

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON DICKINSON AND COMPANY,
Petitioner,
SAGE PRODUCTS, LLC,
Patent Owner.

IPR2021-01202
Patent 10,688,067

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

BRADEN, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background

Becton Dickinson and Company (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–3, 5–8, and 10–19 (the “challenged claims”) of U.S. Patent No. 10,688,067 B2 (Ex. 1001, “the ’067 patent”). Paper 2 (“Pet.”). Sage Products, LLC (“Patent Owner”) filed a Preliminary Response. Paper 6 (“Prelim. Resp.”).

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4. An *inter partes* review may not be instituted unless it is determined that “the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314 (2018); *see also* 37 C.F.R. § 42.4(a) (“The Board institutes the trial on behalf of the Director.”). The reasonable likelihood standard is “a higher standard than mere notice pleading,” but “lower than the ‘preponderance’ standard to prevail in a final written decision.” *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 at 13 (PTAB Dec. 20, 2019) (precedential).

For the reasons provided below and based on the record before us, we determine Petitioner has demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims. We decline to deny the Petition on a discretionary basis as requested by Patent Owner. Accordingly, we institute an *inter partes* review.

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.

C. Related Proceedings

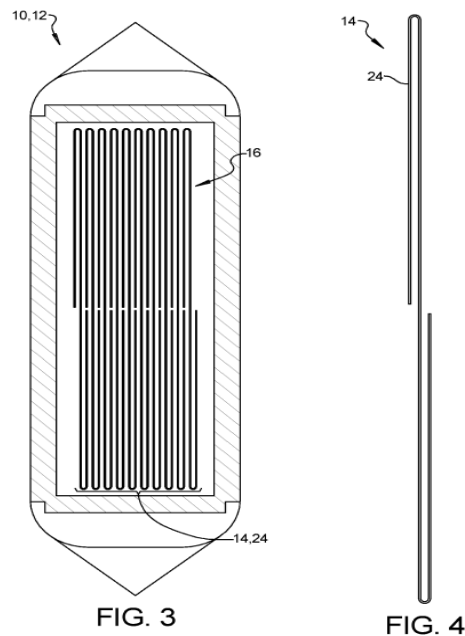
The parties identify the following district court case involving the ’067 patent: *Sage Products, LLC v. Becton, Dickinson and Company*, Case No. 2:20-cv-08000-KMJBC (D. N.J. filed June 30, 2020). Pet. 4; Paper 4, 2. The parties also identify IPR2021-01201 asserted against U.S. Patent No. 10,398,642, which is related to the ’067 patent. Pet. 4; Paper 4, 2.

D. The ’067 Patent (Ex. 1001)

The ’067 patent is titled “Sterilized Chlorhexidine Article and Method of Sterilizing a Chlorhexidine Article,” and issued on June 23, 2020. Ex. 1001, codes (45), (54). It is a continuation of U.S. Patent Nos. 10,398,642 and 10,188,598, and relies on a provisional application filed on Nov. 25, 2015. *Id.* at codes (60), (63).

1. Written Description

The ’067 patent relates to a sterilized chlorhexidine gluconate product that includes (1) a sterilized composition of chlorhexidine gluconate and alcohol, (2) an applicator, and (3) a barrier configured to be compromised to impregnate the applicator with the sterilized chlorhexidine gluconate composition. *Id.* at code (57). One embodiment of the invention is shown in Figures 3 and 4, reproduced below:



As shown above in Figures 3 and 4, sterilized chlorhexidine product **10** comprises package **12** and chlorhexidine article **14**. Ex. 1001, 2:37–40. Package **12** defines interior volume **16**, and chlorhexidine article **14** is removably disposed in interior volume **16** of package **12**. *Id.* at 2:40–42. The '067 patent discloses that package **12** is particularly suitable for terminal sterilization processes. *Id.* at 2:56–58. The '067 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 17:4–8.

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 4:1–3. As shown above in Figure 4, chlorhexidine article **14** comprises applicator **24** and an antiseptic composition. *Id.* at 4:9–10. Applicator **24** facilitates topical application of the antiseptic composition to the skin or mucous membranes of a patient. *Id.*

at 4:11–13. The '067 patent discloses that “[t]he antiseptic composition comprises one or more antibacterial agents and one or more solvents.” *Id.* at 7:27–28.

The '067 patent provides ranges for each of the components of the antiseptic compositions because such ranges “may refer to the amounts of those components in the sterilized antiseptic compositions or the unsterilized anti-septic compositions.” *Id.* at 14:41–45. The '067 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 14:45–48; *see also id.* at 17:19–38 (“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 '067 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 3:58–67. The '067 patent provides examples of sterilizations 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 16:16–22. Such examples include “heat sterilization, radiation

sterilization, ethylene oxide gas sterilization, or combinations thereof.” *Id.* at 16:22–25. 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 19:30–32.

The ’067 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 21:4–11. The ’067 patent explains that in certain other embodiments, “sterilizing the chlorhexidine product **10** further comprises heat sterilizing the chlorhexidine product **10**.” *Id.* at 21:12–14. The ’067 patent then provides another 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 21:14–16.

In addition to cooling, freezing, and heat sterilization, the ’067 patent discloses the irradiating “the chlorhexidine product **10** to form the sterilized chlorhexidine article **14**.” *Id.* at 21:37–39. The ’067 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 21:39–44. The ’067 patent further discloses that “[t]he chlorhexidine product **10** may be irradiated with the radiation type by any suitable radiation unit.” *Id.* at 21:45–46.

2. *Illustrative Claims*

As noted previously, Petitioner challenges claims 1–3, 5–8, and 10–19 of the '067 patent, of which claims 1 and 12 are independent. Pet. 6; Ex. 1001, 27:8–28:46. Claim 1 is illustrative and is reproduced below.

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 barrier configured to be compromised to impregnate the applicator with the sterilized chlorhexidine gluconate composition;wherein the sterilized chlorhexidine gluconate composition comprises chlorhexidine gluconate and alcohol.

Ex. 1001, 27:9–18.

E. *Asserted Challenges to Patentability and Evidence of Record*

Petitioner challenges the patentability of claims 1–3, 5–8, and 10–19 of the '067 patent based on the following references or combination of references:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–3, 5–8, and 10–19	102(a)	ChloraPrep PAR ¹
1–3, 5–8, and 10–19	103 ²	ChloraPrep PAR
1–3, 5–8, and 10–19	103	ChloraPrep PAR, Degala ³

In support of its patentability challenge, Petitioner relies on, *inter alia*, the Declaration of Roger Dabbah, Ph.D. (“Dr. Dabbah”). Ex. 1003.

II. PRELIMINARY MATTERS

A. *Analysis of Discretionary Denial Under 35 U.S.C. § 325(d)*

Section 325(d) provides the Board with express discretion to deny a petition when “the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d); *see also* *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.”). In determining if non-institution under § 325(d) is proper, we follow the two-part framework set forth in *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential, designated March 24, 2020). Specifically, the

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 ’067 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, for purposes of institution, 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).

Board must determine: “(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Id.* at 8.

When evaluating whether to exercise our discretion under § 325(d) in view of the *Advanced Bionics* framework, we weigh the following non-exclusive factors:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
- (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“the *Becton, Dickinson* factors”).

Patent Owner contends that we should exercise our discretion under § 325(d) to deny institution. Prelim. Resp. 51–52. Specifically, Patent Owner argues we should deny institution because “Degala was before the Office” during prosecution of the ’067 patent. *Id.* at 52. Patent Owner further argues,

Petitioner does not explain why the PAR is a better reference particularly because it does not mention any component being sterilized. In the end, Petitioner still has not established that the PTO erred in determining 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.

Petitioner contends that non-institution under § 325(d) would be improper based on a weighing of the *Becton Dickinson* factors. Pet. 64. Petitioner specifically argues that “[w]ith respect to the first prong, the *ChloraPrep* PAR was not before the Examiner during prosecution of the ’067 patent. The ’067 patent was issued without any rejection over or consideration of the prior art.” *Id.* at 65. According to Petitioner, “[w]hile *Degala* was cited in an IDS among tens of references, it was never discussed or used as the basis for rejection.” *Id.* (citing Ex. 1002). Petitioner concludes that “the first part of the *Advanced Bionics* framework favors the Board not exercising its right to deny a petition under this section.” *Id.*

For the second prong under the *Advanced Bionics* framework, Petitioner argues that “the prosecution history contains no substantive record of the Examiner’s consideration of any reference relied on in this petition.” *Id.* According to Petitioner, “[t]his situation is expressly recognized in *Advanced Bionics*: ‘if the record of the Office’s previous consideration of

the art is not well developed or silent, then a petitioner may show the Office erred by overlooking something persuasive under factors (e) and (f).” *Id.* (citing *Advanced Bionics*, Paper 6 at 4). Petitioner asserts that the USPTO was silent with regards to Degala because it never issued a rejection in view of that reference. *Id.* (citing Ex. 1002). Petitioner concludes that “[g]iven the clear disclosures of the *ChloraPrep PAR* and *Degala* of every limitation of the asserted claims, Examiner’s failure to consider them was plainly an error.” *Id.*

Upon consideration of the parties’ respective arguments and the relevant *Becton, Dickinson* factors, discussed below as applied to the record in this case, we find that, on balance, the factors weigh in favor of declining to exercise our discretion under 35 U.S.C. § 325(d) to deny institution.

We begin by considering *Becton, Dickinson* factors (a), (b), and (d), which relate to whether the Examiner considered and relied upon the prior art asserted in the Petition, such that § 325(d) is implicated. *Becton*, Paper 8 at 17–18; *see Advanced Bionics*, Paper 6 at 10. Here, we assume that the Examiner considered Degala, even though it was not used as the basis for any rejection during prosecution, because it is listed on the cover of the ’067 patent. *See* Ex. 1001, code (56).

We cannot agree with Patent Owner that we should deny institution for that reason, however, because the unpatentability grounds at issue here are not based on Degala alone, but on Degala in view of ChloraPrep PAR or ChloraPrep PAR alone under 35 U.S.C § 103. Pet. 21. Under *Becton, Dickinson* factor (a), ChloraPrep PAR was not cited during prosecution and neither was Degala in view of ChloraPrep PAR, and therefore, the combination of prior art is not the same or substantially the same as that

previously presented to the Office. Patent Owner acknowledges that ChloraPrep PAR was not in the record during prosecution (*see* Prelim. Resp. 52), but argues “Petitioner does not explain why the PAR is a better reference particularly because it does not mention any component being sterilized.” *Id.* We need not address whether CloraPrep PAR is more material to patentability than other references disclosed during prosecution because, as discussed below, we find that the Examiner erred in overlooking the teachings of Degala.

We turn next to the second part of the *Advanced Bionics* framework and consider *Becton* factors (c), (e), and (f) in determining “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics*, Paper 6 at 10. As explained below in our patentability analysis, Petitioner has demonstrated a reasonable likelihood that it will prevail in showing that at least one of the challenged claims would have been obvious over the cited art. In this regard, Petitioner has shown the materiality of Degala (as applied in combination with ChloraPrep PAR) to the patentability of the challenged claims. *See infra* §§ III. We find that the Examiner erred in overlooking the teachings of Degala, including specifically Degala’s express description of a “method for sterilizing an antiseptic solution.” Ex. 1007 ¶ 7. Furthermore, Petitioner has presented additional evidence and facts that were not before the Examiner, including support for why an ordinarily skilled artisan would have combined the teachings of Degala and ChloraPrep PAR. *See* Pet. 61–63; Ex. 1003 ¶¶ 163–166. Thus, *Becton* factors (c), (e), and (f) weigh heavily in favor of finding error under the second part of the *Advanced*

Bionics framework. Accordingly, we decline to exercise our discretion to deny institution under 35 U.S.C. § 325(d).

B. Analysis of Discretionary Denial Under 35 U.S.C. § 314(a)

Patent Owner urges us to exercise our discretion under 35 U.S.C. § 314(a) to deny the Petition based on the pending district court case. Prelim. Resp. 52–57 (citing *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 3 (PTAB Mar. 20, 2020) (precedential) (“*Fintiv*”).

In *NHK*, the Board denied institution relying, in part, on § 314(a) because the parallel district court proceeding was scheduled to finish before the Board reached a final decision. *NHK Spring Co. v. Intrix-Plex Techs., Inc.*, IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018) (precedential) (Decision on Institution). “*NHK* applies to the situation where the district court has set a trial date to occur earlier than the Board’s deadline to issue a final written decision in an instituted proceeding.” *Fintiv, Inc.*, IPR2020-00019, Paper 11 at 3. When determining whether to exercise discretion to deny institution under *NHK* due to an earlier trial date, we consider the following factors (“*Fintiv* factors”):

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party; and

6. other circumstances that impact the Board’s exercise of discretion, including the merits.

Id. at 6. “These factors relate to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding.” *Id.* In evaluating these factors, we take “a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review.” *Id.* (citing Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019 (“CTPG”), 584). We address the *Fintiv* factors below..

1. *Whether the Court Granted a Stay or Evidence Exists that One May be Granted if a Proceeding is Instituted*

Fintiv factor 1 recognizes that a stay of litigation pending resolution of the PTAB trial allays concerns about inefficiency and duplication of efforts, which strongly weighs against exercising the authority to deny institution. *Fintiv*, Paper 11 at 6.

Here, neither party has requested a stay of the district court case. Pet. 67; Prelim. Resp. 52. Neither party addresses the likelihood of a stay in their briefing. *Id.* We decline to speculate on the likelihood of a stay. Accordingly, we find that this factor is neutral.

2. *Proximity of the Court’s Trial Date to the Board’s Projected Statutory Deadline for a Final Written Decision*

Fintiv factor 2 looks to the “proximity of the court’s trial date to the Board’s projected statutory deadline.” *Fintiv*, Paper 11 at 9. “If the court’s trial date is earlier than the projected statutory deadline, the Board generally has weighed this fact in favor of exercising authority to deny institution under *NHK*.” *Id.*

Here, the parties represent that a trial date has not yet been set in the district court case. Pet. 68; Prelim. Resp. 52. Petitioner represents that the district court rejected the parties' request for a trial date by December 2022, however, suggesting that trial in the district court will almost certainly take place after the January 2023 due date for our final written decision.

Accordingly, this factor weighs against discretionary denial

3. Investment in the District Court Case by the Court and the Parties

Fintiv factor 3 considers the “investment in the parallel proceeding by the court and parties,” including “the amount and type of work already completed in the parallel litigation by the court and the parties at the time of the institution decision.” *Fintiv*, Paper 11 at 9. For example, if, at the time of institution, the court in the parallel proceeding has issued “substantive orders related to the patent at issue in the petition” or “claim construction orders,” this favors denial. *Id.* at 9–10.

Patent Owner argues there has been substantial investment in the district court case because infringement and invalidity contentions were exchanged and opening claim construction briefs have been filed. Prelim. Resp. 53 (citing Pet. 68; Exs. 2011, 2014, 2016). According to Patent Owner, a claim construction hearing will occur shortly, fact discovery is set to close on December 22, 2021, thousands of documents have been produced by the parties, Petitioner has now served five subpoenas, and depositions have been taken. *Id.* (citing Pet. 68; Ex. 2010).

Patent Owner further argues that this factor weighs against institution because Petitioner was sued in June 2020 (Ex. 1030, 1), but waited a full year to file this Petition (Pet. 73). Prelim. Resp. 55–56. According to Patent Owner, Petitioner delayed because “Petitioner was aware of the claims

asserted and presented invalidity contentions against those claims, and then waited a significant amount of time until learning of Patent Owner's claim constructions before filing the Petition." *Id.* at 56 (quoting *Google LLC v. Personalized Media Commc 'ns, LLC*, IPR2020-00720, 2020 WL 6530766, at *3 (P.T.A.B. Nov. 5, 2020). Thus, Patent Owner contends Petitioner has engaged in deliberate and unnecessary delay, such that the facts favor denial of institution. *Id.* at 54–56.

Petitioner contends the district court litigation is in its early stages with expert discovery set to close in July 2022 and with no trial date set yet. Pet. 68. Petitioner further argues that “there have been no significant investments by the Court or the parties in this case related to invalidity, other than Petitioner's exchange of invalidity contentions with Patent Owner.” *Id.* Thus, Petitioner concludes these factors weigh in favor of institution.

Based on the parties' representations, the investment in the district court case to date is significant. Prelim. Resp. 52; Pet. 69. Patent Owner, however, does not challenge Petitioner's assertion that much of the work that has been done is unrelated to the validity issues raised in the Petition. Moreover, although the work on the district court case to date is significant, much work remains to be done. In this respect, the case here is similar to *Sand Revolution II, LLC v. Continental Intermodal Grp.-Trucking LLC*, IPR2019- 01393, Paper 24 at 11–12 (PTAB June 16, 2020) (informative) (finding that *Fintiv* factor 3 weighed “only marginally, if at all, in favor of exercising discretion to deny institution” where the parties had exchanged infringement and invalidity contentions and the district court had construed the claims because “much work remain[ed] in the district court case as it relates to invalidity”).

As to Petitioner's alleged delay, although the Petition could arguably have been filed earlier, it was filed within the one-year statutory limit. *See* 35 U.S.C. § 315(b). We do not find in Petitioner's timing any evidence of improper gamesmanship.

In sum, considering the work that has been done, the work that remains, and how that work relates to the validity issues raised in the Petition, we find that *Fintiv* factor 3 weighs only marginally, if at all, in favor of exercising discretion to deny institution.

4. Overlap of issues with the district court Proceeding (factor 4)

Fintiv Factor 4 considers whether “the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding.” *Fintiv*, Paper 11 at 12. If the issues in the Petition overlap substantially with those raised in the parallel proceeding, “this fact has favored denial.” *Id.* “Conversely, if the petition includes materially different grounds, arguments, and/or evidence . . . this fact has tended to weigh against exercising discretion to deny institution.” *Id.* at 12–13.

Patent Owner argues “the Petition includes the same claims, grounds, arguments, and evidence presented in the district court, and therefore this factor weighs in favor of denial.” Prelim. Resp. 54 (citing *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 2020 WL 2486683, at *6 (P.T.A.B. May 13, 2020) (informative) (*Fintiv II*)). Patent Owner argues

[R]esolution of an instituted IPR against Petitioner will not eliminate any underlying litigation because, Petitioner alleges prior public use of the alleged invention (*id.* at 12–13), and this is why the Petition states that Petitioner “expressly reserves the right to rely on the ChloraPrep product described in the

ChloraPrep PAR as prior art in the litigation,” which it states “is not eligible for inclusion in this IPR.” (Pet. 69, n.20.)

Prelim. Resp. 54.

Petitioner states that “if this petition is instituted, it will not assert invalidity grounds in the litigation that are included in this petition. Petitioner’s agreement not to use the same grounds if institution is granted reduces the risk of duplicative efforts across proceedings. Thus, this factor weighs in favor of institution.” Pet. 69 (citing *Sand Revolution II, LLC v. Continental Intermodal Grp.-Trucking LLC*, IPR2019- 01393, Paper 24 at 11–12 (PTAB June 16, 2020) (informative) (finding Petitioner’s stipulation not to pursue the same grounds in the district court weighed in favor of institution); *Google LLC et al v. Parus Holdings, Inc.*, IPR2020-00846, Paper 9 at 22 (PTAB October 21, 2020) (“Petitioner has stipulated that it will not pursue the same grounds in the Texas court as it pursues here, which will further lessen the possibility of duplication and inconsistent results between the two forums.”)).

Petitioner’s stipulation echoes the one cited in *Sand Revolution II*, which the Board determined weighed “marginally in favor of not exercising discretion to deny institution.” IPR2019-01393, Paper 24 at 16 (PTAB June 16, 2020) (informative). Patent Owner’s argument that we should discount Petitioner’s stipulation because Petitioner remains free to argue invalidity based on a public use in district court is not persuasive because petitioners would seem always to be free to rely on a prior public use regardless of whether they offer a *Sand-Revolution* type stipulation. Based on Petitioner’s stipulation to “not assert invalidity grounds in the litigation

that are included in this petition,” we find that this factor weighs marginally in favor of not exercising discretion under § 314(a).

5. *Whether the parties to the inter partes review are the same as in the parallel district court proceeding (factor 5)*

Fintiv Factor 5 looks to “whether the petitioner and the defendant in the parallel proceeding are the same party.” *Fintiv*, Paper 11 at 14. “If a petitioner is unrelated to a defendant, the Board has weighed this fact against exercising discretion to deny institution under *NHK*.” *Id.* at 13.

Petitioner acknowledges that it is the defendant in the parallel district court proceeding. Pet. 70. To the extent that trial in the district court may precede the deadline for a final written decision in this proceeding, this factor favors exercising our discretion to deny institution. *Huawei Tech. Co. v. WSOU Inv., LLC*, IPR2021-00225, Paper 11 at 14 (P.T.A.B. June 14, 2021) (finding that “this factor favors denial if trial precedes the Board’s Final Written Decision and favors institution if the opposite is true”) (internal quotation marks omitted); *Google LLC v. Parus Holdings, Inc.*, IPR2020-00846, Paper 9 at 21 (P.T.A.B. Oct. 21, 2020) (“Here, . . . Petitioner is the defendant in the parallel proceeding. This fact could weigh either in favor of, or against, exercising discretion to deny institution, depending on which tribunal was likely to address the challenged patent first.”). As discussed *supra* § II.B.2, trial in the district court is unlikely to take place before our final written decision is due. Accordingly, we do not weigh this factor as favoring exercise of our discretion on the current record.

6. *Other factors (factor 6)*

Fintiv factor 6 looks to whether “other circumstances” exist that might “impact the Board’s exercise of discretion, including the merits.” *Fintiv*, Paper 11 at 14.

Petitioner argues that the strong merits of the case support not exercising our discretion to deny institution. Pet. 70.

Based on the facts of the case as discussed below, we find that the merits of the case support institution. Our determination is preliminary, however, and we are not prepared on this preliminary record to characterize the merits of Petitioner’s challenge as especially “strong.” Accordingly, we find this factor to be neutral.

7. *Summary*

We consider the above factors and take “a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review.” *Fintiv*, Paper 11 at 6. Weighing the factors together, we determine that they weigh against exercising our discretion not to institute *inter partes* review. For the above reasons, we do not exercise our discretion under 35 U.S.C. § 314(a) to deny institution of a trial proceeding.

C. *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, the “words of a claim ‘are generally given their ordinary and customary meaning.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). 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). Thus, 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).

Petitioner contends that all claim terms should receive their “plain and ordinary meaning” and that construction of the challenged claims is unnecessary for resolution of this proceeding. Pet. 15–16.

Patent Owner, however, contends the term “sterilized” requires:

[M]ore than the potential for being sterile and instead requires the product/article/composition to be in a sterile condition after exposure to suitable sterility processing. (*See, e.g.*, Ex. 1001, 3:60–65 (“throughout this disclosure, . . . article, or components, and compositions...may be referred to as the ‘sterilized’ component or composition upon being exposed to suitable processing where such sterility can be validated”), 16:16–22.).

Prelim. Resp. 15. In the parallel district court litigation, Patent Owner argued that “sterilized” means:

“[F]ree from viable microorganisms after exposure to validated sterility processing.” (*See* Ex. 2011 at 6, 8, 11; Ex. 1001, 16:35–38 (“[t]he sterile condition of the chlorhexidine article 14, or components thereof, may be defined as sterile in accordance with one or more ISO standards”).)

Prelim. Resp. 15. Additionally, Patent Owner notes that

In district court, Petitioner construed “sterilized chlorhexidine gluconate composition” as “a solution containing at least chlorhexidine gluconate that has been sterilized” (Ex. 2011 at 6)—a construction it does not address in its Petition. Petitioner presented this construction even though Patent Owner stated the phrase should be given its plain and ordinary meaning. (*Id.*).

Prelim. Resp. 15 n. 4. Patent Owner argues its proposed construction is supported by the Specification, prosecution history, and the historical concern with antiseptic products being contaminated despite being antimicrobials. *Id.* at 10 (citing Ex. 1001, 3:58–65, 16:16–22, 16:22–25, 21:4–23:42), 11 n. 3 (citing Ex. 2004, 2171–72).

During the prosecution of the parent application to the ’067 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: “[a]s explained during the Examiner Interview, 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 “[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.* Consistent with Patent Owner’s arguments, the Examiner’s Reason for Allowance states “as indicated in the parent application, the prior art does not teach a product which is itself necessarily sterilized and comprising sterilized chlorhexidine gluconate as further recited in the

claims.” Ex. 1002, 99. Thus, on this preliminary record, the prosecution history supports Patent Owner’s proposed construction.

Moreover, Patent Owner’s proposed construction is consistent with the Specification, which discloses that “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.” Ex. 1001, 3:58–65.

Accordingly, on this preliminary record, we construe “sterilized” to mean that the “component or composition has been subjected to a suitable sterilization process such that sterility can be validated.” Additionally, based on our review of the Petition and Preliminary Response, we do not believe that any other claim terms require express construction at this stage of the proceeding. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”).

D. 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).

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.⁴ *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.

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).

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

E. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art at the time of the alleged invention 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 states that, for purposes of its Preliminary

⁴ At this stage of the proceeding, Patent Owner has not presented objective evidence of non-obviousness.

Response, it “does not believe the particular definition of a POSA is determinative at this stage because the Petition can be denied under Petitioner’s own proposed skill level.” Prelim. Resp. 16. Patent Owner nonetheless challenges Petitioner’s proposal, stating:

Petitioner’s proposal regarding the level of ordinary skill for a POSA is disconnected from the disclosure of the 067 Patent. (Pet. 15.) As a preliminary matter, even though the 067 Patent relates to sterilized chlorhexidine products, Petitioner’s proposed definition requires no experience with antiseptics or chlorhexidine. Thus, under Petitioner’s definition, the POSA who is generally aware of “sterilization processes, sterile medical devices and/or formulations or tests for evaluating sterility” may be unfamiliar with the unique challenges of sterilizing antiseptics such as CHG or creating antiseptic products and articles that are able to contain and deliver sterilized CHG compositions. Additionally, while not requiring knowledge in the relevant field (experience with sterilization processes for medical products and their components, as well as familiarity with antiseptics such as chlorhexidine), Petitioner artificially inflates the educational requirements without explanation to require a Master’s or PhD.

Id. at 16–17 (emphasis and footnote omitted).

At this stage of the proceeding, we determine that 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. Such level of skill in the art is consistent with the ’067 patent and the asserted prior art of record.

III. ANALYSIS

A. Alleged Anticipation of Claims 1–3, 5–8, and 10–19 by ChloraPrep PAR

Petitioner contends claims 1–3, 5–8, and 10–19 are anticipated by ChloraPrep PAR. Pet. 26–51. Patent Owner disagrees, arguing, *inter alia*, that ChloraPrep PAR does not disclose “a sterilized chlorhexidine gluconate composition” as required by all of the challenged claims. Prelim. Resp. 25–27. For the reasons discussed below, at this stage of the proceeding, we are persuaded by Patent Owner’s arguments.

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.⁵ Ex. 1005, 1. ChloraPrep PAR discloses that:

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

⁵ 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 medical devices and disclose the MHRA’s reasoning and approval process.

Pet. 17.

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.

ChloroPrep PAR begins with a “Lay Summary,” which states that the ChloroPrep 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 ChloroPrep 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.*

ChloroPrep 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 ChloroPrep product each dispensing a different volume of the chlorhexidine gluconate/isopropyl alcohol solution. *Id.* at 5. The figure is reproduced below:

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.* 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.*

ChloraPrep PAR discloses that the pharmaceutical composition contains 20mg/ml of chlorhexidine gluconate and 0.70ml/ml of isopropyl alcohol as well as “Sunset Yellow” as coloring agent. *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.

ChlorPrep 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 ChlorPrep 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 ChlorPrep looks like and contents of the pack
ChlorPrep 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 a except from the product packaging describing “[w]hat ChlorPrep 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, said sterilized chlorhexidine product comprising.”

Ex. 1001, 27:9–10. Petitioner contends that to the extent the preamble is limiting, then ChlorPrep PAR discloses the elements of the preamble.

Pet. 26. Patent Owner does not specifically address whether the preamble is limiting but argues that “Petitioner never points to any disclosure in the PAR

that the chlorhexidine product has been sterilized as required by the claims.”
Prelim. Resp. 25.

“Whether to treat a preamble term as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent.” *American Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010) (internal quotation marks omitted). “Absent clear reliance on the preamble in the prosecution history, or in situations where it is necessary to provide antecedent basis for the body of the claim, the preamble generally is not limiting.” *Symantec Corp. v. Computer Assoc. Int’l, Inc.*, 522 F.3d 1279, 1288 (Fed. Cir. 2008) (internal quotation marks omitted). Additionally, preamble language that merely states the purpose or intended use of an invention generally is not treated as limiting the scope of a claim. *See Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003); *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997). Yet, when the limitations in the body of the claim rely upon or derive essential structure from the preamble, then the preamble acts as a necessary component of the claimed invention and is limiting. *See Eaton Corp. v. Rockwell Int’l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003).

Here, we need not determine whether the preamble is limiting because the claim language from the preamble that Patent Owner contends is not disclosed in the prior art – i.e., sterilized chlorhexidine – is repeated in the body of the claim.

b) “*sterilized chlorhexidine gluconate composition*”

Claim 1 recites a “sterilized chlorhexidine gluconate composition.”
Ex. 1001, 27:11.

Petitioner contends ChloraPrep PAR discloses “a sterilized chlorhexidine gluconate composition.” Pet. 28 (citing Ex. 1003 ¶ 95). Petitioner notes ChloraPrep PAR’s Module 2, Section 6.5 (“Nature and contents of container”) states 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). Petitioner also relies on ChloraPrep PAR’s Product Information Leaflet, which 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 [chlorhexidine gluconate] 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 “component or composition has been subjected to a suitable sterilization process such that sterility can be validated.” Prelim. Resp. 10, 14–15; *see* § II.C, *supra*. Based on the proposed construction, Patent Owner contends the description “sterile” is not the same as “sterilized.” Prelim. Resp. 21. Patent Owner argues that

while the PAR does refer to “ChloraPrep” as “a sterile alcoholic antiseptic solution....in an applicator” (a phrase of questionable meaning as used with regard to antiseptics in 2010, particularly given the ChloraPrep label change reported in 2015 to clarify the product previously labelled as “sterile” was “non sterile” (*see* Ex. 2006, Ex. 2009, 26, 34, 43, 50, 57), that phrase certainly does not state that any composition of CHG and alcohol is sterilized,

much less that components of the product referenced in the PAR are able to contain, deliver, and apply the sterilized composition. Nothing in the PAR suggests that the PAR is describing anything other than a “sterile” antiseptic product capable of acting as an antimicrobial and disinfectant. That is particularly true since Petitioner has not identified any public knowledge of any methods of sterilizing CHG and alcohol compositions existing as of 2010, the purported publication date of the PAR.

Prelim. Resp. 23–24. Patent Owner cites to a ChloroPrep document from 2015 to support its position. Pet 24 (citing Ex. 2006). This document discloses: “[t]hough all ChloroPrep 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 “[t]here is no disclosure in the PAR of exposing any component of the product—much less a composition of [chlorhexidine gluconate] and alcohol—to suitable sterility processing that would render the component sterile.” *Id.* at 26.

Patent Owner further contends that despite Petitioner’s allegation that ChloroPrep PAR was published in 2010, Petitioner cites no prior art describing any known methods of sterilizing chlorhexidine gluconate as of that date. *Id.* at 27 (citing Pet. 14; Ex. 1003 ¶¶ 66–67, 73–76). According to Patent Owner, the only cited reference that pre-dates ChloroPrep PAR is Schlotz, dated 2006 (Ex. 1008), which “reflects the then-existing misconception that sterilization was not necessary for antiseptics because they ‘demonstrate a broad spectrum of antimicrobial activity and thus are generally not terminally sterilized’” Prelim. Resp. 27 (citing Ex. 1008 ¶ 178). Patent Owner argues that Schlotz mentions using preservatives and

terminal sterilization processes on packaging, but describes no methods for sterilizing chlorhexidine gluconate/alcohol compositions. *Id.*

The current record tends to support Patent Owner's position. There appears to be insufficient evidence at this stage of the proceeding to show that the chlorhexidine gluconate composition in ChloraPrep PAR was subject to a separate sterilization process that would allow for validation of the sterility of the composition under our Preliminary construction. ChloraPrep PAR states that its composition was "sterile," but per our preliminary claim construction "sterile" is not equivalent to "sterilized" (*see* § II.C, *supra.*), and art at the time states that microbial compositions such as chlorhexidine gluconate "are generally not terminally sterilized" (*see* Ex. 1008 ¶ 178).

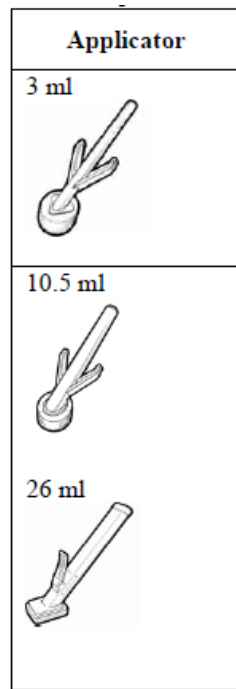
Additionally, the Chiang patent, specifically directed to a ChloraPrep product, discloses that "[o]ne of the challenges associated with using such skin antiseptic compositions is the need to sterilize the exterior of the applicator while minimizing potential byproducts that may be produced when the composition is exposed to sterilization compounds such as ethylene oxide gas." Ex. 2015 ¶ 9. According to the reference, "[r]eactive 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." *Id.* In order to address the problem, the prior art states "[i]n 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." *Id.* ¶ 10.

Moreover, a Frequently Asked Questions (“FAQ”) form published in 2015 regarding a ChloroPrep label change from “sterile” to “non sterile” states that label change was (1) in response to an US FDA request and (2) indicates its contents have not been sterilized individually. *See* Ex. 2006. The FAQ also states “currently, 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.* at 1.

Accordingly, on the current record, Patent Owner’s argument that ChloroPrep PAR does not explicitly or inherently disclose “a sterilized chlorhexidine gluconate composition” under the claim construction adopted for purposes of this Decision appears to have merit.

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

Petitioner contends ChloroPrep 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 Figure from page 5 of ChloroPrep PAR, reproduced, as excerpted by Petitioner, below.



Id. (citing Ex. 1005, 5). The excerpted figure 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. Based on this explicit disclosure of at least one applicator for use with the ChloraPrep composition, we agree with Petitioner that the current record supports that ChloraPrep PAR discloses an applicator for applying a composition.

d) a barrier configured to be compromised to impregnate the applicator with the sterilized chlorhexidine gluconate composition

Petitioner contends ChloraPrep PAR discloses “a barrier configured to be compromised to impregnate the applicator with the sterilized chlorhexidine gluconate composition” as required by claim 1. Pet. 31–32 (citing Ex. 1003 ¶¶ 99–100). Petitioner argues that ChloraPrep PAR

describes “a barrier configured to be compromised to impregnate the applicator in the form at least one glass ampoule housed within the applicator’s plastic barrel which contains the sterilized [chlorhexidine gluconate] composition.” Pet. 32 (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 the following passage from Section 4.2 of ChloroPrep PAR to support its position:

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 (quoted in full at Pet. 32–33).

Based on this explicit disclosure in ChloroPrep PAR of an ampule that is broken to release a composition, we agree with Petitioner that the current record supports that ChloroPrep PAR discloses a barrier configured to be compromised to impregnate the applicator with the sterilized chlorhexidine gluconate composition.

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. 33–34 (citing Ex. 1003 ¶¶ 101–02).

For the same reason provided above with regards to the limitation “a sterilized chlorhexidine gluconate composition,” on the current record, Patent Owner’s argument that ChloraPrep PAR does not explicitly or inherently disclose “a sterilized chlorhexidine gluconate composition” under the claim construction adopted for purposes of this Decision appears to have merit.

3. Analysis of Claims 2, 3, 5–8, and 10–19

As relates to the common requirement for “sterilized chlorohexidine,” Petitioner relies on the same arguments and evidence for claims 2, 3, 5–8, and 10–19 as it put forth for claim 1. *See* Pet. 34–50. Thus, for the same reasons discussed above for claim 1, Patent Owner’s argument that ChloraPrep PAR does not explicitly or inherently disclose “a sterilized chlorhexidine gluconate composition” under the claim construction adopted for purposes of this Decision appears to have merit.

B. Alleged Obviousness of Claims 1–3, 5–8, and 10–19 in View of ChloraPrep PAR

Petitioner contends claims 1–3, 5–8, and 10–19 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 many of the same arguments asserted in its anticipation challenge. Pet. 51–55. Patent Owner disagrees, arguing, *inter alia*, that the reference does not teach or suggest “a sterilized

chlorhexidine gluconate composition” because a person of ordinary skill in the art at the time of the invention would not understand the word “sterile” to mean “sterilized.” Prelim. Resp. 35–43. For the reasons discussed below, Petitioner’s showing is sufficient to support institution.

1. *Overview of ChloroPrep PAR (Exs. 1004, 1005)*

See § III.A.1., *supra*.

2. *Overview of Degala (Ex. 1007)*

Degala is a U.S. Patent Application Publication titled “System, Methods, and Devices for Sterilizing Antiseptic Solutions” that published on July 9, 2015 and was filed on January 8, 2014. Ex. 1007, code (22), (43), (54). Degala is directed to a method for sterilizing a topical antiseptic solution of chlorhexidine, including chlorhexidine gluconate. *Id.* ¶¶ 22, 30. Degala further discloses that the antiseptic solution may contain an alcoholic solvent. *Id.* ¶ 28.

Degala discloses the state of both the prior art methods and regulatory schemes requiring sterilization of antiseptic solutions, specifically discloses:

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. . . .

The known method of sterilization involves heat treating glass ampoules containing the chlorhexidine gluconate solution in a convection oven at 76–80° C. for 24–31 hours. It is currently believed that relatively low temperature and relatively long processing time is necessary to sufficiently sterilize the solution without overly degrading the antimicrobial molecules, thereby avoiding reducing the concentration and purity of the chlorhexidine gluconate contained therein as an antiseptic.

Id. ¶¶ 2–3. Degala further discloses that “[i]t is the industry belief that high temperature sterilization is not suitable due to the expected degradation.” *Id.* ¶ 4.

In order to “address the unmet need in the art for a method of sterilizing antiseptic solutions” (*id.* ¶ 5), in one embodiment, Degala teaches a method for sterilizing an antiseptic solution comprising:

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. After terminating the heating, the antiseptic solution has a post-sterilization purity.

Id. ¶ 7. Degala teaches further discloses “by selecting an appropriate combination of sterilization temperature and sterilization time, the post-sterilization purity may be maintained relatively close to the initial purity, while still being sterile.” *Id.* ¶ 39.

3. Analysis of the Challenged Claims

As discussed above, Petitioner has demonstrated sufficiently that ChloroPrep PAR discloses all elements of the challenged claims except “a sterilized chlorhexidine gluconate composition.” Accordingly, we will focus our discussion here on this contested claim limitation.

Petitioner contends 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. 52. Petitioner bases its contention on the relevant requirements in the relevant UK standards (which

Petitioner argues were consistent with ISO and FDA standards and guidelines at the relevant time). *Id.* (citing Ex. 1003 ¶ 144). 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.” *Id.*

Petitioner also relies on the testimony of its declarant, Dr. Dabbah, to support its position. *Id.* at 53. Dr. Dabbah testifies 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 (citing Ex. 1017, 8, 13). 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 and ‘sterile’ in a UK regulatory document.” *Id.*

Petitioner then 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. 53–54 (citing Ex. 1028). According to Petitioner, under the section “Sterilization Information for Devices Labeled as Sterile,” it provides 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 54 (citing Ex. 1028, 8–9) (alteration in original).

Petitioner again relies on the testimony of Dr. Dabbah, who states:

Based on my review of the *ChloraPrep PAR*, it is my opinion that as part of developing the ChloraPrep products for the UK described above, Petitioner also sterilized both the solution (and ampoule) and the applicator. Petitioner described both prior art processes for this sterilization and its development of a new process for the product in *Degala*, filed January 8, 2014. Ex. 1007. As explained in *Degala*, and consistent with my experience, the US did not at the time regulate sterilization requirements of topical antiseptic solutions. But outside the U.S., “[i]n other jurisdictions, however, such as European Union (EU) countries, some degree of sterilization [of chlorhexidine gluconate] is required.” *Id.* at ¶ 2. Thus, *Degala* describes that “[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”—low heat sterilization. *Id.* at ¶¶ 2–3. As set out further below, *Degala* also goes on to describe a new, higher volume method for sterilizing the ampoules and solution via a cascading water process. *Id.* at ¶¶ 6–20.

Ex. 1003 ¶ 76 (alterations in original). Dr. Dabbah then testifies that a person of ordinary skill in the art at the time of the invention “would have been familiar with every aspect of the technology addressed in the ’067 patent.” *Id.* ¶ 77. Thus, 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. 55.

Patent Owner contends Petitioner’s obviousness challenge is both cursory and unsupported by the evidence of record. Prelim. Resp. 35. Patent Owner argues that Petitioner’s challenge is based on an incorrect view that a person of ordinary skill in the art would have “translate[d] the word ‘sterile’ to mean ‘sterilized’ in what it claims is a regulatory document.” *Id.* at 36. Patent Owner then asserts that references to “UK

standards” are irrelevant because it relates to sterilization of “Medical Devices” generally and not sterilization of antiseptic compositions. *Id.* at 35, 37–38 (citing Pet. 52; Ex. 1017, cover). Patent Owner further argues that

Petitioner’s own ChloraPrep documents from 2015 show that terminal sterilization of a product does not result in the sterilization of the antiseptic composition within that product:

If ChloraPrep Products are sterilized, why do they not contain sterile solution?

A product labeled as non sterile does not suggest that it is contaminated with bacteria; instead, its contents have not been sterilized individually. 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.

Prelim. Resp. 38–39 (citing Ex. 2006). Moreover, according to Patent Owner, the 2015 ChloraPrep label change announcement indicates that ChloraPrep solution was “not sterile” despite having labels that included the word “sterile,” thereby undermining Petitioner’s theories about what would have been understood about the labels or the word “sterile.” *Id.* at 39 (citing Ex. 2006; Ex. 2009, 26, 34, 43, 50, 57). Therefore, Patent Owner concludes that “Petitioner has not established that the bare use of the word ‘sterile’ in a ‘Public Assessment Report’ in 2010—especially on a ChloraPrep product—means that any CHG composition had actually been sterilized.” *Id.*

We agree with Patent Owner that 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. But Petitioner has

established sufficiently for purposes of institution that it would have been obvious to sterilize the chlorhexidine gluconate composition within ChloroPrep product in 2015. Specifically, the currently un rebutted 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 a chlorhexidine gluconate composition individually in a ChloroPrep product using techniques such as that disclosed by Degala in July 2015. *See* Ex. 1003 ¶ 76; Ex. 1007 ¶¶ 2–4, 7, 28, 30, 50.

Additionally, we credit the currently un rebutted testimony of Dr. Dabbah that other prior art references such as Margoosian (Ex. 1009) and Schlotz (Ex. 1008) provide additional techniques for sterilizing a chlorhexidine gluconate composition. *See* Ex. 1003 ¶¶ 73–75. Degala, Margoosian, and Schlotz are indicative of the level of skill and the knowledge possessed by an ordinary artisan at the relevant time. *See In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (“The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art.”); *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.”).

We acknowledge Patent Owner’s arguments regarding its objective indicia of nonobviousness (Prelim. Resp. 40–43) and the teachings of Chiang (Ex. 2015), but at this time these indicia do not outweigh the un rebutted testimony of Dr. Dabbah and the explicit teachings of the other cited prior art references. Accordingly, Petitioner shows sufficiently for

purposes of institution that the teachings of ChloroPrep PAR in view of the knowledge of one of ordinary skill in the art at the time of the invention would have rendered it obvious to use “a sterilized chlorhexidine gluconate composition” as required by the challenged claims.

C. Alleged Obviousness of Claims 1–3, 5–8, and 10–19 in View of ChloroPrep PAR and Degala

Petitioner contends claims 1–3, 5–8, and 10–19 would have been obvious to a person of ordinary skill in the art at the time of the invention in view of ChloroPrep PAR and Degala. Pet. 55–64. Patent Owner disagrees, arguing, *inter alia*, that the combination of references does not cure the problem with ChloroPrep PAR because “Petitioner *again* argues that the PAR discloses the ‘sterilized’ limitation because ‘sterile’ means ‘sterilized.’” Prelim. Resp. 44–47. Patent Owner also argues that Petitioner fails to explain why a person of ordinary skill in the art would have been motivated to combine ChloroPrep PAR and Degala or why there would be a reasonable expectation of success. *Id.* at 47–51.

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

See § III.A.1., *supra*.

2. Overview of Degala (Ex. 1007)

See § III.B.2., *supra*.

3. Analysis of the Challenged Claims

For the same reasons detailed above, *see* Section III.B.3, *supra*, we do not agree with Patent Owner at this stage of the proceeding. Rather, for purposes of institution, the present record supports that ChloroPrep PAR and Degala teach or suggest all the limitations of the challenged claims, including the separately sterilizing a chlorhexidine gluconate composition

within a product. Additionally, the present record supports that a person of ordinary skill in the art would have had reason to combine ChloraPrep PAR and Degala and would have had a reasonable expectation of success in combining the teachings of both references.

Specifically, we credit the currently unrebutted 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 ¶ 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.”). Given that Degala is directed to a new technique for sterilizing a chlorhexidine gluconate composition and, per Dr. Debbah, this composition appears to be the one described in ChloraPrep PAR, we are persuaded 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.).

IV. CONCLUSION

For the foregoing reasons, we determine Petitioner has demonstrated there is a reasonable likelihood it would prevail in establishing the unpatentability of claims 1–3, 5–8, and 10–19 as having been obvious over the teachings of ChloroPrep PAR alone or in combination with Degala. Based on the Supreme Court’s holding that a decision under § 314 may not institute review on fewer than all claims challenged in the petition, we institute on all three proposed challenges. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355–56 (2018); *see also PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition”). Additionally, we decline to exercise our discretion under 35 U.S.C. § 325(d) or § 314 to deny the proposed challenges to patentability.

Our factual findings, conclusions of law, and determinations at this stage of the proceeding are preliminary, and based on the evidentiary record developed thus far. At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim. Our final decision will be based on the record as fully developed during trial.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1–3, 5–8, and 10–19 of the '067 patent on all grounds presented in the Petition, namely:

- (1) Claims 1–3, 5–8, and 10–19 under 35 U.S.C. § 102 as unpatentable over ChloraPrep PAR;
- (2) Claims 1–3, 5–8, and 10–19 under 35 U.S.C. § 103 as unpatentable over ChloraPrep PAR; and
- (3) Claims 1–3, 5–8, and 10–19 under 35 U.S.C. § 103 as unpatentable over ChloraPrep PAR and Degala;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, the trial commencing on the entry date of this Decision.

IPR2021-01202
Patent 10,688,067

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