that its sterilization process can be validated," as required by the Board's claim construction. *Id.* at 25.

For the reasons discussed below, Petitioner has established by a preponderance of the evidence that the ChloraPrep PAR discloses "a sterilized chlorhexidine product for topical disinfection."[5] We do not agree with Patent Owner's arguments to the contrary.

We begin our analysis by considering the disclosure of the ChloraPrep PAR itself. The ChloraPrep PAR states: "ChloraPrep with Tint is for single use only and is sterile until the packaging is opened." Ex. 1005, 10. The ChloraPrep PAR defines "ChloraPrep with Tint" as "a sterile alcoholic antiseptic solution . . . in an applicator." *Id.* at 7. It then defines the applicator as consisting of "a latex-free sponge attached to a plastic handle/barrel which holds a latex-free dyed pledget and glass ampoule containing the antiseptic solution" – i.e. the entire product other than the antiseptic solution. *Id.* Thus, the ChloraPrep PAR defines "ChloraPrep with Tint" as being the entire product (applicator plus antiseptic solution). *Id.* In addition, "ChloraPrep with Tint" is the name of the product described in the ChloraPrep PAR. *Id.* at 1 (identifying the product as "ChloraPrep with Tint 2% w/v/70% v/v Cutaneous Solution"), 10 (teaching that "[t]his medicinal product is "authorised in the Member States of the EEA under the following names: . . . UK – ChloraPrep with Tint"). For these reasons, we

[5] We do not determine whether the preamble is limiting because, regardless of whether the preamble is limiting, Petitioner has shown that the recitation in the preamble is satisfied by the prior art.

find that a person of ordinary skill in the art would have understood the phrase "ChloraPrep with Tint" as used in the ChloraPrep PAR to refer to the entire product. Thus, based on the disclosure of the ChloraPrep PAR, a person of ordinary skill in the art would have understood "ChloraPrep with Tint . . . is sterile until the packaging is opened," to mean that the entire product is sterile until the package is open.

This finding is supported by the teaching that ChloraPrep is "packaged in an ethyl vinyl acetate film." *Id.* In this regard, we credit the testimony of Dr. Dabbah that a person of ordinary skill in the art would know that ethyl vinyl acetate "is a common material used in medical packaging to ensure that the contents of the package remain sterile." Ex. 1003 ¶ 94.

Our finding that the entire ChloraPrep with Tint product has been sterilized is supported further by what Chiang[6] teaches was known about the "ChloraPrep® applicator, provided by CareFusion." Chiang teaches that it is necessary to sterilize the exterior of the applicator for skin antiseptic applicator devices, but that doing so may compromise the antiseptic solution. Chiang explains:

> One of the challenges associated with using such skin antiseptic compositions is the need to sterilize the exterior of the applicator while minimizing potential byproducts that may be produced when the composition is exposed to sterilization compounds such as ethylene oxide gas. Reactive sterilants such as ethylene oxide may react with the active antimicrobial agent or with other components in the skin antiseptic composition, altering the potency or producing potentially toxic compounds.

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[6] Chiang et al., U.S. Patent Publication No. 2014/0371695 A1, published Dec. 18, 2014 ("Chiang," Ex. 2015).

Ex. 2015 ¶ 9.

Chiang teaches that "ChloraPrep® applicator, provided by CareFusion" solves this problem by using a glass ampule to protect its antiseptic from the ethylene oxide gas used during the sterilization process:

> To address this problem, various solutions have been proposed. For example, the 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. CareFusion has a number of patents and patent applications including: U.S. Pat. Nos. 5,772,346 and 5,752,363 and U.S. Application Publication No. 2012/003029. Each of these teach the use of a sealed glass ampule containing CHG inside a skin antiseptic applicator.

Id. ¶ 10. Thus, Chiang teaches that the ChloraPrep® applicator uses a glass ampule to protect CHG from the ethylene oxide used to sterilize the exterior of the applicator.

Chiang's disclosure is consistent with Dr. Rutala's testimony on terminal sterilization. "Terminal sterilization" is a common process where a product is placed "in some type of packaging such that the sterilant permeates and sterilizes the internal item, but the packaging prevents microorganisms from contaminating that internal item." Ex. 1040, 190:6–20 (Dr. Rutala's testimony). According to Dr. Rutala, one way to conduct terminal sterilization is using ethylene oxide in conjunction with a gas-permeable packaging. *Id.* at 141:18–143:6; *see also* 147:10–11 ("[A]s I alluded to, ethylene oxide is a sterilization process."). Furthermore, Dr. Rutala explains that "most plastics are permeable" and "it is not a far

stretch to believe that ethylene oxide permeates and is permeable to . . . ethylene-vinyl acetate." *Id.* at 145:2–147:21.

We find that the disclosure of Chiang reflects the knowledge of a person of ordinary skill in the art at the time of the alleged invention. *See* Ex. 2023 ¶ 206 (testimony of Dr. Rutala that "Chiang set forth the prevailing knowledge that 'In the ChloraPrep® applicator, the sealed glass ampule protects the CHG composition during the sterilization process from ethylene oxide penetration which would otherwise compromise the efficacy of the antiseptic composition"); *see also* Ex. 1003 ¶ 138 (testimony of Dr. Dabbah that "sterilization of the applicator via ETO and other sterilization processes was a well-known and routine process for a POSA"). Chiang thus reinforces our finding that the ChloraPrep PAR discloses sterilization of the entire ChloraPrep with Tint product by teaching how that sterilization is achieved: by using the combination of ETO and ethylene vinyl acetate ("EVA") to sterilize the applicator, while relying on the glass ampule to protect the CHG from degradation caused by the ETO.

Patent Owner does not specifically discuss Chiang, but argues that Petitioner "manufactures a new theory that the PAR discloses 'the entire product is sterile' because 'a POSA would understand . . . that . . . ethyl [sic] oxide gas ('ETO')' would penetrate 'EVA film' packaging." Sur-reply 9. According to Patent Owner, "the Petition never asserted the 'entire product' was sterile (only the applicator and solution)." *Id.* We do not agree.

The Petition directs us to the teaching in the ChloraPrep PAR that "ChloraPrep with Tint . . . is sterile until the packaging is opened" as well as the teaching that the applicators are "individually packaged in an ethyl vinyl acetate film." Pet. 27. The Petition also asserts that ethyl vinyl acetate is "a

common material used in medical packaging to ensure that the contents of the package remain sterile." *Id.* at 28. From this, we understand the Petition to assert that everything contained in ChloraPrep PAR's ethyl vinyl acetate packaging – i.e., the entire ChloraPrep with Tint product – had been sterilized. As to the use of ethylene oxide gas to achieve sterilization, in arguing that ChloraPrep PAR was enabled, the Petition asserts that "sterilization of the applicator via, for instance, ETO was a well-known and routine process." *Id.* at 52.

We now consider how a person of ordinary skill in the art at the critical time would have understood the term "sterile" as used in the ChloraPrep PAR. The evidence of record supports that a person of ordinary skill in the art would understand the term "sterile" as used in a U.K. regulatory document, like the ChloraPrep PAR, to mean "sterilized," as we have construed that term here. Ex. 1003 ¶ 91 (Dr. Dabbah testimony that "using the term 'sterile' [in] a regulatory approval of a medical device means unequivocally that the product has been sterilized"). We credit the testimony of Dr. Dabbah, who explains, "[t]he use of the term sterile in that strict regulatory context is a term with a precise meaning." Ex. 1003 ¶ 130.[7] According to Dr. Dabbah, a person of ordinary skill in the art would have

[7] Dr. Dabbah's testimony at paragraphs 129–134 addresses limitations in dependent claims 10 and 20 requiring a particular sterility assurance level. Both claims remain at issue, requiring us to consider the testimony. Although not necessary to support our factual findings with respect to claim 1, we find it helpful to consider and discuss this testimony here as it relates directly to, and further supports, our findings. For completeness, and because they also relate directly to our findings with respect to claim 1, we also consider and discuss here, the arguments made by Patent Owner in response to this testimony.

understood the term "sterile" in a regulatory document to "unequivocally disclose[] a SAL [sterility assurance level][8] from 10^{-3} to 10^{-9} to a POSA." *Id.* That is because BS EN-556-1, the applicable regulatory standard, "specifies a probability of a viable microorganism on a device of 10^{-6} or less (e.g. 10^{-7}, et seq.) which must be achieved in order to designate a terminally sterilized medical device as 'sterile,' particularly in such a regulatory document." *Id.* ¶ 131; Ex. 1017, 8 (BS EN 556-1, stating: "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 x 10^{-6}."). We credit Dr. Dabbah's testimony (Ex. 1003 ¶¶ 91, 129–134) and find that a person of ordinary skill in the art would have understood that the product described in the ChloraPrep PAR was required to comply with applicable standards, including BS EN-556-1, and thus a person of ordinary skill in the art would have understood the term "sterile" as used in the ChloraPrep PAR to require a SAL of 10^{-6}.

Patent Owner seeks to undermine the argument that a person of ordinary skill in the art would have understood that the product described in the ChloraPrep PAR needed to comply with applicable regulations by arguing that "Petitioner's declarants conceded that 'ChloraPrep is regulated as a medicinal product' and did not know if BS EN 556-1 was followed." Sur-reply 15. We find these arguments misleading and unpersuasive.

Patent Owner is correct that Petitioner's declarants, Messrs. Noble-Clark and McGinley, testified that ChloraPrep is regulated as a medicinal product. Ex. 2044, 40:1–7; Ex. 2045, 44:1–6. But that does not preclude

[8] A "sterility assurance level" or "SAL" refers to "[t]he probability of survival of a single microorganism." Ex. 1003 ¶ 132.

that ChoraPrep was also regulated as a medical device. Indeed, Mr. McGinley testified that ChloraPrep was subject to multiple sets of regulations:

> As part of my work, I am aware of the British Standard corresponding to EN556-1, which establishes the requirements for labeling a medical device as "STERILE." I understand from my work that during the initial discussions for licensing the ChloraPrep UK products that the MHRA required that the ChloraPrep UK products, including the CHG solution, be sterilized to a SAL of 10^{-6}, ***consistent with the requirements of the EC Guidelines of Good Manufacturing Practice (1990) and the Ph. Eur 5.1.1*** (copies of which are attached as Exs. 1048-1049 from BD's files) ***which apply to medicinal products, as well as EN556-1[,] which was used to validate the sterility of the complete device.***

Ex. 1038 ¶ 16 (emphasis added). Accordingly, the testimony of Petitioner's declarants that ChloraPrep was regulated as a medicinal product supports a finding that BS EN 556-1 was applicable to ChloraPrep with Tint, particularly when considered together with the repeated testimony from multiple sources to the same effect. *See e.g., id.*; Ex. 1037 ¶ 4; Ex. 1003 ¶ 131.

As to Patent Owner's argument that Petitioner's declarant was unaware whether BS EN 556-1 was followed, we find Patent Owner to have unfairly interpreted Mr. McGinley's deposition testimony. Mr. McGinley was asked: "Do you know whether compliance with British Standard EN556-1 is documented anywhere in the dossier application for ChloraPrep with Tint?" And he responded: "Sitting here right now, I'm not in a position to say whether that specific reference was included within the dossier itself." Ex. 2045, 118:8–14 (cited at Sur-reply 15). Being unable to say whether compliance with BS EN 556-1 was documented in a particular dossier is a

far cry from being unable to say whether BS EN 556-1 was "followed." Moreover, in his declaration, Mr. McGinley unequivocally testified that ChloraPrep with Tint was sterilized in a manner "consistent" with BS EN 556-1. Ex. 1038 ¶ 16. Particularly in view of this declaration testimony, we find Patent Owner's interpretation of Mr. McGinley's deposition testimony unhelpful and unpersuasive.

Patent Owner also raises three arguments in connection with dependent claims 10 and 20 that warrant consideration here because they relate to whether BS EN 556-1 applies to the ChloraPrep PAR. First, Patent Owner argues: "Petitioner provides no evidence that any 'British Standard' . . . – including BSEN556-1 directed to 'medical devices' – governs the use of the term 'sterile' in a PAR relating to topical CHG products. PO Resp. 34. Patent Owner notes that the British Standard Institution ("BSI")[9] states that its "[s]tandards are voluntary in that they are tools devised for the convenience of those who wish to use them." *Id.* at 34–35 (citing Ex. 2037; Ex. 2038; Ex. 2023 ¶¶ 287–292). We do not agree with this argument.

Petitioner provides the testimony of multiple witnesses whose testimony supports that BS EN 556-1 applied to the ChloraPrep PAR and that compliance with that standard was "required." Ex. 1038 ¶ 16 (testimony of Mr. McGinley); Ex. 1037 ¶ 4 (Noble-Clarke testimony); Ex. 1003 ¶ 131 (testimony of Dr. Dabbah). And BS EN 556–1 itself repeatedly uses mandatory language in connection with its sterilization standards. *See, e.g.*, Ex. 1017, 1 ("Sterilization of medical devices – ***Requirements*** for medical devices to be designated 'STERILE'"; "Part 1:

[9] According to Dr. Rutala, BSI is the organization that publishes the British Standards, which include BS EN 556-1. Ex. 2023 ¶ 288.

Requirements for terminally sterilized medical devices"), 3 (same), 6 ("European Standards for *medical devices* ***require***, when it is necessary to supply a *sterile* product item, that adventitious microbiological contamination of a *medical device* from all sources is minimized by all practical means"; "This European Standard specifies the ***requirements*** for a terminally-sterilized *medical device* to be designated '*STERILE.* '), 8 (section heading "***Requirements***" setting forth the standard that "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 $x10^{-6}$.") (bolded emphasis added).

We recognize that the British Standards Institution website states that the "[s]tandards are voluntary in that they are tools devised for the convenience of those who wish to use them." Ex. 2037. We also acknowledge Dr. Rutala's opinion that Dr. Dabbah has not shown that the ChloraPrep PAR was required to comply with BS EN 556-1. Ex. 2023 ¶ 292. To the extent this evidence conflicts with the evidence provided by Petitioner that compliance was required, we find Petitioner's evidence more persuasive. In this regard, we credit the testimony Dr. Dabbah, and Messrs. Noble-Clarke and McGinley as well as the evidence provided by BS EN 556-1 itself over the evidence provided by Patent Owner on this topic.

Second, Patent Owner argues that BS EN 556-1 "defines 'Medical Device' to exclude products that 'achieve [their] principal intended action in or on the human body by pharmacological . . . means.'" PO Resp. at 35. Patent Owner also argues that the ChloraPrep PAR "identifies ChloaPrep as a 'medicinal product' – not a 'medical device.'" *Id.* (internal citation to Ex. 1005, 2 omitted). And Patent Owner argues that the MHRA classifies

chlorhexidine topical antiseptics as 'medicinal products' – not 'medical devices.'" *Id.* (citing Ex. 2039, 48–50; Ex. 2023 ¶¶ 296–297). We do not find these arguments compelling.

As discussed above, multiple witnesses testify that BS EN 556-1 applied to the ChloraPrep PAR. We credit these witnesses over Patent Owner's interpretation of BS EN 556-1. Moreover, we do not read BS EN 556-1 to exclude the ChloraPrep PAR. Although Patent Owner is correct that BS EN 556-1 defines "medical device" to exclude devices that "achieve [their] principal intended action in or on the human body by pharmacological, immunological or metabolic means," BS EN 556-1 expressly includes within its definition, devices which are "assisted in [their] function by such means." Ex. 1017, 7. To the extent ChloraPrep PAR's CHG composition is considered to be pharmacological means, we find that the CHG composition assists the applicator in its function, and thus we find the product described in the ChloraPrep PAR falls within the scope of BS EN 556-1. As to Patent Owner's argument that the ChloraPrep PAR identifies and the MHRA classifies ChloraPrep as a "medicinal product," as discussed above, we find that this does not preclude it also being subject to standards for medical devices.

Third, Patent Owner argues that "BS EN 556-1 states that the medical device can be designated 'sterile' if it is 'terminally-sterilized' (Part 1) or 'aseptically processed' (Part 2)." PO Resp. 36 (citing Ex. 1017, 6). This is significant, Patent Owner argues, because Part 2 of the BSI "states that aseptically-processed products can include unsterilized components." *Id.*

We do not agree with this argument because Petitioner provides testimony from multiple witnesses that BS EN 556-1 applies to the

ChloraPrep PAR and Patent Owner does not direct us to any evidence that BS EN 556-2, i.e., Part 2, applies. Moreover, based on our review of BS EN 556-2, it does not appear to apply to the ChloraPrep PAR. BS EN 556-2 states:

> Medical devices designated "STERILE" are prepared using appropriate and validated methods. Whenever possible, sterile medical devices are terminally-sterilized using a properly validated and controlled sterilization process (see EN 556-1, EN 550, EN 552, EN 554 and EN ISO 14937). When a medical device is intended to be sterile but cannot be terminally-sterilized, aseptic processing is the method of manufacture (see EN 13824 and EN ISO 14160).

Ex. 2013, 6. Thus, BS EN 556-2 only applies when a medical device "is intended to be sterile but cannot be terminally-sterilized." Here, there is no evidence that ChloraPrep PAR cannot be terminally sterilized. Indeed, as discussed *supra,* the evidence is to the contrary.

With respect to Patent Owner's argument that the Petitioner has not shown that the sterility of ChloraPrep with Tint has been validated, we note that Petitioner has shown that BS EN 556-1 required products to have a particular SAL. On cross-examination, Dr. Rutala conceded that "you have to have a validated sterility process to have a sterility assurance level." Ex. 1043, 159:20–25. This supports that a person of ordinary skill in the art would have understood the ChloraPrep PAR to disclose a product with a validated sterility process. *Id.*; *see also* Ex. 1003 ¶¶ 129–134 (Dr. Dabbah testimony on use of the word "sterile" in a regulatory context as requiring a specific SAL); Ex. 1017, 6 (BS EN 556-1, stating: "designation of a medical device as *"STERILE"* is only permissible when a validated sterilization process has been applied."); 2013, 6 (BS EN 556-2, stating: "Medical

devices designated 'STERILE' are prepared using appropriate and validated methods.").

b) "sterilized chlorhexidine gluconate composition"

Claim 1 recites a "sterilized chlorhexidine gluconate composition." Ex. 1001, 27:27. Petitioner contends ChloraPrep PAR discloses this limitation. Pet. 28 (citing Ex. 1003 ¶ 95). According to Petitioner ChloraPrep PAR's "Module 2 . . . describes . . . in Section 6.5 ('Nature and contents of container'), that the solution is sterile: 'ChloraPrep with Tint is a ***sterile*** alcoholic antiseptic solution containing chlorhexidine gluconate and isopropyl alcohol in an applicator." *Id.* at 29 (citing Ex. 1005, 7; Ex. 1003 ¶ 95; Ex. 1001, 16:25-29). In addition, Petitioner points to ChloraPrep PAR's Product Information Leaflet ("PIL"), which, like Module 2, Section 6.5, describes the chlorhexidine gluconate composition as a "sterile alcoholic antiseptic solution containing chlorhexidine gluconate and isopropyl alcohol in an applicator." *Id.* (citing Ex. 1005, 10). Petitioner then argues that ChloraPrep PAR's Module 5 includes a "discussion regarding the acceptance and validation of the methods for manufacturing the sterile CHG solution and applicator, further confirming the validated sterility of the device and solution." *Id.*

As discussed above, Patent Owner argues the phrase "a sterilized chlorhexidine gluconate composition" means the "component or composition has been subjected to a suitable sterilization process such that sterility can be validated." PO Resp. 17–20; *see* § II.C, *supra*. Based on this construction, Patent Owner contends the description "sterile" is not the same as "sterilized." PO Resp. 21–22. Patent Owner argues:

> While the PAR refers to "a sterile alcoholic antiseptic solution . . . in an applicator," the word "sterile" had questionable meaning as used with regard to antiseptics in 2010, particularly given the ChloraPrep label change described in 2015 that clarified the product previously labelled as "sterile" was in fact "nonsterile." (*Id.*; Ex. 2006; Ex. 2009, 26, 34, 43, 50, 57.) Thus, the PAR's use of the word "sterile" at that time did not teach that ChloraPrep or its CHG composition were sterilized or that it could contain, deliver, and apply the sterilized composition.
>
> Nothing in the PAR suggests to a POSA that it is describing anything other than an antiseptic capable of acting as an antimicrobial. (Rutala¶176.) That is particularly true since, as the Board recognized, Petitioner cites no prior art describing any known methods of sterilizing chlorhexidine gluconate as of 2010. (Dec. 33; §II.C.; Rutala¶¶172-175.) Indeed, the public knowledge well after 2010 was that, "[i]n the ChloraPrep® applicator, the sealed glass ampule protects the CHG composition during the sterilization process . . . which could otherwise compromise the efficacy of the antiseptic composition" and "the solution inside of the [ChloraPrep] applicators is not treated with a separate sterilization process and, therefore, is not sterile." (*Id.*; Ex. 2015, ¶10; Ex. 2006, 1.)

Id. at 22–23. Patent Owner cites to the FAQ to support its position. PO Resp. 25–26 (citing Ex. 2006). The FAQ document discloses: "[t]hough all ChloraPrep applicators are sterilized at the end of the manufacturing process, the solution inside of the applicators is not treated with a separate sterilization process and, therefore, is not sterile." Ex. 2006, 1. Thus, Patent Owner argues "nothing in the PAR teaches that the solution is sterilized" and, more specifically, "[t]here is no disclosure of exposing any component of the product to a suitable sterilization process such that sterility can be validated." PO Resp. 26. Finally, Patent Owner argues that "Petitioner

failed to show that the CHG composition had been subjected to validated sterility processing." *Id.* at 27.

In determining whether the ChloraPrep PAR discloses "a sterilized chlorahexidine gluconate composition," we begin our analysis with the document itself. The ChloraPrep PAR states that its antiseptic is "a sterile alcoholic antiseptic solution containing chlorhexidine gluconate and isopropyl alcohol." Ex. 1005, 7; *see also id.* at 10 (same). This strongly supports that the solution is sterilized. In this regard, we credit the testimony of Dr. Dabbah, who states:

> Based on my extensive expertise with both the development of international standards for sterile products and sterilization, and my regulatory experience complying with the same, using the term 'sterile' to a regulatory approval of a medical device means unequivocally that the product has been sterilized.

Ex. 1003 ¶ 91; *see also id.* ¶¶ 129–134. For the reasons discussed, *supra* § III.A.2.a., we find that a person of ordinary skill in the art would have understood BS EN 556-2 to apply to the ChloraPrep PAR and we do not agree with Patent Owner's arguments to the contrary. The totality of the evidence supports that a person of ordinary skill in the art would have understood the ChlorPrep PAR described the "alcoholic antiseptic solution" as being sterilized, as claimed.

In addition to teaching that the antiseptic solution is sterilized, the ChloraPrep PAR separately states that the applicators are "sterile." Ex. 1005, 7 ("The sterile applicators are individually packaged in ethyl vinyl acetate."), 10 (same). By separately describing "a sterile alcoholic antiseptic solution" and "sterile applicators," the ChloraPrep PAR suggests that each

component – the antiseptic solution and the applicators – has been separately sterilized. This also supports that the solution has been sterilized.

Patent Owner and Dr. Rutala cite the FAQ to support that "the word 'sterile' had questionable meaning as used with regard to antiseptics in 2010, particularly given the ChloraPrep label change described in 2015 that clarified the product previously labelled as 'sterile' was in fact 'nonsterile.'" PO Resp. 22. Thus, according to Patent Owner, a person of ordinary skill in the art would have understood that the CHG solution disclosed in the ChloraPrep PAR is not sterilized. PO Resp. 26 (citing Ex. 2006 (the FAQ); Ex. 2023 ¶¶ 206–208 (Dr. Rutala's testimony, which cites Ex. 2006)). While this argument has some superficial appeal, we do not agree with it when considering the FAQ in the context of known differences between products and regulations in the U.S. and in Europe.

The FAQ was generated after the U.S. Food and Drug Administration ("FDA") requested that "all manufacturers . . . voluntarily revise the product labels for topical antiseptics to indicate whether the drug is manufactured as a sterile or nonsterile product." Ex. 2006, 1. "CareFusion adhered to the request and submitted revised labeling to the FDA." *Id.* In connection with this label change, CareFusion issued a document responding to frequently asked questions, like: "Why is CareFusion updating the ChloraPrep® label to state 'nonsterile solution?'" *Id.*

The FAQ includes several statements that support that the antiseptic solution in the product that was the subject of the label update is not sterilized. For example, the FAQ states: "Though all ChloraPrep applicators are sterilized at the end of the manufacturing process, the solution inside of the applicators is not treated with a separate sterilization process and,

therefore, is not sterile." Ex. 2006, 1. And the FAQ states "[c]urrently, sterile chlorhexidine gluconate-based products are not available because an efficient method does not exist to sterilize these antiseptic solutions on a large scale and within a time frame that meets customer demand." *Id.*[10]

Importantly, however, the FAQ is directed to a product marketed in the United States. Ex. 2006, 1 (explaining that revised label was responsive to request from the U.S. Food and Drug Administration). In contrast, the ChloraPrep PAR is a regulatory filing by the MHRA concerning authorization to market ChloraPrep with Tint in the United Kingdom. Ex. 1005, 1 (identifying "UK licence no: PL 31760/0001"), 10 (stating that the "[t]his medicinal product is authorized in the Member States of the EEA under the following names: . . . UK – ChloraPrep with Tint"), 14 (identifying the United Kingdom as the "Reference Member State" for the marketing authorization).

The distinction between the U.S. ChloraPrep product and the U.K's ChloraPrep product is significant because, as Degala teaches, the U.S. and European Union countries have different regulations regarding sterilization

[10] The FAQ also states: "Unless a product says 'sterile solution' on the label, health care professionals should be aware that they are using a nonsterile solution product." Ex. 2006, 1. This suggests that if a product is labeled "sterile solution," the solution is sterile. In this regard, we note that the CloraPrep PAR states that the product has a "sterile solution" but the pre-label change packaging for the U.S. ChloraPrep product does not. *Compare* Ex. 1006, 7, 10 (U.K. packaging disclosing a "sterile alcoholic antiseptic solution"), *with* Ex. 2009 (U.S. pre-label change packaging, stating "sterile" and stating "[a]pplicator is sterile if package is intact," but not separately calling out the solution as "sterile").

requirements and, a CareFusion product with sterilized CHG is manufactured for EU countries:

> In the United States there are currently no regulations regarding the sterilization requirements of topical antiseptic solutions. Therefore, antiseptic solutions currently sold in the United States generally do not undergo a sterilization process. In other jurisdictions, however, such as European Union (EU) countries, some degree of sterilization is required. A 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.

Ex. 1007 ¶ 2. Patent Owner argues that this statement "has no bearing on 'sterile' in the [ChloraPrep] PAR" because "[t]here is no evidence that anyone in the public (including Dr. Dabbah) knew of any 'sterilized' ChloraPrep UK product or UK requirement about sterilizing CHG" and Petitioner "never contended that a POSA would be a UK regulatory expert versed in ChloraPrep." Sur-reply. 13–14. We disagree.

Degala itself teaches that the chlorhexidine gluconate in a product made by CareFusion Corp, and matching the description of the product described in the ChloraPrep PAR, "is sterilized for EU countries." *Compare* Ex. 1007 ¶ 2 (disclosing antiseptic solution containing 2% w/v chlorhexidine gluconate in 70% v/v isopropanol in water), *with* Ex. 1005, 5 (disclosing antiseptic solution containing "[c]hlorhexidine gluconate 20mg/ml" and "[i]sopropyl alcohol 0.70ml/ml"). And, two of Petitioner's employees confirm that the version of the CloraPrep product sold in the U.K. had sterilized chlorhexidine gluconate. Ex. 1037 ¶¶ 2, 7 (testimony from Simon Noble-Clarke, the person who was "primarily responsible for the ChloraPrep product line as sold in the UK/Ireland," that "the ChloraPrep UK product,

unlike the US product was fully sterilized, including both the solution and the complete product"); Ex. 1038 ¶¶ 3, 4, 6, 10 (testimony of Christopher McGinley, who helped to support ChloraPrep products as sold in the US and as sold under license from the MHRA in the UK and EU, that "the CHG solution in the ChloraPrep UK product is sterilized to a SAL of 10^{-6} and has been since it was first sold in the UK" and that "the CHG solution in the ChloraPrep US products was not sterilized, nor was it required by the FDA to be sterilized."). [11] Finally, in response to questions at an FDA hearing about sterile chlorhexidine gluconate products that were available overseas, Timothy P. Manthei, who is listed as an inventor of the '642 patent, admitted to having heard of such a product, responding "I have heard that, that there's a formulation out there, but I don't know what it is, or how it's used, or how they got to sterilization." Ex. 1044, 41; Ex. 1001 code (72). Accordingly, the record supports that information about a product with a sterilized CHG composition was available to and known by the public, and a POSA considering the ChloraPrep PAR would have known this.

As to Patent Owner's attempt to discount the difference in regulatory regimes between the U.S. and the U.K. by arguing that "Petitioner never contended that a POSA would be a UK regulatory expert," we have already found that a person of ordinary skill in the art would have understood that the product described in the ChloraPrep PAR was required to comply with

[11] We do not agree with Patent Owner's argument that Messrs. Noble-Clark and McGinley lacked personal knowledge of the pertinent facts. Sur-reply 11 n.6. Both witnesses were employed in roles that we expect would provide them personal knowledge as to whether the CHG solution in the UK ChloraPrep product was separately sterilized during the relevant time period. Ex. 1037 ¶¶ 1–3; Ex. 1038 ¶¶ 1–4, 6.

applicable standards, including BS EN-556-1. *See supra* § III.A.2.a. We credit the testimony of Dr. Dabbah that a person of ordinary skill in the art would have been "very familiar" with processes for validating the sterility of various products to industry standards and "would consider them routine." Ex. 1003 ¶ 71. Implicit in developing these processes for validating sterility is an understanding of what the standards require in order to establish sterility. *Id.* We further credit the testimony of Dr. Dabbah that a person of ordinary skill in the art would "immediately understand . . . that U.K. and European standards for SAL applied to the *ChloraPrep PAR*." *Id.* ¶ 133; *see also* Ex. 1040, 199:24–200:18 (Dr. Rutala testimony that "I would agree that it's likely that a POSA would be aware of ISO standards. And likely, they would be aware of the ISO standards for steam sterilization or moist heat as well as ethylene oxide, dry heat.").

Moreover, both parties agree that a person of ordinary skill in the art would have at least four years of industry experience. Pet. 15; PO Resp. 15; Ex. 2023 ¶ 143. Our definition of the POSA reflects this. *See supra* § II.D. We find 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.

Accordingly, we do not agree with Patent Owner's argument that a person of ordinary skill in the art would have understood the word "sterile" as used with regard to antiseptics in the ChloraPrep PAR to have "questionable meaning" in view of the U.S. label change. We find that a person of ordinary skill in the art would have been aware of regulatory differences between the U.S. and the U.K. and would have been aware that a

product with a sterilized CHG solution was sold in Europe. With this understanding, a person of ordinary skill in the art would not have found the word "sterile" in the ChloraPrep PAR to have "questionable meaning." To the contrary, as discussed above, a person of ordinary skill in the art would have understood the term "sterile" in a regulatory document to have a specific meaning, and thus understood the phrase "a sterile alcoholic antiseptic solution containing chlorhexidine gluconate and isopropyl alcohol" in the ChloraPrep PAR to refer to a sterilized CHG solution. *See* Ex. 1005, 7, 10; Ex. 1003 ¶¶ 91, 129–134.

Patent Owner next argues that a person of ordinary skill in the art "would not conflate 'sterile' in the PAR with 'sterilized'" particularly given that "Petitioner identifies no known methods of sterilizing CHG existing in 2010," the date when the ChloraPrep PAR was published. PO Resp. 26. According to Patent Owner, in 2010, it was thought that "sterilization was unnecessary because antiseptics 'demonstrate a broad spectrum of antimicrobial activity.'" *Id.* (citing Ex. 1008). In addition, Patent Owner argues that in 2010, it was known that ChloraPrep's glass ampules prevented sterilization of the solution within them. *Id.* (citing Ex. 2015 (Chiang, which was discussed *supra* § III.A.2.a)). We do not agree with these arguments.

There is some support in the record for Patent Owner's argument that a person of ordinary skill in the art in 2010 would have thought that sterilization of antiseptic solutions was unnecessary. *See e.g.*, Ex. 1008 ¶ 178 (Scholz, disclosing that "[m]any of the compositions of [Scholz's] invention demonstrate a broad spectrum of antimicrobial activity and thus are generally not terminally sterilized."); Ex. 1007 ¶ 2 (Degala, teaching that "[i]n the United States there are currently no regulations regarding the

sterilization requirements of topical antiseptic solutions"). There also is support in the record for the proposition that a person of ordinary skill in the art in 2010 would have thought sterilization of antiseptic solutions was important. Ex. 2023 ¶¶ 54–55 (Dr. Rutala, explaining that "[a]round 2010 to 2011, a serious infectious outbreak occurred that was linked to contamination of antiseptic alcohol swabs" and that, "[b]y the early 2010s, the concerns about contamination of antiseptic products became a significant concern"). However, it is irrelevant whether a person of ordinary skill in the art would have thought sterilization of antiseptics was necessary as of 2010 because, we do not agree that a person of ordinary skill in the art would have understood that CareFusion, the author of the ChloraPrep PAR, could describe an antiseptic solution as "sterile" in a regulatory document when it was not, in fact, sterile.

As to Patent Owner's argument that the Petitioner does not identify known methods of sterilizing CHG dating back to the ChloraPrep PAR's publication date, Petitioner cites Scholz, which was published in 2006, as disclosing "sterilizing the claimed chlorhexidine gluconate solution composition via any number of "industry standard techniques," including electron beam, gamma radiation, or heat." Pet. 14 (citing Ex. 1008 ¶ 178). The parties dispute whether Scholz teaches sterilized CHG. The relevant disclosure from Scholz is reproduced below.

> Many of ***the compositions*** of [Scholz's] invention demonstrate a broad spectrum of antimicrobial activity and thus are generally not terminally sterilized but if necessary may be sterilized by a variety of industry standard techniques. For example, it may be preferred to sterilize ***the compositions*** in their final packaged form using electron beam. It may also be possible to sterilize ***the sample*** by gamma radiation or heat. Other forms

> of sterilization may be acceptable. It may also be suitable to include preservatives in ***the formulation*** to prevent growth of certain organisms. Suitable preservatives include [list of compounds], as well as combinations of these compounds.

Ex. 1008 ¶ 178 (emphasis added). Dr. Dabbah testifies that this disclosure "describes sterilizing the claimed gluconate solution composition" using techniques that a person of ordinary skill in the art "would have been familiar with." Ex. 1003 ¶ 75. Dr. Rutala disagrees asserting that "Scholz suggests that sterilization processes can be used on packaging, but provides no successful methods for sterilizing a CHG composition within that packaging." Ex. 2023 ¶ 78; *see also, generally, id.* ¶¶ 74–78.

Despite Dr. Rutala's testiomony, Scholz states, unequivocally, that "the compositions of [Scholz's] invention . . . may be sterilized by a variety of industry standard techniques." Ex. 1008 ¶ 178. And this disclosure is presumed enabled. *In re Sasse*, 629 F.2d 675, 681 (CCPA 1980); *see also In re Antor Media Corp.*, 689 F.3d 1282, 1288 (Fed. Cir. 2012). As are Scholz's disclosures regarding sterilizing "the compositions . . . using electron beam" and sterilizing "the sample by gamma radiation or heat." *Id.* Dr. Rutala does not explain why a person of ordinary skill in the art would have understood Scholz to disclose sterilization of only the packaging. *See* Ex. 2023 ¶¶ 74–78. Nor does Dr. Rutala provide sufficient evidence or a compelling explanation why a person of ordinary skill in the art would disregard Scholz's teaching that "a variety of industry standard techniques," including, e.g., an "electron beam," and "heat," can be used to sterilize "the composition" and/or "the sample." Absent such explanation or evidence, we do not credit Dr. Rutala's opinions on Schloz. *See In re Am. Acad, of Sci.*

Tech Ctr., 367 F.3d 1359, 1368 (Fed. Cir. 2004) ("[T]he Board is entitled to weigh the declarations and conclude that the lack of factual corroborations warrants discounting the opinions expressed in the declarations.").

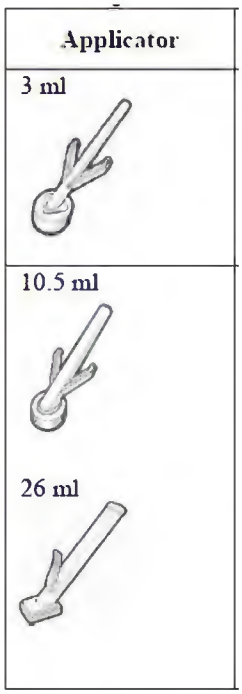
Even if we were to credit Dr. Rutala's testimony, and disregard Scholz as evidence that it was known CHG could be sterilized as of 2006, we would still disagree with Patent Owner's argument that the absence of knowledge about techniques for sterilizing CHG in 2010 supports that a person of ordinary skill in the art would have understood the ChloraPrep PAR to disclose an unsterilized composition. In this regard, we note that one of the inventors of the '642 patent stated, on December 12, 2012, that he was aware of a sterilized CHG product sold in Europe. Ex. 1044, 1, 20 (statement of '642 patent inventor Timothy P. Manthei at December 12, 2012, FDA hearing). This supports that a person of ordinary skill in the art would have known that sterilization of CHG was possible at least as early as December 2012. Consistent with this finding, Degala describes a sterilization process for CHG as prior art *to Degala,* which was filed on January 8, 2014. Ex. 1007 ¶ 2 ("A known antiseptic solution containing [CHG] . . . is sterilized for EU countries *using a known sterilization method*.") (emphasis added). Given that it was known that CHG could be sterilized shortly after the publication of the ChloraPrep PAR, we do not agree that a person of ordinary skill in the art, reading the ChloraPrep PAR at the time of the invention, would have understood "sterile alcoholic antiseptic solution containing chlorhexidine gluconate and isopropyl alcohol" to refer to an unsterilized CHG solution. To the contrary, particularly in light of the applicable regulations discussed above, we find

that a person of ordinary skill in the art would have understood it to refer to sterilized CHG.

With respect to Patent Owner's argument that Petitioner has not shown that the sterility of CHG in the product disclosed in the ChloraPrep PAR has been validated, we note, as we did above in connection with the preamble, that Petitioner has shown that BS EN 556-1 requires products to have a particular SAL. On cross-examination, Dr. Rutala conceded that "you have to have a validated sterility process to have a sterility assurance level." Ex. 1043, 159:20–25. This supports a conclusion that a person of ordinary skill in the art would have understood the ChloraPrep PAR to disclose a product in which CHG had been sterilized using a validated sterility process. *Id.*; *see* Ex. 1003 ¶¶ 129–134.

c) "an applicator for facilitating application of the sterilized chlorhexidine composition"

Petitioner contends ChloraPrep PAR discloses "an applicator for facilitating application of the sterilized chlorhexidine composition" as required by claim 1. Pet. 30 (citing Ex. 1003 ¶ 96). Petitioner relies on the Figure from page 5 of ChloraPrep PAR, reproduced, as excerpted by Petitioner, below.



Id. (citing Ex. 1005, 5). The figure excerpted above depicts three differently size applicators (3 ml, 10.5 ml, and 26 ml). *Id.* "The applicators consist of a latex-free sponge attached to a plastic handle/barrel which holds a latex-free dyed pledget and glass ampoule containing the antiseptic solution." Ex. 1005, 7.

Patent Owner argues that "a POSA at the time [would have understood] that the challenge was not only creating a sterilized CHG composition but also providing for an applicator that facilitated application of it." PO Resp. 27. Patent Owner further argues that "Petitioner identifies an applicator, but does not address how it is configured to facilitate application of a sterilized composition." *Id.* We do not agree with this argument.

The Petition and Dr. Dabbah explain how the applicator facilitates application of CHG by block quoting Section 4.2 of the ChloraPrep PAR,

which discusses how the applicator is used. Pet. 32; Ex. 1003 ¶ 98. The quoted passage reads as follows:

> The applicator is removed from the wrapper and held with the sponge facing downward. The applicator is squeezed gently to break the ampoule containing the antiseptic solution, which is released onto the sponge in a controlled flow (for the 26 ml applicator the lever is pressed). The broken ampoule remains safely contained within the applicator. The sponge is gently pressed against the patient's skin in order to apply the antiseptic solution. A back and forth action of the sponge should be used for 30 seconds.

Ex. 1005, 5. This passage makes clear that the configuration of the applicator facilitates application of CHG by providing a convenient way to release a controlled flow of antiseptic solution in such a way that it can be applied to the patient's skin. Accordingly, we agree with Petitioner that the ChloraPrep PAR discloses an applicator for facilitating application of a composition.

d) "a receptacle containing the sterilized chlorhexidine gluconate composition to provide the sterilized chlorhexidine gluconate composition to impregnate the applicator when the receptacle is compromised"

Petitioner contends the ChloraPrep PAR discloses "a receptacle containing the sterilized chlorhexidine gluconate composition to provide the sterilized chlorhexidine gluconate composition to impregnate the applicator when the receptacle is compromised" as required by claim 1. Pet. 32–33 (citing Ex. 1003 ¶¶ 99–100). Petitioner argues that the ChloraPrep PAR describes "a receptacle in the form at least one glass ampoule housed within the applicator's plastic barrel which contains the sterilized CHG composition." *Id.* (citing Ex. 1005, 7, 18). According to

Petitioner, "[w]hen compromised by breaking it ('the applicator is squeezed gently to break the ampoule'), the ampoule provides the sterilized CHG composition to impregnate the applicator by releasing the CHG into the sponge portion of the applicator ('the antiseptic solution . . . is released onto the sponge in a controlled flow')." *Id.* Petitioner quotes from Section 4.2 of the ChloraPrep PAR (quoted *supra* § III.2.c) to support its position. Pet. 32–33.

Patent Owner argues:

> While Petitioner identifies a "glass ampoule containing the antiseptic solution," Petitioner does not identify anything in the PAR that indicates the ampoule contains a sterilized composition or how it is configured "to provide the sterilized CHG composition to impregnate the applicator when the receptacle is compromised." (Rutala¶¶216-219.) Petitioner's arguments simply assume the element.

PO Resp. 27–28. We do not agree with this argument.

For the reasons discussed *supra* § III.A.2.b, we find that a person of ordinary skill in the art would have understood the ChloraPrep PAR to disclose a sterilized CHG composition. Thus, we do not agree with Patent Owner's argument that "Petitioner does not identify anything in the PAR that indicates the ampoule contains a sterilized composition." The Petition also explains that "[w]hen compromised by breaking it ('the applicator is squeezed gently to break the ampoule'), the ampoule provides the sterilized CHG composition to impregnate the applicator by releasing the CHG into the sponge portion of the applicator ('the antiseptic solution . . . is released onto the sponge in a controlled flow')." Pet. 33 (block quoting Section 4.2 of the ChloraPrep PAR). The Petition thus explains that the ampule is configured such that it is breakable and such that it releases the antiseptic

solution into the sponge when it is broken. *Id.* For this reason, we do not agree with Patent Owner's argument that Petitioner "does not identify anything in the PAR that indicates . . . how [the ampule] is configured 'to provide the sterilized CHG composition to impregnate the applicator when the receptacle is compromised.'" PO Resp. 27–28.

Based on the disclosure in ChloraPrep PAR of an ampule that is broken to release a CHG composition, we agree with Petitioner that the ChloraPrep PAR discloses a receptacle that impregnates the applicator with chlorhexidine gluconate when the receptacle is compromised.

e) "wherein the sterilized chlorhexidine gluconate composition comprises chlorhexidine gluconate and alcohol"

Petitioner contends ChloraPrep PAR discloses that "the sterilized chlorhexidine gluconate composition comprises chlorhexidine gluconate and alcohol" as required by claim 1. Pet. 34–35 (citing Ex. 1005, 4, 5, 7, 10; Ex. 1003 ¶¶ 101–02). Patent Owner argues that Petitioner "does not explain how" the ChloraPrep PAR discloses "that *both* the CHG and alcohol have been subjected to the requisite sterilization process." PO Resp. 28.

For the reasons discussed *supra* § III.A.2.b, we find that a person of ordinary skill in the art would have understood the ChloraPrep PAR to disclose a sterilized CHG composition. As to the argument that Petitioner has not established that both the CHG and the alcohol have been sterilized, the ChloraPrep PAR discloses "a sterile alcoholic antiseptic solution containing chlorhexidine gluconate and isopropyl alcohol." Ex. 1005, 7. The word "sterile" in this disclosure modifies the term "solution," and the "solution" is described as "containing chlorhexidine gluconate and isopropyl alcohol." *Id.* Accordingly, we find that a person of ordinary skill in the art

would have understood that both the CHG and the alcohol in the "sterile alcoholic antiseptic solution" had been sterilized.

3. Analysis of Independent claim 12

a) preamble "a method of using a sterilized chlorhexidine article, said method comprising"

Claim 12 recites a "method of using a sterilized chlorhexidine article." Ex. 1001, 28:15–16. Petitioner contends that to the extent the preamble is limiting, the ChloraPrep PAR discloses the elements of the preamble. As proof, Petitioner directs us to its poof with respect to the preamble of claim 1, which we discussed *supra* § III.A.2.a. Pet. 35. In addition, Petitioner directs us to Section 4.2 of the ChloraPrep PAR, which Petitioner contends provides "a detailed explanation of use of the product for topical disinfection, including choice of size of applicator and particular procedure requiring topical disinfection." *Id.* (citing Ex. 1005, 5). According to Petitioner, "Section 4.2 specifically teaches the steps for using the product for topical disinfection." *Id.* at 35–36 (citing Ex. 1005, 5, 9).

Patent Owner argues: "Petitioner failed to explain how the 'sterilized . . . article' is disclosed for the same reasons it failed to explain how a 'sterilized . . . product' is disclosed." PO Resp. 49. More specifically, Patent Owner argues that "[t]he PAR does not disclose that the article as a whole is sterile, let alone subjected to a suitable sterilization process where sterility can be validated." *Id.* We do not agree with Patent Owner's arguments for the reasons discussed *surpa* § III.A.2.a.

We find that the ChloraPrep PAR discloses a method of using the product it describes. Ex. 1005, 5, 9. Furthermore, for the reasons discussed *supra* § III.A.2.a, a person of ordinary skill in the art would have understood

the ChloraPrep PAR to disclose that the entire produced described in the ChloraPrep PAR was sterilized. Accordingly, we find that the ChloraPrep PAR discloses a sterilized chlorhexidine article.[12]

b) "providing a sterilized chlorhexidine article"

Claim 12 recites the step of "providing a sterilized chlorhexidine article." Ex. 1001, 28:17–18. Petitioner contends that the ChloraPrep PAR discloses this claim element, and directs us to its proof for the preamble of claim 1, which we discussed *supra* § III.A.2.a. Pet. 36. Petitioner then directs us to its proof that the article is comprised of an applicator, a receptacle, and a solution of chlorhexidine gluconate and alcohol. *Id.* Finally, Petitioner notes that the ChloraPrep PAR describes using the article for topical disinfection. *Id.*

Patent Owner relies on the same arguments it made with respect to the preamble of claim 12, which we discussed *supra* § III.A.3.a. PO Resp. 36. For the reasons discussed *supra* § III.A.3.a, we find that the ChloraPrep PAR discloses a sterilized chlorhexidine article.

c) "a sterilized chlorhexidine gluconate composition comprising chlorhexidine gluconate and alcohol"

Claim 12 recites "a sterilized chlorhexidine gluconate composition comprising chlorhexidine gluconate and alcohol." Ex. 1001, 28:19–20. This limitation overlaps with the limitations of claim 1 discussed *supra* §§ III.A.2.b and III.A.2.e. Petitioner relies on the same proof discussed in

[12] As with claim 1, we do not determine whether the preamble to claim 12 is limiting because, regardless of whether the preamble is limiting, Petitioner has shown that the recitation in the preamble is satisfied by the prior art.

those sections and Patent Owner relies on the same arguments in opposition. Pet. 37; PO Resp. 29. For the reasons discussed *supra* §§ III.A.2.b and III.A.2.e, we find that the ChloraPrep PAR discloses a "sterilized chlorhexidine gluconate composition comprising chlorhexidine gluconate and alcohol."

d) "an applicator for facilitating application of the sterilized chlorhexidine"

Claim 12 recites "an applicator for facilitating application of the sterilized chlorhexidine." Ex. 1001, 28:21–22. This limitation overlaps with the limitations of claim 1 discussed *supra* §§ III.A.2.a and III.A.2.c. Petitioner relies on the same proof discussed in those sections and Patent Owner relies on the same arguments in opposition. Pet. 37; PO Resp. 30. For the reasons discussed *supra* §§ III.A.2.a and III.A.2.c, we find that the ChloraPrep PAR discloses a "an applicator for facilitating application of the sterilized chlorhexidine."

e) "a receptacle containing the sterilized chlorhexidine gluconate composition"

Claim 12 recites "a receptacle containing the sterilized chlorhexidine gluconate composition." Ex. 1001, 28:23–24. This limitation overlaps with the limitations of claim 1 discussed *supra* §§ III.A.2.a and III.A.2.d. Petitioner relies on the same proof discussed in those sections and Patent Owner relies on the same arguments in opposition. Pet. 37; PO Resp. 30. For the reasons discussed *supra* §§ III.A.2.a and III.A.2.d, we find that the ChloraPrep PAR discloses a "an applicator for facilitating application of the sterilized chlorhexidine."

f) "compromising the receptacle to provide the sterilized chlorhexidine gluconate composition to impregnate the applicator"

Claim 12 recites the step of "compromising the receptacle to provide the sterilized chlorhexidine gluconate composition to impregnate the applicator." Ex. 1001, 28:25–27. Petitioner contends that the ChloraPrep PAR discloses this step because it "instructs users to 'remove the applicator from the wrapper,' at which point '[t]he applicator is squeezed gently to break the ampoule containing the antiseptic solution, which is released into the sponge in a controlled flow.'" Pet. 37–38 (citing Ex. 1005, 5).

Patent Owner argues that the ChloraPrep PAR does not disclose this limitation "because no sterilized CHG composition is disclosed." PO Resp. 30. We do not agree with this argument for the reasons discussed *supra* §§ III.A.2.b. Patent Owner also argues that the ChloraPrep PAR does not disclose this limitation "there is no description of how a receptacle is configured 'to provide the sterilized [CHG] composition to impregnate the applicator.'" *Id.* We do not agree with this argument for the reasons discussed *supra* §§ III.A.2.d.

g) "applying the sterilized chlorhexidine gluconate composition to a patient's skin"

Claim 12 recites the step of "applying the sterilized chlorhexidine gluconate composition to a patient's skin." Ex. 1001, 28:28–29. Petitioner contends that the ChloraPrep PAR discloses this step because it "teaches the steps for using the product for topical disinfection, including squeezing the applicator [to] 'break the ampoule containing the antiseptic solution' which is released into a sponge which 'is gently pressed against the patient's skin in order to apply the antiseptic solution.'" Pet. 38–39 (citing Ex. 1005, 5, 9).

Patent Owner relies on the same arguments it made with respect to the limitation discussed *supra* § III.A.3.f. PO Resp. 36. We find that the ChloraPrep PAR discloses this limitation. Ex. 1005, 5, 9. We do not agree with Patent Owner's arguments for the reasons discussed *supra* § III.A.3.f.

4. Claims 2 and 13

Claim 2 depends from claim 1 and additionally requires that "the receptacle contains the sterilized chlorhexidine gluconate composition in an amount between 0.1 and 100 mL." Ex. 1001, 27:36–39. Claim 13 depends from claim 12 and additionally requires that "the applicator is impregnated with 0.1 to 100 mL of the sterilized chlorhexidine gluconate composition." *Id.* at 28:30–34. Petitioner contends that the ChloraPrep PAR discloses these limitations because it teaches three amounts falling with in claimed range, 3 ml, 10.5 ml, and 26 ml. Pet. 39.

Patent Owner argues that the ChloraPrep PAR does not disclose these limitations "[b]ecause the PAR fails to disclose the sterilized CHG composition." PO Resp. 31. We do not agree with this argument for the reasons discussed *supra* §§ III.A.2.b.

Patent Owner also argues: "Petitioner does not explain how the PAR discloses the distinct requirement of Claim 13 that 'when the receptacle is compromised, the applicator is impregnated with 0.1 to 100 mL of the sterilized [CHG] composition.'" PO Resp. 31. Patent Owner cites to the testimony of Dr. Rutala who contends that Dr. Dabbah "addresses the volume of CHG solution in the device," but does not explain how recited volume of sterilized CHG impregnates the applicator when the receptacle is compromised. Ex. 2023 ¶ 254. We do not agree with this argument.

Petitioner explains that, "[t]he *ChloraPrep PAR* . . . teaches that when the receptacle is compromised, the antiseptic CHG solution is 'released onto the sponge in a controlled flow,' thus impregnating the applicator with 0.1 to 100 mL of the sterilized chlorhexidine gluconate composition." *Id.* at 40 (citing Ex. 1005, 5). This is sufficient. Given the broad range recited in the claims, which extends to as little as 0.1 mL, and the comparatively large amounts exemplified in the ChloraPrep PAR, which may be as large as 26 mL, it not plausible that the amount of CHG solution that would be "released onto the sponge in a controlled flow" when the ampule is broken (Ex. 1005, 5) would fail to fall within the recited range. Accordingly, we find that the ChloraPrep PAR discloses impregnating the applicator with 0.1 to 100 mL of sterilized CHG when the receptacle is compromised.

5. Claims 3 and 14

Claim 3 depends from claim 1 and additionally recites that the CHG composition comprises a specific amount of chlorhexidine gluconate ("from 1.5 to 5.0 wt. % based on the total weight of said sterilized antiseptic composition") and a specific amount of alcohol ("50 wt. % based on the total weight of the sterilized antiseptic composition"). Claim 14 depends from claim 12 and recites the same amounts of chlorhexidine gluconate and alcohol as are recited in claim 3. Petitioner contends that the ChloraPrep PAR discloses a CHG composition in which the amount of chlorhexidine gluconate and the amount of alcohol fall within the claimed ranges. Pet. 41.

Patent Owner does not dispute that the amounts of chlorhexidine gluconate and alcohol disclosed in the ChloraPrep PAR fall within the claimed ranges, but repeats its argument that the composition is not sterilized and thus does not meet the additional limitations of claims 3

and 14. PO Resp. 31. We do not agree with this argument for the reasons discussed *supra* §§ III.A.2.b. We find that the ChloraPrep PAR discloses a composition meeting the additional limitations of claims 3 and 14 for the reasons set forth in the Petition. *See* Pet. 41–43.

6. Claims 5 and 15

Claim 5 depends from claim 1 and additionally recites that the alcohol in the sterilized CHG composition is isopropyl alcohol. Claim 15 depends from claim 12 and also additionally recites that the alcohol is isopropyl alcohol. Petitioner contends that the ChloraPrep PAR discloses a CHG composition where the alcohol is isopropyl alcohol. Pet. 43–44.

Patent Owner does not dispute that CHG composition disclosed in the ChloraPrep PAR comprises isopropyl alcohol, but repeats its argument that the composition is not sterilized and thus does not meet the additional limitations of claims 3 and 14. PO Resp. 31. We do not agree with this argument for the reasons discussed *supra* §§ III.A.2.b. We find that the ChloraPrep PAR discloses a composition meeting the additional limitations of claims 5 and 15 for the reasons set forth in the Petition. *See* Pet. 43–44.

7. Claims 6 and 16

Claim 6 depends from claim 1 and additionally recites that the sterilized CHG composition comprises water. Claim 16 depends from claim 12 and also additionally recites that the sterilized CHG composition comprises water. Petitioner contends that the ChloraPrep PAR discloses a CHG composition where "purified water" is listed as an excipient and as an "inactive ingredient. Pet. 44.

Patent Owner does not dispute that CHG composition disclosed in the ChloraPrep PAR comprises water, but repeats its argument that the

composition is not sterilized and thus does not meet the additional limitations of claims 3 and 14. PO Resp. 32. We do not agree with this argument for the reasons discussed *supra* §§ III.A.2.b. We find that the ChloraPrep PAR discloses a composition meeting the additional limitations of claims 6 and 16 for the reasons set forth in the Petition. *See* Pet. 44.

8. Claims 7, 8, 17, and 18

Claims 7 and 17 recite that "the sterilized chlorhexidine gluconate composition [of claim 1/12] further comprises one or more additives selected from the group consisting of [seven "sterilized" additives including] a sterilized colorant." Claims 8 and 18 depend from claims 7 and 17 and further recite that "the additive is a colorant." Petitioner contends that the ChloraPrep PAR meets the additional limitations of claims 7, 8, 17, and 18 because it discloses an "Orange Solution" which uses the excipient "Sunset Yellow E110)." Petitioner argues that "[a]s an excipient included within the sterilized chlorhexidine gluconate solution, that colorant is similarly sterile and sterilized." Pet. 50; *see* Ex. 1003 ¶ 127.

Patent Owner argues that "Petitioner identifies nothing in the PAR that states the tint is in the 'alcoholic antiseptic solution'" and "the PAR does not disclose[] that the 'tint' is sterile – much less sterilized." PO Resp. 32, 33. In addition, Patent Owner points to Chiang as teaching that the "dye is separate from the solution." *Id.* And in its Sur-reply, Patent Owner cites the testimony of Mr. Noble-Clark to support that "the dye is not in the solution but in the applicator head." Sur-reply 17 (citing Ex. 2044, 64:5–65:19).

The evidence of record supports that the dye in the product described in the ChloraPrep PAR is not initially stored in the reservoir with the CHG

composition. The ChloraPrep PAR states that its applicators "consist of a latex-free sponge attached to a plastic handle/barrel which holds a latex-free dyed pledget and glass ampoule containing the antiseptic solution." Ex. 1005, 7. Thus, the applicator includes both a sponge and a pledget. A pledget is a device positioned "between the glass ampoule and the sponge." Ex. 2044, 64:10–65:12. According to Mr. Noble-Clarke, "when you . . . break the ampoule, the solution runs through the pledget picking up the dye so that what the sponge in fact dispenses onto the patient becomes a tinted rather than a clear chlorhexidine." Ex. 2044, 65:5–8. Mr. Noble-Clarke's testimony that solution picks up the dye when it runs through the pledget is consistent with the repeated description of a "dyed pledget" in the ChloraPrep PAR. Ex. 1005, 7, 10, 18. It also is consistent with Chiang, which teaches that "the ChloraPrep® applicators have the CHG composition in a glass ampule and the dye composition is provided in the foam applicator head." Ex. 2015 ¶ 13.

Although the dye in the ChloraPrep PAR product is initially in the pledget rather than the ampule as part of the CHG solution, the ChloraPrep PAR still identifies the dye as an "excipient." *Id.* at 7 (identifying "[p]urified water" and "Sunset Yellow (E110)" as excipients), 17 ("Other ingredients consist of excipients, namely sunset yellow (E110) and purified water."). An excipient is "an inactive ingredient in the composition" and is "essentially the medium in some way for the active substance." Ex. 1040, 234:15–239:7 (testimony of Dr. Rutala).

In order to reconcile the evidence that Sunset Yellow is in the pledget with the evidence that it is an "excipient," we find that Sunset Yellow must become an excipient when CHG solution passes through the

pledget. This explanation is consistent with the explanation Patent Owner's counsel provided at oral argument:

> Now you asked earlier about an excipient. It [the dye] is an excipient. It's an excipient in the barrel or handle. But there's nothing that requires it to be in the solution. And it is also an excipient when it's finally applied onto the patient when it, in fact, becomes an orange solution. But in terms of what's disclosed as sterile, there's no indication that that pledget was ever sterile.

Tr. 61. In sum, regardless of when the Sunset Yellow (E110) enters into solution with the remainder of the CHG solution, it is still considered an excipient.

The identification of the dye in the ChloraPrep PAR as an excipient supports that it is sterile. In his deposition, Dr. Rutala explained:

> Q: . . . For -- for a composition to be considered sterile, the excipients have to be sterile, too, right?
>
> A: If you're -- only want a definition of the word "sterile," the excipients would have to be sterile and devoid of microbial contamination.

Ex. 1040, 238:20–239:7; *see generally* 234:15–239:7. This testimony is consistent with that of Dr. Dabbah, who testifies: "[a]s an excipient included within the sterilized chlorhexidine gluconate solution, that colorant [Sunset Yellow] is similarly sterile and sterilized." Ex. 1003 ¶ 127. Dr. Dabbah further testifies that "approval of ChloraPrep's description as a sterile composition in the ChloraPrep PAR, requires the sterilization of all substances in the solution." *Id.*

Accordingly, we find that the colorant disclosed in the ChloraPrep PAR is sterile. This finding is additionally supported by the statement in the ChloraPrep PAR that "ChloraPrep *with Tint* is a sterile alcoholic antiseptic

solution." Ex. 1005, 7. In this statement, the word "sterile" modifies the whole term "ChloraPrep with Tint."

For the reasons discussed above, we find that ChloraPrep PAR discloses the additional limitations recited in claims 7, 8, 17, and 18.

9. Claims 10 and 20

Claims 10 and 20 depend from claims 1 and 12 and further recites that the sterilized chlorhexidine article "has a sterility assurance level of from 10^{-3} to 10^{-9}." Petitioner contends that because the ChloraPrep PAR is a UK regulatory document, a person of ordinary skill in the art would have understood that "when the ChloraPrep PAR describes the product and its components as 'sterile,' it is directly and necessarily referring to a sterility assurance level within the range from 10^{-3} to 10^{-9} – specifically 10^{-6}." Pet. 46–47. More specifically, Petitioner contends that the regulations applicable to medical devices require that "to describe the medical device and its components as 'sterile,' they must have a sterility assurance level of 10^{-6}." *Id.* at 47 (citing BS EN 556-1).

In response Patent Owner repeats its argument that Petitioner has not established that the entire product or article disclosed in the ChloraPrep PAR has been sterilized. PO Resp. 34. We do not agree with this argument for the reasons discussed *supra* § III.A.2.a.

Patent Owner also makes several arguments as to why BS EN 556-1 does not apply to the ChloraPrep PAR. We discussed these arguments *supra* § III.A.2.a, and do not agree with them for the reasons discussed therein. In that section, which we incorporate herein, we found that a person of ordinary skill in the art would have understood BS EN 556-1 to apply to the product disclosed in the ChloraPrep PAR. BS EN 556–1 requires a sterility

assurance level of 10^{-6}. Ex. 1017, 8. In addition, Dr. Rutala testified that a SAL of 10^{-6} is the common, widely accepted standard for designating a component or device as "sterile." *See* Ex. 1040, 235:16–237:22. For these reasons, we find that a person of ordinary skill in the art would have understood the product disclosed in the ChloraPrep PAR to have a sterility assurance level of 10^{-6}, thus meeting the sterility assurance level requirement recited in claims 10 and 20.

10. Claim 11

Claim 11 depends from claim 1 and further recites that the applicator comprises a foam. Petitioner contends that the ChloraPrep PAR discloses this additional limitation by disclosing that the applicator includes a sponge. Pet. 49–51 (citing Ex. 1005, 5). Petitioner cites the testimony of Dr. Dabbah, who testifies that "[a] POSA would recognize . . . that a sponge is a foam." Ex. 1003 ¶ 137 (cited at Pet. 51); *see also* Ex. 1001, 7:14–22 (disclosing that "the foam may comprise an open-celled foam").

Patent Owner does not dispute that the ChloraPrep PAR discloses that the applicator comprises a foam, arguing only that Petitioner has not established anticipation of independent claim 1. We do not agree with this argument for the reasons discussed *supra* §§ III.A.2. We find that the ChloraPrep PAR discloses a composition meeting the additional limitations of claim 11 for the reasons set forth in the Petition. *See* Pet. 49–51.

11. Enablement of the ChloraPrep PAR

"[A] prior art reference cannot anticipate a claimed invention 'if the allegedly anticipatory disclosures cited as prior art are not enabled.'" *In re Antor Media Corp.*, 689 F.3d 1282, 1289 (Fed. Cir. 2012). "Enablement requires that the prior art reference must teach one of ordinary skill in the art

to make or carry out the claimed invention without undue experimentation.'" *Elan Pharm., Inc. v. Mayo Found.*, 346 F.3d 1051, 1054 (Fed. Cir. 2003).

Patent Owner argues: "Petitioner does not establish that the PAR enables a POSA to make the claimed sterilized product/article, sterilized CHG composition, or sterilized additives." PO Resp. 36–37. According to Patent Owner, "[t]he PAR provides no information regarding sterilization of any products or their components, mentions no sterilization processes whatsoever (much less validated ones), and does not describe how to achieve the claimed SALs with any validated sterilization processes." *Id.* at 37. Patent Owner points to "numerous challenges existing at the time regarding making sterilized chlorhexidine" and argues that "Petitioner offers no explanation how other prior art enables a POSA to make the claimed sterilized CHG composition . . . when the PAR itself does not suggest sterilization whatsoever." *Id.* at 37–38. Finally, Patent Owner argues that Petitioner's assertions of enablement are "belied by its own admissions" that it "'overcame the 'impossible' when it released a fully sterilized ChloraPrep product, which, according to Petitioner, required '6 years,' 'Millions of dollars,' and '>50,000 R&D hours.'" *Id.* at 38 (citing Ex. 2007, 15, 17).

As an initial matter, it is Patent Owner's burden to demonstrate that the ChloraPrep PAR is not enabled. *Sasse*, 629 F.2d 675; *Antor Media Corp.*, 689 F.3d 1282; *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 n.22 (Fed. Cir. 2003). Patent Owner has not carried its burden to do so.

The evidence supports Petitioner's assertion that "sterilization of the applicator, via, for instance ETO was a well-known and routine process." Pet. 52; Ex. 1003 (unrebutted testimony of Dr. Dabbah that a person of

ordinary skill in the art would be very familiar with terminal sterilization processes, such as using ETO, and would consider them routine); Ex. 2015 (Chiang teaching that ChloraPrep was sterilized using ethylene oxide); *see also* Ex. 1040, 141:18–147:21 (Dr. Rutala testimony discussing sterilization using ETO).

The evidence also supports that a person of ordinary skill in the art would have been able to sterilize CHG based on the disclosure of the ChloraPrep PAR and what was known in the art without undue experimentation. As discussed *supra* § III.A.2.b, Degala describes a prior art sterilization process for CHG. Ex. 1007 ¶ 2 ("A known antiseptic solution containing [CHG] . . . is sterilized for EU countries *using a known sterilization method*."). In addition, Degala discloses an allegedly improved sterilization process that addresses the "need in the art" for a sterilizing process with a "shorter, more efficient processing time." *Id.* ¶¶ 5–7.

We recognize the evidence identified by Patent Owner regarding the challenges of developing sterilized CHG. Ex. 2007, 15, 17. In the absence of a disclosed method for sterilizing CHG, these concerns might be persuasive. But here, methods for sterilizing CHG were known and disclosed in the Degala patent.[13] *United States v. Telectronics, Inc.*, 857

[13] Based on what was known in the art, the challenges reflected in Petitioner's purported admission appear to relate not to sterilizing CHG, but to finding a "shorter, more efficient" method for doing so. *See* Ex. 1007 ¶¶ 3, 5 (describing a "known method of sterilization" that occurs over 24–31 hours and identifying an "unmet need in the art for a method . . . that has a shorter, more efficient processing time"). Moreover, the disclosure that Patent Owner cites to support that it took Petitioner six years and millions of dollars to develop a sterilization method itself cited Degala, suggesting that the method that took such effort to develop may, in fact, be the method

F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.").

Considering all of the evidence of record, the purported deficiencies in the ChloraPrep PAR's disclosure identified by Patent Owner, and the evidence that Petitioner expended considerable effort in developing a method of sterilizing CHG, do not overcome the presumption that the ChloraPrep PAR is enabled. This is particularly true given the knowledge in the art regarding terminal sterilization and sterilization of CHG.

B. Alleged Obviousness of Claims 1–3, 5–8, 10–18, and 20 in View of ChloraPrep PAR

Petitioner contends claims 1–3, 5–8, 10–18, and 20 would have been obvious to a person of ordinary skill in the art at the time of the invention, in view of ChloraPrep PAR and relies on the same arguments asserted in its anticipation challenge, plus the assertion that if certain of the limitations recited in the challenged claims are not anticipated, they would have been obvious. Pet. 52–56. Patent Owner disagrees, arguing, *inter alia*, that the reference does not teach or suggest "a sterilized chlorhexidine gluconate composition" because "Petitioner's vague reference to unidentified standards and guidelines" does not "transform[] the word 'sterile' to a requirement that the ChloraPrep product and its components 'must' be 'subjected to validated sterility processing.'" PO Resp. 40 (citing Pet. 52), *see generally id.* at 40–

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disclosed in Degala. Ex. 2007, 16 n.1; Ex. 1007 code (71) (Degala, identifying "CAREFUSION 2200, INC" as the applicant).

47. For the reasons that follow, we determine Petitioner has shown by a preponderance of the evidence that the challenged claims would have been obvious to a person of ordinary skill in the art at the time of the alleged invention in view of the ChloraPrep PAR under 35 U.S.C. § 103.

1. Analysis of Challenged Claims 1–3, 5–8, 10–18 and 20

As discussed above, Petitioner has demonstrated sufficiently that ChloraPrep PAR discloses all elements of the challenged claims. We find that Petitioner's arguments that the ChloraPrep PAR renders obvious "a sterilized chlorhexidine product" and "a sterilized chlorhexidine gluconate composition" provide an additional basis on which the challenged claims are unpatentable.[14]

In addition to the evidence introduced as part of its anticipation ground, Petitioner contends that to the extent "the disclosures referring to the antiseptic solution containing CHG, the applicator[,] or the ChloraPrep with Tint product as 'sterile' do not disclose that the elements (or product/article) have been 'sterilized,'" it would have been obvious to a person of ordinary skill in the art at the time of the invention that "a product described as 'sterile' in a regulatory document such as a PAR must have each component subjected to validated sterility processing that renders the product free of viable microorganisms." Pet. 53. Petitioner also asserts that to the extent the ChloraPrep PAR does not disclose the SAL recited in claim 10 and 20, it

[14] As noted above, we do not determine whether the preambles of claims 1 and 12 are limiting because, regardless of whether the preamble is limiting, Petitioner has shown that the recitation in the preamble is satisfied by the prior art.

would have been obvious "to sterilize the components of the product described as 'sterile' in the *ChloraPrep PAR* within the required SAL range in order to comply with the relevant standards," for the reasons discussed in connection with its anticipation argument.

Petitioner bases its obviousness position largely on the requirements in the relevant UK standards published as regulatory document, EN 556-1. *Id.* (citing Ex. 1003 ¶ 144); Tr. 11:7–9, 23:24–25:25, 28:6–25; *see also* Reply 12–13 (anticipation argument citing Ex. 1048–1049; Ex. 1037 ¶¶ 4–6; Ex. 1038 ¶¶ 6–17). According to Petitioner, "[i]f any component or subcomponent of the product had not been subjected to such a process, the entire product or solution could not be described as 'sterile' as it would contaminate the larger whole." Pet. 53. Petitioner further argues that per the UK standard, EN 556-1, "each component must be sterilized to a SAL of 10^{-6}." Reply 13 (citing Ex. 1017, 8 in connection with anticipation ground).

Petitioner relies on the testimony of its declarant, Dr. Dabbah, to support its position. Pet. 53–54. Dr. Dabbah testifies that a sterility assurance level ("SAL") of "10^{-3} is a well-established baseline for products," and "a SAL of 10^{-6} is a well-established and universally recognized requirement for describing a product—as is done in the *ChloraPrep PAR*—as 'sterile.'" Ex. 1003 ¶ 145 (testimony relating to SAL recited in claims 10 and 20) citing Ex. 1017, 8, 13); *see also, id.* ¶ 144 (testimony on claims 1 and 12). Dr. Dabbah further testifies "it would have been obvious to a POSA to sterilize the components of the product described in the *ChloraPrep PAR* within the required range. Indeed, a POSA would have considered this to be the only way to describe the device and composition

a[s] 'sterile' in a UK regulatory document." *Id.*; *see also* Ex. 1037 ¶ 4 (testimony of Mr. Noble-Clarke regarding application of BS EN556-1 to ChloraPrep UK products); Ex. 1045 (email from Mr. Noble-Clarke regarding same). Petitioner argues that although "not applicable to a UK medical device, the relevant FDA guidelines for a device labeled as 'sterile' are practically identical to the UK standard, and were issued in draft form on December 12, 2008 and issued on January 21, 2016." Pet. 54–55 (citing Ex. 1028). According to Petitioner, under the section "Sterilization Information for Devices Labeled as Sterile," the FDA guidelines provide that "[t]he sponsor should state the sterility assurance level (SAL) of 10^{-6} for devices labeled as sterile unless the device is intended only for contact with intact skin. FDA recommends a SAL of 10^{-3} for devices intended only for contact with intact skin." *Id.* at 55 (citing Ex. 1028, 8–9) (alteration in original). Petitioner concludes that "even if Patent Owner contends that 'sterile' does not necessarily refer to the claimed SAL, it would have been obvious to a POSA to sterilize the claimed components to the required SAL." Pet. 56.

Patent Owner contends that Petitioner's obviousness challenge is conclusory and fails for a number of reasons. PO Resp. 39–40. **First,** Patent Owner argues that Petitioner cannot establish the existence of missing limitations with "conclusory assertion[s]. . . about general knowledge in the art without evidence on the record, particularly where it is an important structural limitation that is not evidently and indisputably within the common knowledge of those skilled in the art." *Id.* at 40 (citing *K/S Himpp v. Hear-Wear Techs., LLC*, 751 F.3d 1362, 1365-66 (Fed. Cir. 2014); *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir. 2016))."

Second, Patent Owner contends Petitioner has not established "that the bare use of the word 'sterile' in 2010 in ChloraPrep PAR means that any chlorhexidine gluconate composition had been sterilized." *Id.* Patent Owner asserts that "Petitioner's vague reference to unidentified 'standards and guidelines'" does not establish obviousness or the requisite knowledge in the art. *Id.* (citing Pet. 52; Ex. 2023 ¶¶ 325–329). According to Patent Owner, "[t]here is no evidence that any 'standard and guideline' transforms the word 'sterile' to a requirement that the ChloraPrep product and its components 'must' be 'subjected to validated sterility processing.'" *Id.* (citing Ex. 2023 ¶¶ 327–328). Patent Owner further argues that Petitioner's "failure of proof is problematic given the 'difficulty' and 'impossibility' at that time, the numerous outbreaks from contaminated antiseptics, and the nascent state of the art." *Id.* at 41.

Third, Patent Owner contends that Petitioner's position is undermined by "the FDA's guidance that advised manufacturers to clarify their labelling, coupled with CareFusion's 2015 reported label change to indicate that its solution was 'not sterilized' (despite including the word 'sterile' on its label)." *Id.* at 41 (citing Exs. 2005–2006; Ex. 2009, 26, 34, 43, 50, 57; Ex. 2023 ¶¶ 330–332).

Fourth, Patent Owner contends that, "even if unidentified 'standards' compelled a POSA to translate 'sterile' to 'sterilized,' Petitioner does not explain how that would further compel a POSA to understand that the product, article, or composition would have been subjected to validated sterility processing." *Id.* (citing Ex. 2023 ¶ 333).

Fifth, Patent Owner argues that our Institution Decision cites references (i.e., Degala, Margoosian, or Scholz) that were not explicitly

presented in the obviousness challenge in the Petition, and that these references should be ignored. *Id.* at 42; Sur-Reply 18–19. Patent Owner states that the obviousness arguments in the Petition "focus solely on regulatory 'standards' – not knowledge based on the prior art references," and therefore, Petitioner should be limited to only what is in the Petition. PO Resp. 42–43. Even relying on these references, Patent Owner asserts, Petitioner cannot establish obviousness. *Id.* at 43 (citing Ex. 2023 ¶¶ 346–347). According to Patent Owner, "***Scholz*** reflects the then-existing misconception that antiseptics need not be sterilized and describes no methods for sterilizing CHG compositions but mentions sterilizing packaging." *Id.* at 44. Patent Owner asserts that "Petitioner's own testing of Margoosian established that Margoosian 'results in a solution that is not sterile'—despite suggesting the contrary in 2015." *Id.* As to Degala, Patent Owner asserts that it "documents the ongoing uncertainty regarding existing sterilization methods and describes neither a sterilized product or article or any validated sterility processing." *Id.*

Finally, Patent Owner asserts that the field was nascent and none of the cited references describe a CHG composition "subjected to a suitable sterilization process such that sterility can be validated." PO Resp. 44 (citing Ex. 2023 ¶¶ 104, 310, 412); Sur-Reply 20.

For the reasons discussed *supra* § III.A, we find that Petitioner has established, by a preponderance of the evidence, that a person of skill in the art would have understood the use of the word "sterile" in 2010 in ChloraPrep PAR to mean that the things labeled "sterile" – i.e., "ChloraPrep with Tint," the "sterilized alcoholic antiseptic solution," and the "applicators" – had been sterilized, as required by the challenged claims. In

addition, Petitioner has established by a preponderance of the evidence that it would have been obvious to one of skill in the ordinary art at the time of the invention to sterilize the things labeled "sterile" in the ChloraPrep PAR.

Specifically, as discussed *supra* §§ III.A.2.a. and III.A.2.b, Petitioner has shown that "some degree of sterilization [was] required in European Union (EU) countries" (*see* Ex. 1007 ¶ 2) and that its ChloraPrep products sold within the United Kingdom (UK) were subject to UK regulatory requirements as outlined in EN 556-1. *See* Ex. 1003 ¶ 144; Ex. 1017; Ex. 1037 ¶¶ 1–12; Ex. 1038 ¶¶ 6–16. The EN 556-1 standard states that a product can be designated as "sterile" only if it had undergone a validated sterilization process. *See* Ex. 1017, 6. Moreover, as discussed *supra* §§ III.A.2.a and III.A.2.b, the evidence supports that a person of ordinary skill in the art would have been aware of the standards for calling a product "sterile" in a regulatory document and thus motivated to follow them. Ex. 1003 ¶¶ 71, 91, 129–134, 144–145; Ex. 1017; *see also*, Ex. 1040, 199:24–200:18 (Dr. Rutala testimony that "I would agree that it's likely that a POSA would be aware of ISO standards. And likely, they would be aware of the ISO standards for steam sterilization or moist heat as well as ethylene oxide, dry heat.").

Additionally, the testimony of Dr. Dabbah establishes that it was within the knowledge of one of ordinary skill in the art at the time of the invention (i.e., Nov. 25, 2015) to sterilize the chlorhexidine gluconate composition individually in the ChloraPrep product using techniques such as that disclosed by Degala in July 2015. *See* Ex. 1003 ¶ 76; Ex. 1007 ¶¶ 2–4, 7, 28, 30, 50. We credit the testimony of Dr. Dabbah that prior art references such as Degala (Ex. 1007) are indicative of the level of skill and

the knowledge possessed by an ordinary artisan at the relevant time. *See* Ex. 1003 ¶¶ 73–75; *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) ("The issue of obviousness is determined entirely with reference to a hypothetical 'person having ordinary skill in the art.' It is only that hypothetical person who is presumed to be aware of all the pertinent prior art.").

Furthermore, given the disclosures of Degala (Ex. 1007), we do not agree with Patent Owner that the field of chlorhexidine gluconate sterilization was a nascent field. Rather, Degala explicitly states that CHG can be sterilized using a "known method" and presents an improvement on that method. Ex. 1007 ¶¶ 3, 7. Degala also discloses the results of testing to determine how long it took to reach a SAL of 10^{-6} for a CHG solution sterilized at three different temperatures. *Id.* ¶ 52. Thus, Degala supports our finding that CHG sterilization was a developed field. Although not necessary to this determination, we note that for the reasons discussed *supra* § III.A.2.b, Scholz also supports that it was known that CHG could be sterilized using "a variety of industry standard techniques." Ex. 1008 ¶ 178.[15]

For the reasons discussed *supra* § III.A.2.a, the evidence also supports that a person of ordinary skill in the art would have known how to terminally sterilize the product disclosed in the ChloraPrep PAR and would have considered it routine to do so. *See, in particular, discussion of* Ex. 1003 ¶ 138; Ex. 2015 ¶ 10; Ex. 1040, 141:18–143:6, 145:2–147:21 190:6–20; Ex.

[15] As the record already includes ample support for our finding that a person of ordinary skill in the art would have known how to sterilize CHG, we need not determine here whether Margoosian further supports this finding.

2023 ¶ 206; *see also*, Ex. 1003 ¶ 71 (discussed *supra* § III.A.2.b). Accordingly, we find that a person of ordinary skill in the art would have known how to sterilize the entire product described in the ChloraPrep PAR.

The evidence of record also supports that a person of ordinary skill in the art would have had a reasonable expectation of success. As discussed *supra* § III.A.2.b, the record supports that a person of ordinary skill in the art would have known of the existence of a product containing sterilized CGH. *See, in particular, discussion of* Ex. 1005, Ex. 1007 ¶ 2; Ex. 1044, 41; Ex. 1037 ¶¶ 2, 7; Ex. 1038 ¶¶ 3, 4, 6, 10. In addition, the record supports that a person of ordinary skill in the art would have known of the existence of terminally sterilized CHG products. For example, as discussed *supra* § III.A.2.a, Chiang discloses terminal sterilization of CareFusion's ChloraPrep applicator using ethylene oxide. Ex. 2015 ¶ 10. The knowledge of terminally sterilized products and products with sterilized CHG solutions, coupled with the knowledge of methods of sterilizing, supports that a person of ordinary skill in the art would have had a reasonable expectation of success in sterilizing all of the things labeled "sterile" in the ChloraPrep PAR.

In sum, we find that given the UK regulatory requirements, a person of ordinary skill in the art would have been motivated to "sterilize" the things described in the ChloraPrep PAR as "sterile" – i.e., the "alcoholic antiseptic solution," the "applicator," and the "ChloraPrep with Tint" product itself. Ex. 1003 ¶¶ 144–145. We also find that a person of ordinary skill in the art would have known how to sterilize each of the things described in the ChloraPrep PAR as "sterile" to the SAL recited in claims 10

and 20, and that a person of ordinary skill in the art would reasonably have expected success in doing so.

We turn now to Patent Owner's arguments. **First,** we are not persuaded by Patent Owner's arguments that Petitioner has not established that it would have been obvious to sterilize CHG because Petitioner relies on "conclusory assertion[s] . . . about general knowledge in the art without evidence on the record." Petitioner and its expert, Dr. Dabbah, provided more than mere conclusory assertions about the general knowledge in the art at the critical time. The circumstances here are distinguishable from *K/S Himpp*, because here, to the extent the ChloraPrep PAR does not disclose a sterilized product with a sterilized CHG solution, it includes an explicit suggestion that they should be "sterile." *See, e.g.*, Ex. 1005, 7. Furthermore, the record here is not limited to "general knowledge," but includes specific teachings of products having sterilized CHG and terminally sterilized products having CHG compositions.

Second, Patent Owner's argument that Petitioner's obviousness challenge fails because it relies on "vague reference to unidentified 'standards and guidelines,'" is also unpersuasive. The evidence of record includes specific standards and guidelines, including BS EN 556-1 and corresponding FDA guidelines. *See* Ex. 1017; Ex. 1028. In addition, Dr. Rutala confirmed that a SAL of 10^{-6} is the common, widely accepted standard for designating a component or device as "sterile." *See* Ex. 1040, 235:16–237:22; *see* Ex. 1013 (ISO 11137-1 International Standard for "Sterilization of health care products—Radiation"), 13.

Third, Patent Owner's arguments regarding the FDA's guidance and CareFusion's 2015 label change are irrelevant, because Petitioner's

obviousness arguments are premised on (1) a ChloraPrep regulatory document relating to a product sold within the United Kingdom and (2) the knowledge of those of ordinary skill in the art as demonstrated by evidence found in EN 556-1 (Ex. 1017), Degala (Ex. 1007), and Scholz (Ex. 1008).

Fourth, we do not agree with Patent Owner's argument that Petitioner does not explain how the evidence of record would further compel a person of ordinary skill in the art to understand that the product, article, or composition would have been subjected to validated sterility processing. We do not understand Petitioner to argue that it would have been obvious that the product described in the ChloraPrep PAR had been sterilized. Rather, Petitioner argues that, to the extent the product described in the ChloraPrep PAR is found not to be sterilized, it would have been obvious to sterilize it. Pet. 56 ("Thus, even if Patent Owner contends that 'sterile' does not necessarily refer to the claimed SAL, it would have been obvious to a POSA to sterilize the claimed components to the required SAL.").

Fifth, we do not agree with Patent Owner's arguments that Petitioner's evidence regarding the Degala, Margoosian, and Scholz references should be ignored because these references are not argued explicitly in the Petition as part of Petitioner's first obviousness challenge. *See* PO Resp. 42; Sur-Reply 18–19. Petitioner's challenge asserts that its ChloraPrep product was sold within the United Kingdom and person of ordinary skill in the art at that time would have known the composition was sterilized as demonstrated by evidence found in EN 556-1 (Pet. 52; Ex. 1003 ¶ 144 (citing Ex. 1017)). Degala (Ex. 1007) is part of the basis for Petitioner's second obviousness challenge, but it explicitly references regulatory standards in the EU, which supports Petitioner's arguments

regarding EN 556-1. Petitioner explains this in its at Reply, which is appropriate rebuttal argument. Reply 8, 23. Additionally, "a person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art." *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Moreover, we do not agree with Patent Owner's characterization of Degala and Scholz. *See* PO Resp. 43. As discussed above, Degala and Scholz support that the person of ordinary skill in the art would have known how to sterilize CHG compositions.

Finally, as discussed *supra* § III.A.2.a, applicable standards required a specific SAL and Dr. Rutala conceded that "you have to have a validated sterility process to have a sterility assurance level." Ex. 1043, 159:20–25. Accordingly, we are not persuaded by Patent Owner's argument that none of the cited references describe a CHG composition "subjected to a suitable sterilization process such that sterility can be validated." PO Resp. 44. For these reasons, we find that all the limitations of claims 1–3, 5–8, 10–18 and 20 were taught or suggested at the critical time in view of the ChloraPrep PAR.

Before reaching a final conclusion regarding Petitioner's obviousness challenge to the '642 patent, however, we consider Patent Owner's objective indicia evidence to determine if it outweighs Petitioner's showing regarding the ChloraPrep PAR.

2. Analysis of Objective Indicia of Non-Obviousness

Factual inquiries for an obviousness determination include an evaluation and crediting of objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17. Objective evidence of non-obviousness "may often be the most probative and cogent evidence in the record" and "may often

establish that an invention appearing to have been obvious in light of the prior art was not." *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012). Thus, notwithstanding what the teachings of the prior art would have suggested to one skilled in the art, secondary considerations (objective evidence of nonobviousness) may lead to a conclusion that the challenged claims would not have been obvious. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984). Objective indicia of non-obviousness can include any of the following: long-felt but unsolved needs, failure of others, unexpected results, commercial success, copying, licensing, and praise. *See Graham*, 383 U.S. at 17; *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

In order to accord substantial weight to objective evidence of nonobviousness, "the evidence of secondary considerations must have a 'nexus' to the claims, i.e., there must be 'a legally and factually sufficient connection' between the evidence and the patented invention." *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (quoting *Demaco Corp. v. F. Von Lang-sdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988)). Although the patent owner bears the initial burden of proving a nexus (*WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999)), a presumption of nexus may be appropriate if the patent owner shows "the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features, and is *coextensive with them*.'" *Polaris Indus, Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018) (quoting *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) (emphasis added)). On

the other hand, "[w]hen the [product] is not coextensive with the patented invention—for example, if the patented invention is only a component of a commercially successful machine or process," the patent owner is not entitled to a presumption of nexus. *Demaco*, 851 F.2d at 1392.

Here, we find nexus because the '067 patent claims are embodied by and coextensive with the ChloraPrep product. *See* Ex. 1030 ¶¶ 17–45; *see also* Section III.A. (finding the '067 patent claims anticipated by ChloraPrep PAR). Regardless of whether we find a nexus our ultimate conclusions regarding each of Patent Owner's alleged objective indicia of non-obviousness would not change.

Regarding the specific objective indicia of non-obviousness, Patent Owner argues that long-felt but unresolved need, skepticism and failure of others, industry praise, and commercial success linked to the invention indicates that the claims would not have been obvious to a person of ordinary skill in the art. PO Resp. 58–68.

a) Long-Felt but Unsolved Need

Patent Owner argues that the inventors of the '642 Patent "solved a long-felt but unmet need for a sterilized chlorhexidine product that allows for the containment, delivery, and application of a sterilized CHG composition." PO Resp. 58. Patent Owner also argues that the industry "was very concerned about mitigating ongoing outbreaks and deaths due to contaminated antiseptic products." *Id.* (citing Ex. 2023 ¶¶ 421–423; Ex. 2003). And, according to Patent Owner, to address mounting concerns, the FDA convened hearings in 2012 to address whether sterilization should be required. *Id.* Patent Owner asserts that "[d]uring the hearings, numerous stakeholders commented on the 'technical challenges' associated with

sterilizing antiseptics including comments that sterilization would be '<u>impossible or impractical</u>.'" *Id.* at 58–59 (citing Ex. 2023 ¶¶ 423–424; Ex. 2002, 23, 25; Ex. 2004, 2172; Ex. 2007, 14–15, 17). Patent Owner further asserts that "industry representatives emphasized the challenges these processes entailed and the <u>difficulties of achieving sterility</u>" with CHG being "known as particularly problematic." *Id.* at 59 (citing Ex. 2002, 24; Ex. 2023 ¶¶ 425–426).

We are not persuaded. To establish a long-felt need, three elements must be proven: First, the need must have been a persistent one that was recognized by ordinarily skilled artisans. *In re Gershon*, 372 F.2d 535, 538 (CCPA 1967). Second, the long-felt need must not have been satisfied by another before Appellant's invention. *See Newell Companies, Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Third, the invention must, in fact, satisfy the long-felt need. *In re Cavanagh*, 436 F.2d 491, 496 (CCPA 1971). Patent Owner's argument is lacking as to all elements. The articles cited by Patent Owner range from 2007 to 2012 but fail to account for the disclosure in Degala that demonstrates sterilization of a chlorhexidine gluconate composition was known and being improved upon by 2015. *See* Ex. 1007 ¶¶ 2, 3, 7, 50, 52. *Newell Companies*, 864 F.2d at 768 ("[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved."). And, Patentee's expert stated he was unaware of any evidence of long-felt need or skepticism after the publication of Degala. *See, e.g.*, Ex. 1040, 309:7–310:20; 307:16–308:17.

Patent Owner's citations to a marketing brochure of a product being released in 2019 in the U.S. do not alter the fact that methods of sterilizing CHG compositions were known and that a product including a sterilized

CHG composition was being sold in the UK. *See* PO Resp. 60–61 (citing Ex. 2007, 14, 17); ; Ex. 1007 ¶ 2; Ex. 1044, 41; Ex. 1007 ¶ 2; Ex. 1037 ¶¶ 1–7; Ex. 1038 ¶ 6. Additionally, Scholz teaches that products containing chlorhexidine gluconate compositions may be terminally sterilized by known techniques (Ex. 1008 ¶ 178) and Chiang teaches that CareFusion's ChloraPrep applicator, which included a CHG composition, was terminally sterilized using ethylene oxide (Ex. 2015 ¶ 10). These disclosures further indicate there was not a long-felt but unmet need in the industry.

Accordingly, we give little weight to Patent Owner's argument that there was a long-felt but unmet need.

b) Skepticism in the Industry

Patent Owner argues there was concern among manufacturers of sterilized antiseptics that the "FDA would impose a requirement that topical antiseptics be sterilized because they were skeptical that [a person of ordinary skill in the art] could develop sterilized antiseptic products. *See* PO Resp. 61 (citing Ex. 2023 ¶¶ 435–440). According to Patent Owner, "[m]any comments from the FDA hearings were directed to the challenges associated with manufacturing sterilized antiseptics." *Id.* Patent Owner cites to a 2013 article from The Society for Healthcare Epidemiologists, which "agree[d] that products used for aseptic procedures need be sterile, however, it acknowledge[d] that sterilization of topical antiseptics is problematic." *Id.* (citing Ex. 2002, 10). Patent Owner notes that the 2013 article "urge[d] FDA to engage manufacturers however on the possible technical limitations of sterilization of select topical antimicrobials such as chlorhexidine gluconate (CHG)." *Id.*

For the same reasons discussed above with regard to "long felt but unmet need," we are unpersuaded by Patent Owner's position. Accordingly, we give little weight to Patent Owner's argument that there was skepticism in the industry.

c) Failure of Others

Patent Owner argues that a person of ordinary skill the art would have recognized that, "at the time of the invention, others tried and failed to develop sterilized chlorhexidine products and articles including sterilized CHG and the field was nascent." PO Resp. 63 (citing Ex. 2023 ¶¶ 441–447.) Patent Owner cites to the '642 Patent, Degala, and Margoosian to bolster its argument that "there were many challenges faced by [a person of ordinary skill the art] in trying to create sterilized CHG products and articles including the potential for degradation" and that others failed to describe or create "any validated methods for sterilizing CHG compositions." *Id.* at 63–64 (citing Ex. 1001, 14:42–45; 17:14–18; Ex. 1007 ¶¶ 3–4; Ex. 2023 ¶¶ 444–446; Ex. 2035, 7–8).

For the same reasons discussed above with regard to "long felt but unmet need," we are unpersuaded by Patent Owner's position. Accordingly, we give little weight to Patent Owner's argument that there was failure of others in the industry.

d) Industry Praise and Commercial Success of the ChloraPrep USA Product

Patent Owner contends that Petitioner's fully-sterilized ChloraPrep products released in the United States in 2019 are covered by the claims of the '642 Patent and quickly became successful. PO Resp. 64–65 (citing Ex. 1030, 8–16; Ex. 2041, 97, 98–103; Exs. 2026–2030). According to

Patent Owner, "the difference between Petitioner's original [unsterilized] products and the fully-sterilized ones are the invention itself—fully sterilized products with sterilized CHG composition"—which demonstrates the commercial success of the '642 patent. *Id.* at 66 (citing Ex. 2025; Ex. 2031, 4, 7, 12).

Patent Owner argues that "[d]espite the impact of COVID-19 on elective surgeries, Petitioner's fully-sterilized ChloraPrep product generated millions in revenue after launch in 2019." *Id.* at 66–67 (citing Ex. 2023 ¶ 451; Ex. 2026, 3 (over [redacted] in FY 2020); Ex. 2027, 4 (over [redacted] in FY 2021); Ex. 2028, 2 (over [redacted] from FY Dec. 2021-FY Nov. 2022); Ex. 2029 (high volume of sales by customer)). Indeed, according to Patent Owner, from April 2020 to March 2021, Petitioner captured over half of the U.S. market for preoperative skin preparation products with its sterilized products. *Id.* at 67 (citing Ex. 2030, 2). Patent Owner further argues that upon recognizing the value of the invention, Petitioner initiated a plan to discontinue its non-sterilized products and [redacted] for its fully-sterilized products. *Id.* (citing Ex. 2031, 8, 11.)

We agree that the market share and sales information presented by Patent Owner demonstrates considerable sales of the ChloraPrep USA products within the U.S. market. We do not agree, however, that Petitioner's release of its ChloraPrep UK product into the U.S. market demonstrates commercial success for several reasons.

As an initial matter, Dr. Rutala testified that there could be many factors beyond the use of the invention that contributes to revenue or units sold but that he did not evaluate those other factors because "[he] didn't

have the information nor would [he] know how to use it if [he] had it." *See* Ex. 1040, 292:9–293:8.

Moreover, Sean Sheridan, Ph.D. ("Dr. Sheridan") testified that "the introduction of the Sterilized ChloraPrep products did not lead to any material change in sales of ChloraPrep products which were significant and growing for years prior to Q4 2019." *See* Ex. 1039 ¶ 33; *see also, id.* ¶ 30 (Dr. Sheridan's testimony that the release of the sterilized U.S. product did not result in "materially different" unit sales than would have been expected based on sales of the unsterilized U.S. product). Dr. Sheridan further testified that "[t]he profitability data in the documents cited by Dr. Rutala indicate that the introduction of the Sterilized ChloraPrep products [redacted] *Id.* ¶ 35. Dr. Sheridan went on to testify that "the introduction of the Sterilized ChloraPrep products appears to be correlated with a decrease in BD's share of the relevant market." *Id.* ¶ 39. We credit Dr. Sheridan's testimony.

Accordingly, we give little weight to Patent Owner's argument that sales of the ChloraPrep USA products demonstrate commercial success.

For industry praise, Patent Owner relies on the marketing materials accompanying the release of Petitioner's sterilized U.S. product, arguing:

> Petitioner has touted its sterilized products as "[n]ew, advanced technology" with "the lowest risk of intrinsic contamination available." . . . And in its marketing materials, Petitioner praised its product development, telling customers that "[s]terilizing antiseptic solutions is a difficult challenge" and that "manufacturers have asserted . . . is 'impossible or impractical'" because "[c]onventional terminal sterilization processes . . . are not compatible with common antiseptics, including CHG and can damage the chemical integrity of the active ingredient."

PO Resp. 65 (citing Ex. 2007, 4, 14, 15). Petitioner's marketing puffery does not weigh heavily in our analysis because the evidence supports that it was selling a product including a sterilized CHG composition well before the introduction of its sterilized U.S. product. Moreover, to the extent there was a technology advance accompanying the launch of Petitioner's sterilized U.S. product, the advance appears to relate not to the ability to sterilize CHG, but to a method for doing so with a "shorter, more efficient processing time." *See* Ex. 1007 ¶¶ 2, 5, 7 (describing known sterilization method and improved method addressing the need for a "shorter, more efficient" method). In this regard, we note that the challenged claims do not restrict the method by which CHG is sterilized.

e) Summary of Analysis of Secondary Considerations of Non-Obviousness

Patent Owner has demonstrated a sufficient nexus between the claimed invention and the ChloraPrep UK products. For the reasons discussed above, however, we give little weight to Patent Owner's assertions that the claimed invention satisfies a long-felt but unmet need for the claimed invention, was met by skepticism, was preceded by the failure of others to develop similar products, enjoyed commercial success, or was received with praise in the industry.

3. Conclusion on Claims

As discussed above, the record supports that a person of ordinary skill in the art would have had reason to comply with relevant standards, that it was known how to sterilize CGH and how to terminally sterilize a product using, e.g., ethylene oxide, and that it was known that there were products on the market that had been terminally sterilized and that included sterilized

CGH. Considering this evidence together with the objective indicia of non-obviousness presented by Patent Owner, we find that the preponderance of the evidence supports that it would have been obvious to sterilize everything identified as "sterile" in the ChloraPrep PAR.

4. Conclusion

For the foregoing reasons, we find Petitioner has proven by a preponderance of the evidence that ChloraPrep PAR teach or suggest all elements of challenged claims 1–3, 5–8, 10–18, and 20 of the '642 patent. Furthermore, we find that the use of the ChloraPrep PAR would have been within the level of ordinary skill in the art, as evidenced by the prior art of record. We, therefore, conclude Petitioner has demonstrated by a preponderance of the evidence that claims 1–3, 5–8, 10–18, and 20 would have been obvious in view of ChloraPrep PAR, and thus, are unpatentable under 35 U.S.C. § 103.

C. Alleged Obviousness of Claims 1–3, 5–8, 10–18, and 20 in View of ChloraPrep PAR and Degala

Petitioner contends claims 1–3, 5–8, 10–18, and 20 would have been obvious to a person of ordinary skill in the art at the critical time in view of ChloraPrep PAR and Degala. Pet. 56–64. Patent Owner disagrees, arguing, *inter alia*, that the combination of references does not cure the problem with ChloraPrep PAR because PAR does not disclose the "sterilized" limitation[s]." PO Resp. 47–54. Patent Owner also argues that Petitioner fails to explain why a person of ordinary skill in the art would have been motivated to combine ChloraPrep PAR and Degala or why there would be a reasonable expectation of success. *Id.* at 54–56. As discussed in detail below, we find Petitioner has demonstrated by a preponderance of the

evidence that challenged claims 1–3, 5–8, 10–18, and 20 would have been obvious to a person of ordinary skill in the art under 35 U.S.C. § 103 in view of ChloraPrep PAR and Degala.

1. Analysis of the Challenged Claims

a) Claims 1 and 12

Petitioner relies on its arguments regarding ChloraPrep PAR in addition to Degala's disclosure when contending that the combined teachings of ChloraPrep PAR and Degala would have rendered challenged claims 1 and 12 obvious to a person of ordinary skill in the art at the critical time. Pet. 56–64 (citing Ex. 1003 ¶¶ 148–166). Petitioner argues that in addition to the ChloraPrep PAR's disclosure, Degala provides a detailed description of a method to sterilize an "antiseptic solution":

> [T]he method for sterilizing an antiseptic solution comprises providing a container containing the antiseptic solution . . . ; selecting a sterilization temperature from about 85° C. to about 135° C. and a sterilization time from about 1 minute to about 19 hours; heating the antiseptic solution to the selected sterilization temperature; maintaining the antiseptic solution at the selected sterilization temperature for the selected sterilization time; and terminating the heating of the antiseptic solution when the selected sterilization time expires.

Id. at 56 (citing Ex. 1007 ¶ 7). According to Petitioner, "Degala teaches that this process can be used with an antiseptic solution that 'comprises about 70% v/v isopropanol in water and about 2.0% w/v chlorhexidine gluconate,'" which Petitioner contends is "the same solution described in the ChloraPrep PAR." *Id.* (citing Ex. 1007 ¶ 16). And, Petitioner asserts that Degala teaches that "'the container may be made of a frangible material such that upon application of sufficient force the container fractures,' which again

is consistent with the ChloraPrep PAR." *Id.* (citing Ex. 1007 ¶ 26). Petitioner also asserts that "Degala discusses the ChloraPrep product as embodied in the ChloraPrep PAR and states that is 'sterilized for EU countries using a known sterilization method.'" *Id.* at 59 (citing Ex. 1007 ¶ 2).

Petitioner contends that "Degala's disclosure in totality refers to means of sterilization to achieve a sterile condition, including through validated sterility processing that renders the product free of viable microorganisms." Pet. 58. Petitioner notes that Degala "defines 'sterile' based on international requirements for qualification as sterile, stating, '[a]s used herein, sterile means '7 day sterility' as tested following the procedures described in U.S. Pharmacopeial Convention (USP) Chapter 55 'Biological Indicators—Resistance Performance Tests.'" *Id.* (citing Ex. 1007 ¶ 40). Thus, Petitioner concludes that the combined teachings of ChloraPrep PAR and Degala would have rendered claims 1 and 12 obvious to a person of ordinary skill in the art. *Id.* at 58.

Patent Owner contends that the combination of ChloraPrep PAR and Degala fails to fill numerous missing elements from claims 1 and 12. PO Resp. 48. Patent Owner first argues that Degala does not disclose a sterilized CHG composition that is subject to a suitable sterilization process such that sterility can be validated. *Id.* (citing Ex. 2023 ¶¶ 363, 370–372). According to Patent Owner, a person of ordinary skill in the art would have understood that "passing a sterility test on a particular instance does not mean that a particular sterilization process itself has been validated, i.e., that procedures have been established to show that the process consistently, reliably, and reproducibly results in a product that is sterile (e.g., according

to that sterility test)." *Id.* at 49. Patent Owner asserts that the "7-day sterility test" in Degala only "provides a way to check 'viable spore count' resulting from a particular process" regardless of whether or not that process was validated. *Id.*

Patent Owner then contends that even if a "sterilized [CHG] composition" were disclosed, "Petitioner failed to establish how the combination discloses a 'sterilized chlorhexidine product' or a 'sterilized chlorhexidine article.'" *Id.* (citing Ex. 2023 ¶¶ 363, 367–369). Patent Owner asserts that "Petitioner glosses over these limitations," but "in allowing the claims, the PTO emphasized that 'the prior art does not teach a product which is itself necessarily sterilized and comprising sterilized chlorhexidine gluconate as further recited in the claims.'" *Id.* (citing Ex. 1002, 99).

Lastly, Patent Owner again argues that a person of ordinary skill in the art at the critical time would not understand "sterile" to mean "sterilized" based on "unidentified 'international standards regarding sterility.'" *Id.* (citing Pet. 58).

For the reasons detailed above, *see* Sections III.A and B., *supra*, the trial record supports a finding that the ChloraPrep PAR teaches or suggests all the limitations of the challenged claims, including separately sterilizing a chlorhexidine gluconate composition within a product and sterilizing a complete final article. In addition to the teachings of ChloraPrep PAR explained previously, Degala explicitly discloses sterilizing a chlorhexidine gluconate composition via a cascading-water sterilization process and further discloses that the process produces a SAL of 10^{-6}. *See* Ex. 1007 ¶¶ 41, 43, 45, 49, 52, 54, Tables 11, 12, and 14; *see also* Ex. 1040, 325:9–

327:22 (Dr. Rutala testifies "Degala teaches a CHG method to achieve sterilization of a CHG composition"). Additionally, as discussed previously, Dr. Rutala conceded that "you have to have a validated sterility process to have a sterility assurance level." Ex. 1043, 159:20–25.

Taking the complete record into account, including the objective indicia of non-obviousness (discussed *supra* § III.B.2), we find that the combination of ChloraPrep PAR and Degala would have rendered obvious the sterilization of a complete final product that includes a sterilized chlorhexidine gluconate composition. As discussed previously, the ChloraPrep PAR states that the ChloraPrep UK product has both a sterile CHG solution and a sterile applicator. Ex. 1006, 7, 10, 17. Additionally, as discussed previously *see* Sections III.A.1., *supra*, terminal sterilization techniques and their use on packaging of products containing chlorhexidine gluconate compositions were well-known and routine as of 2015 ¶ 10. *See* Ex. 1003 ¶ 71; Ex. 1040, 141:18–143:6, 147:10–11, 190:6–20; Ex. 2015; Ex. 1017, Part 1. In fact, the ChloraPrep USA product was subject to termination sterilization in 2015. Ex. 2006.

Therefore, considering the knowledge of those skilled in the art and the regulatory requirements for the ChloraPrep UK product, as well as the other evidence of record, including the objective indicia of non-obviousness, we find that after reading the ChloraPrep PAR and Degala, a person of ordinary skill in the art in at the time of the invention would have found it obvious to sterilize the CHG solution and to terminally sterilize the product described in the ChloraPrep PAR if it had not already been subject to such a process.

Accordingly, based on the entirety of the proceeding record, we conclude Petitioner has demonstrated by a preponderance of the evidence that independent claims 1 and 12 would have been obvious under 35 U.S.C. § 103 in view of ChloraPrep PAR and Degala.

Patent Owner argues that Petitioner fails "to present any cogent reason why a [person of ordinary skill in the art] would have been motivated to combine [ChloraPrep] PAR and Degala or why there would be a reasonable expectation of success." PO Resp. 54 (citing Ex. 2023 ¶¶ 403–414). According to Patent Owner, a person of ordinary skill in the art would not have understood a reference "to an unidentified CareFusion product somewhere in the EU in 2014 as a 'specific reference' to the ChloraPrep UK products allegedly referenced in a 2010 PAR." *Id.* at 55 (citing Ex. 2023 ¶¶ 406, 364–65). Patent Owner additionally argues that Degala teaches away from the product in the ChloraPrep PAR because "the product is heavily criticized Paragraphs 3 to 5 due to its numerous 'undesired impurities' from 'overly degrading the antimicrobial molecules.'" *Id.* (citing Ex. 1007 ¶¶ 3–5; Ex. 2023 ¶¶ 407–408). Patent Owner further argues "Petitioner has no evidence that a [person of ordinary skill in the art] would have a reasonable expectation of success at arriving at the claimed inventions given the numerous challenges facing POSAs and the prior failures by others." *Id.* at 56–57 (citing Ex. 2023 ¶¶ 410–414).

We do not agree with Patent Owner. The record supports a finding that a person of ordinary skill in the art would have had reason to combine the teachings of ChloraPrep PAR and Degala and would have had a reasonable expectation of success in combining the teachings of both references. First, we do not agree that Degala disparages or heavily

criticized the ChloraPrep product. *See* Ex. 1007 ¶¶ 3–5. Rather, Degala teaches an improvement upon the method used previously in the industry. *Id.* Based on Degala's own teachings, we find a person of ordinary skill in the art would have readily applied Degala's technique to that in the ChloraPrep PAR. An improvement suggested by the prior art is not a teaching away, particularly when the purpose of the prior art is not destroyed, but improved upon. *Ricoh Co., Ltd. v. Quanta Comp. Inc.*, 550 F.3d 1325, 1332 n. 5 (Fed.Cir.2008) (citing *In re Fulton*, 391 F.3d 1195, 1201 (Fed.Cir.2004) (refusing to conclude that prior art disclosure taught away from the claimed invention where the disclosure did not "criticize, discredit, or otherwise discourage the solution claimed")).

Second, we credit the testimony of Dr. Dabbah who notes that "Degala expressly references the product discussed in the ChloraPrep PAR, noting prior techniques for sterilizing the solution and ampoule were known and describing additional methods. Therefore, I consider that it would have been obvious to combine these teachings." Ex. 1003 ¶ 146; *see also* Ex. 1007, code 71 (Applicant: CareFusion 2200, Inc.), ¶ 2 ("A 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."); Ex. 1005, 4. Lastly, the record is replete with citations indicating that CareFusion, the applicant for Degala, was the company that originally produced the ChloraPrep product. *See* Ex. 2006; Ex. 2008 (FDA website referencing ChloraPrep labels); Ex. 2015 ¶ 8 ("the ChloraPrep® products commercially available from CareFusion") ¶ 10; Ex. 2016, 12, 13.

Given that (1) Degala teaches that in some jurisdictions, such as EU countries, some degree of sterilization is required, (2) Degala discloses an improved technique for sterilizing a chlorhexidine gluconate composition, (3) Degala was filed by CareFusion, the same company that originally produced the ChloraPrep and (4) per Dr. Dabbah, the composition in Degala is the same one described in ChloraPrep PAR, we find that one skill in the art would have had a reason to and a reasonable expectation of success in combining the teachings of the prior art references. *See Power-One, Inc., v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1351 (Fed. Cir. 2010) (an invention is not obvious just "because all of the elements that comprise the invention were known in the prior art;" rather a finding of obviousness at the time of invention requires a "plausible rational [sic] as to why the prior art references would have worked together."); *Amgen Inc. v. F. Hoffman-LA Roche Ltd.*, 580 F.3d 1340, 1362 (Fed. Cir. 2009) ("An obviousness determination requires that a skilled artisan would have perceived a reasonable expectation of success in making the invention in light of the prior art."); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 538, 416 (2007) (The primary basis for a rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art.). Considering the entire record, including the objective indicia of non-obviousness, we find that the person of ordinary skill in the art would have had reason to sterilize the things identified as

"sterile" in the ChloraPrep PAR and would have had a reasonable expectation of success in doing so.

b) Dependent Claims 7, 8, 17, and 18

Claims 7, 8, 17, and 18 include limitations requiring a sterilized additive, specifically a sterilized colorant. Ex. 1001, 27:40–48, 28:35–43.

Petitioner contends that ChloraPrep PAR in combination with Degala renders this claim limitation obvious because the improved sterilization methods disclosed in Degala are generally applicable to "antiseptic solution[s] contained in a container" and that the "[p]referred antiseptic agents include octenidine, such as octenidine dihydrochloride, and chlorhexidine, such as chlorhexidine gluconate." Pet. 60 (citing Ex. 1007 ¶¶ 25, 30); Reply 21. Moreover, according to Petitioner, Degala teaches that its novel sterilization methods can be applied more generally to "medicaments, chemical compositions, cleansing agents, cosmetics, or the like." Pet. 60 (citing Ex. 1007 ¶ 27). Therefore, Petitioner argues that a skilled artisan would have been motivated to apply the sterilization methods described in Degala to the particular antiseptic solution described in the ChloraPrep PAR, which contains, inter alia, a colorant. *Id.* Petitioner further argues that "a skilled artisan would be particularly motivated to do so in light of the description in the ChloraPrep PAR that the antiseptic solution is 'sterile.'" *Id.* at 60–61 (citing Ex. 1005, 7). Petitioner asserts that a skilled artisan also would have understood that "the sterilization process applied to the ampoule containing the chlorhexidine gluconate composition must also be applied to additives included therein." *Id.* at 61. Thus, Petitioner concludes that "applying the sterilization methods of Degala to the

antiseptic solution of the ChloraPrep PAR would result in a 'sterilized colorant.'" *Id.* (citing Ex. 1003 ¶¶ 159–62).

Patent Owner disagrees with Petitioner and notes that Degala teaches its "sterilization methods can be applied more generally to 'medicaments, chemical compositions, cleansing agents, cosmetics, or the like.'" PO Resp. 52 (citing Pet. 60). But, Patent Owner argues, "none of these is alleged to be one of the seven claimed additives and, in any case, Degala does not teach subjecting any to its sterilization method." *Id.* (citing Ex. 1007 ¶ 27 ("[w]hile antiseptic solutions are of particular focus herein, the container may alternatively contain medicaments, . . ."); Ex. 2023 ¶¶ 396–397).

Patent Owner further argues "Petitioner has not established the PAR discloses a CHG composition containing a colorant." *Id.* (citing Ex. 2023 ¶¶ 272, 395). Patent Owner then asserts that "Petitioner cites no evidence that it was known to sterilize any additive (much less a colorant in a CHG composition) or that it could be done with a reasonable expectation of success." *Id.* (citing Ex. 2023 ¶¶ 397–398, 400). Indeed, according to Patent Owner, "Chiang stated that the dye in ChloraPrep was separate from the CHG composition and described how the combination of dyes with CHG presented further stability challenges." *Id.* (citing Ex. 2015 ¶ 13, Ex. 2023 ¶ 398).

We do not agree with Patent Owner and find that the preponderance of the evidence in the record supports Petitioner's position. Specifically, as discussed previously *supra* § III.A.7, we find that the ChloraPrep PAR has a colorant because it states explicitly that the ChloraPrep includes a tint. *See* Ex. 1006, 1 (the coversheet states "ChloraPrep *with Tint* 2% w/v/70%v/v

Cutaneous Solution"), 7 (when describing the nature and contents of the container, it states "ChloraPrep *with Tint* is a sterile alcoholic antiseptic solution.").

The ChloraPrep PAR also lists the colorant Sunset Yellow (E110) as an excipient. *Id.* at 7, 17. The ChloraPrep PAR explains that "Sunset yellow (E110) is commonly used as an excipient or additive in medicinal and food products." *Id.* at 19. Dr. Rutala testified that an excipient in a CHG composition is "an inactive ingredient in the composition" and is "essentially the medium in some way for the active substance." Ex. 1040, 234:15–239:7. He further testified that if a "composition is sterile . . . the excipients have to be sterile." *Id.* This testimony is supported by Dr. Dabbah, who testifies regarding Sunset Yellow that "[a]s an excipient included within the sterilized chlorhexidine gluconate solution, that colorant is similarly sterile and sterilized" and "approval of ChloraPrep's description as a sterile composition in the ChloraPrep PAR, requires the sterilization of all substances in the solution." Ex. 1003 ¶ 127.

Therefore, as discussed previously *supra* § III.A.7, we find that Sunset Yellow is a colorant and a commonly used excipient for medicinal products, and as such is part of the sterilized composition. Accordingly, we conclude Petitioner has demonstrated by a preponderance of the evidence that challenged dependent claims 7, 8, 17, and 18 would have been obvious to a person of ordinary skill in the art under 35 U.S.C. § 103 in view of ChloraPrep PAR and Degala.

c) Dependent Claims 10 and 19

Petitioner contends Degala renders dependent claims 10 and 19 obvious because it provides detailed disclosure of achieving a SAL of 10^{-3} to 10^{-9}:

> In another aspect of the present invention, it was found that the inventive method has a sterility assurance level (SAL) of at least about 10^{-6} under particular combination of sterilization temperature and sterilization time…. For example, it has been found that a method of exposing the antiseptic solution to a temperature of 100° C. for about 50 minutes, a temperature of 105° C. for about 17 minutes, or 110° C. for about 6 minutes would each have a SAL of at least 10^{-6} (i.e., a 1/1,000,000 chance that a viable microbe will be present in a sterilized solution).

Pet. 60 (citing Ex. 1007 ¶ 41); *see* Reply 21 (citing Ex. 1017, 8). Additionally, Petitioner notes Degala's statement that, "further testing was conducted to determine at what time the Sterility Assurance Level (SAL) of 10^{-6} can be reached at a certain temperature." *Id.* (citing Ex. 1007 ¶ 52).

Patent Owner contends that ChloraPrep PAR and Degala do not render claims 10 and 19 obvious because the claims require the product or article to have a "sterility assurance level from 10^{-3} to 10^{-9}" and this limitation is not satisfied by a sterilized solution. PO Resp. 53 (citing Ex. 2023 ¶¶ 381–382). Patent Owner cites to the '642 Patent to support its position that "the SAL of a product/article is not the same as the SAL of a solution":

In some embodiments, the chlorhexidine article 14 has a SAL of from 10^{-3} to 10^{-9}. As described above, the components of the sterilized chlorhexidine article 14 may also have a SAL corresponding to the SAL of the sterilized chlorhexidine article 14 . . .*Id.* (citing Ex. 1001, 16:63–67; Ex. 2023 ¶ 382). Patent Owner further contends Petitioner failed to establish

that the claimed SAL range would have been obvious to a person of ordinary skill in the art. *Id.* (citing Ex. 2023 ¶¶ 379–387).

We do not agree with Patent Owner. Rather, for the same reasons discussed previously *supra* §§ III.A.1.a and III.A.8., we find that the record supports that claims 10 and 19 would have been obvious to a person of ordinary skill in the art at the critical time.

d) Dependent Claims 2, 3, 5, 6, 11, and 13–16

Petitioner argues dependent claims 2, 3, 5, 6, 11, and 13–16 are each rendered obvious in view of ChloraPrep PAR in combination with Degala. Pet. 38–43, 48 (citing Ex. 1003 ¶¶ 114–126, 135–137); Reply 20 (citing Ex. 1006, 5).

Patent Owner argues the ChloraPrep PAR fails to disclose the limitations required by dependent claims 2, 3, 5, 6, 11, and 13–16. PO Resp. 54 (citing Ex. 2023 ¶ 402). Patent Owner specifically argues that these challenged dependent claims are not obvious at least because they are not anticipated by the ChloraPrep PAR and claims 1 and 12, from which these claims depend, are not obvious in view of the ChloraPrep PAR alone or in combination with Degala. *Id.*

We have considered carefully all arguments and supporting evidence in light of the limitations recited in challenged dependent claims 2, 3, 5, 6, 11, and 13–16. Based on the entirety of the proceeding record, we conclude Petitioner has demonstrated by a preponderance of the evidence that challenged dependent claims 2, 3, 5, 6, 11, and 13–16 would have been obvious to a person of ordinary skill in the art under 35 U.S.C. § 103 in view of ChloraPrep PAR and Degala.

IV. MOTIONS FOR A PROTECTIVE ORDER AND TO SEAL

Patent Owner moves for entry of a stipulated protective order and for an order sealing Exhibits 2026–2032 and 2045 as well portions of the Patent Owner Response and the Declaration of Dr. Rutala (Ex. 2023) that quote these exhibits. Paper 25; Paper 36. These motions are unopposed.

A party may move to seal confidential information including, *inter alia*, sensitive commercial information. Consolidated Patent Office Trial Practice Guide, 19 (Nov. 2019); 37 C.F.R. § 42.54. It is the movant's burden to show good cause for sealing such information, and we balance the party's asserted need for confidentiality with the strong public interest in open proceedings. *Argentum Pharms. LLC v. Alcon Research, Ltd.*, IPR2017-01053, Paper 27 at 4 (PTAB Jan. 19, 2018) (informative).

Patent Owner provides a sufficient explanation for sealing the identified exhibits and the portions of the Patent Owner Response and the Rutala Declaration that quote those exhibits. Exhibits 2026–2030 include Petitioner's sales data and projections. Exhibit 2031 is a document relating to Petitioner's business strategy for ChlorPrep. Exhibit 1032 comprises internal meeting minutes relating to a U.S. FDA public hearing. And portions of Exhibit 2045 specify confidential parameters of Petitioner's manufacturing process.

Our Decision does not rely heavily on any of the material at issue and Patent Owner has established good cause for sealing 2026–2032 and 2045 as well the portions of the Patent Owner Response and the Declaration of Dr. Rutala that quote those exhibits. Accordingly, we grant Patent Owner's request to seal Exhibits 2026–30 and the portions of the Patent Owner

Response and the Declaration of Dr. Rutala that quote those exhibits. Additionally, we enter the default Protective Order in this case.

Patent Owner has not filed a public version of the Declaration of Dr. Rutala (Ex. 2023) in this case. Patent Owner is ordered to do so within five business days of the entry of this Decision.

V. CONCLUSION

Based on the evidence presented with the Petition, the evidence introduced during the trial, and the parties' respective arguments, Petitioner has shown by a preponderance of the evidence that the challenged claims 1–3, 5–8, 10–18 and 20 would have been obvious in view of ChloraPrep PAR alone or in combination with Degala.[16]

In summary:

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–3, 5–8, 10–18, 20	102	ChloraPrep PAR	1–3, 5–8, 10–18, 20	
1–3, 5–8, 10–18, 20	103(a)	ChloraPrep PAR	1–3, 5–8, 10–18, 20	

[16] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding after the issuance of this Final Written Decision, we draw Patent Owner's attention to the April 2019 Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–3, 5–8, 10–18, 20	103(a)	ChloraPrep PAR, Degala	1–3, 5–8, 10–18, 20	
Overall Outcome			1–3, 5–8, 10–18, 20	

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–3, 5–8, 10–18, and 20 in the '642 patent is determined to be unpatentable; and

FURTHER ORDERED that Patent Owner's Motion for Entry of Stipulated Protective Order (Appendix A to Paper 19) and to Seal is *granted*;

FURTHER ORDERED that Petitioner's Motion to Seal (Paper 30) is *granted*;

FURTHER ORDER that Patent Owner shall file a redacted public version of Ex. 2023 within five business days of the entry of this order;

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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