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Paper 76
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NESTLÉ HEALTHCARE NUTRITION, INC.,
Petitioner,

v.

STEUBEN FOODS, INC.,
Patent Owner.

Case IPR2015-00249
Patent 6,481,468 B1

Before PHILLIP J. KAUFFMAN, RAMA G. ELLURU, and BEVERLY M. BUNTING, *Administrative Patent Judges*.

KAUFFMAN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION

35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. PROCEDURAL OVERVIEW

Petitioner, Nestlé Healthcare Nutrition, Inc., filed a Petition (Paper 2, "Pet.") to institute an *inter partes* review of claims 1–3, 7, 9, and 20–23 ("the challenged claims") of U.S. Patent No. 6,481,468 B1 (Ex. 1001, "the '468 patent"). Patent Owner, Stueben Foods, Inc., filed a timely Preliminary Response (Paper 9, "Prelim. Resp.").[1] Pursuant to our authorization in a related case, Petitioner filed a reply to the Patent Owner Preliminary Response, and Patent Owner filed a sur-reply.[2] Papers 11, 14.[3]

In the June 3, 2015, Decision to Institute (Paper 25, "Dec."[4]), we instituted trial on claims 1–3, 7, and 9 on the following grounds[5]:

A. Claims 1, 2, and 7 under 35 U.S.C. § 102(b) over Takei[6];

B. Claims 1, 2, and 7 under 35 U.S.C. § 103(a) over Takei;

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[1] A redacted, public version can be found at Paper 17.

[2] The Reply and Sur-Reply dealt with the issue of Patent Owner's allegation of privity between Petitioner and a third party, GEA Process Engineering, Inc. ("GEA"), and were authorized during a conference call. *See* IPR2015-00195, Ex. 1025, 40:4–10.

[3] A redacted public version can be found at Papers 13 and 21, respectively.

[4] A jointly submitted redacted public version can be found at Exhibit 1018.

[5] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, took effect on March 18, 2013. Because the application from which the '468 patent issued was filed before that date, our citations to 35 U.S.C. §§ 102 and 103 are to the pre-AIA version.

[6] Ex. 1005, Japanese Pat. App. Publ. No. H4-154501 (with translation) (May 27, 1992).

C. Claims 1–3 and 7 under 35 U.S.C. § 103(a) over Biewendt[7], Takei, Bev Tech[8], and David[9];

D. Claim 9 under 35 U.S.C. § 103(a) over Biewendt, Takei, and ZFL[10];

E. Claims 1-3 and 7 under 35 U.S.C. § 103(a) over ZFL, Takei, and Bev Tech; and

F. Claim 9 under 35 U.S.C. § 103(a) over ZFL, Takei, and Bev Tech.

Petitioner's Request for Rehearing was denied. Paper 29 (request), Paper 37 (decision).

Subsequently, Patent Owner filed a Patent Owner Response (Paper 42, "PO Resp.")[11], and Petitioner filed a Reply (Paper 46, "Pet. Reply").

Patent Owner did not file a motion to amend.

Patent Owner and Petitioner each filed a Motion to Exclude Evidence as discussed in Section II below.

Oral hearing was held on Wednesday, January 27, 2016, and a transcript of the oral hearing is included in the record.[12] Paper 73 ("Tr.").

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[7] Ex. 1006, H.-G. Biewendt et al., *Report on the Type Testing of the Aseptic Filling and Sealing Plant for Glass Bottles for UHT Milk* (1996).

[8] Ex. 1007, Luigi Baiocchi, *Latest Innovations In Aseptic Filling*, Int'l Soc. of Beverage Technologists, Prcdgs. of 44th Ann. Conf. "Bev Tech 97," Ft. Lauderdale, FL, Apr. 28-30, 1997, 123-130.

[9] Ex. 1008, J.R.D. David et al., *Aseptic Processing and Packaging of Food: A Food Industry Perspective*, chs. 6, 8 (1996).

[10] Ex. 1012, N. Buchner, *Aseptic Filling of Glass and Plastic Containers*, ZFL Magazine, Vol. 41, No. 5, 295-300 (with translation).

[11] A redacted, public version can be found at Paper 51.

[12] The hearing was held with the hearing for IPR2015-00195, and a single transcript was produced for both proceedings.

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is entered pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 as to the patentability of the challenged claims of the '468 patent. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–3 and 7 of the '468 patent are unpatentable, but has not made such a showing with regard to claim 9.

B. RELATED PROCEEDINGS

Patent Owner has asserted the '468 patent in the following pending litigations in the U.S. District Court for the Western District of New York: *Steuben Foods, Inc. v. Oystar USA, Inc.*, No. 1:10-cv-00780 (filed 9/29/10); *Steuben Foods, Inc. v. Shibuya Hoppmann Corp.*, No. 1:10-cv-00781 (filed 9/29/10); *Steuben Foods, Inc. v. HP Hood LLC*, No. 1:12-cv-00211 (filed 3/12/12); *Steuben Foods, Inc. v. GEA Process Eng'g, Inc.*, No. 1:12-cv-00904-WMS-HKS (filed 9/24/12) (the "'904 litigation"); *Steuben Foods, Inc. v. Nestle, USA*, No. 1:13- cv-00892 (filed 9/3/13); and *Steuben Foods, Inc. v. Jasper Prods., LLC*, No. 1:13-cv-01118-WMS (filed 11/14/13). Pet. 53-54; Paper 4, 3-4.

As indicated in the table below, the '468 patent is related to four other U.S. patents. As shown below, these five patents were the subject of *inter partes* review petitions filed by GEA ("GEA petitions"), and by the present Petitioner ("Nestlé petitions"). *See* Pet. 54; Paper 4.

U.S. Patent No.	"GEA petitions"	"Nestlé petitions"
6,945,013[13]	2014-00041	2014-01235
6,475,435	2014-00043	2015-00195
6,209,591	2014-00051	2015-00094
6,481,468	2014-00054	2015-00249
6,536,188	2014-00055 2014-00056	2015-00023

The GEA petitions were terminated. *See, e.g.*, IPR2014-00041, *GEA Process Engineering, Inc. v. Steuben Foods, Inc.*, (PTAB Feb. 11, 2015) (Paper 140).

II. PRELIMINARY MATTERS

A. TIME BAR UNDER SECTION 315(b)

Patent Owner contends that GEA Process Engineering, Inc. ("GEA") was served with a complaint alleging infringement of the '468 patent more than one-year before the Petition was filed, and because GEA is a privy of Petitioner, the present petition is time barred under 35 U.S.C. § 315(b). PO Resp. 47–58. Prior to institution, Patent Owner's arguments regarding privity were based primarily on Petitioner's agreement to indemnify GEA as

[13] The '013 patent is also the subject of Reexamination Control No. 95/001,452, Appeal No. 2015-007987.

part of Petitioner's purchase of a bottling machine from GEA ("the Line 8 Agreement," Ex. 2051).[14] Prelim. Resp. 3–31.

The question of whether Petitioner is time-barred under §315(b) is considered part of the determination whether to institute an *inter partes* review. *See Achates Reference Publ'g, Inc. v. Apple Inc.*, 803 F.3d 652, 657–59 (Fed. Cir. 2015). In our Institution Decision, we determined that the district court complaint filed by Patent Owner against GEA did not time bar the Petitioner under § 315(b) because Patent Owner had not provided a sufficient factual basis upon which to conclude that Petitioner and GEA are privies.[15] *See* Inst. Dec. 7–19. In particular, we were not persuaded that the Line 8 agreement shows that Petitioner and GEA have a substantive legal relationship, or that Petitioner and GEA shared control of this *inter partes* review and/or the related litigation in the manner required for a privity relationship. *Id.* We incorporate that analysis here, and reconsider Patent Owner's contention only to the extent it is warranted by subsequent

[14] Petitioner purchased seven bottling machines from GEA Process Engineering, Inc. ("GEA") and GEA's predecessor, Procomac SpA. Paper 65, 2. These seven machines were purchased in three groupings: (1) lines 1–5, (2) line 6/7, and (3) line 8. *Id.* Patent Owner explains that line 7 is sometimes referred to as line 6, and for that reason we refer to it as "line 6/7." Paper 54, 3–4.

[15] Patent Owner's exhibits 2001–2051 were entered prior to Institution. Patent Owner Exhibits 2052–2069 were submitted in conjunction with the Patent Owner Response (post-institution).

argument and evidence.[16] *See Achates*, 803 F.3d at 658 ("The Board's reconsideration of the time-bar [in the final determination] is 'still fair[ly] characterize[ed] as part of the decision to institute.") (citations omitted).

Since our Institution Decision, the only new arguments made by Patent Owner with regard to its privity assertion relate to the purchase of certain other aseptic bottling machines as reflected in the agreements for lines 1–6/7. According to Patent Owner, Petitioner and GEA are privies because these agreements obligate Petitioner to indemnify GEA. PO Resp. 47–58. Patent Owner makes three supporting contentions.

First, Patent Owner contends that the machines purchased by Petitioner for lines 1–6/7 were made and built to Petitioner's specifications, quoting the following excerpt from Exhibit 2064:

> GEA Procomac designs and manufactures complete customized bottling plants. The scope of supply range from individual units and systems to complete integrated bottling lines including:
> - Aseptic and sanitary fillers
> - Blow-fil systems for PET bottles
> - Container treatment systems (rinsers and sterilizers)
> - Palletizing and de-palletizing systems
> - Conveyors and bottle / PET handling systems

PO Resp. 48 (citing Ex. 2064). Exhibit 2064 is a printout of a website that is dated January 22, 2015, titled, "GEA Procomac Bottling Plants." The Exhibit does not mention the sale of lines 1–6/7 to Petitioner. Although the Exhibit states that GEA Procomac was acquired by GEA Group in April

[16] In IPR2014-01235, another *inter partes* review between these parties, the Board determined in a Final Written Decision on similar facts, that Patent Owner had not provided a sufficient factual basis upon which to conclude Petitioner and GEA are privies. IPR2014-01235 (PTAB Dec. 21, 2015) (Paper 63, 5–10).

2007, the Exhibit neither states nor implies how long GEA Procomac had been designing and manufacturing customized bottling plants.

Second, Patent Owner asserts that Petitioner was subject to the version of the Uniform Commercial Code adopted as the California Commercial Code, citing Exhibit 2065 as proof of where Petitioner does business. PO Resp. 48. Exhibit 2065 provides no information about the purchase of lines 1–6/7. Moreover, Patent Owner's arguments regarding the California Commercial Code rely upon an alleged indemnification obligation based on Petitioner's purchase of custom-made machines. PO Resp. 47. We previously held, with respect to the Line 8 Agreement, that indemnity does not create the type of substantive legal relationship that amounts to privity. Inst. Dec. 11–16.

Third, Patent Owner asserts that Petitioner has refused to produce the joint defense agreement between GEA and Petitioner. PO Resp. 51 (citing Ex. 2067). Exhibit 2067 is an e-mail chain regarding a request from Patent Owner's counsel to Petitioner's counsel for any agreements between Petitioner and GEA that form the basis of a joint defense privilege, and the subsequent discussion.[17] Ex. 2067, 8. Our prior analysis in the Institution Decision examined the joint defense relationship between Petitioner and GEA and explained that such a relationship does not demonstrate privity. Inst. Dec. 12–14.

[17] In IPR2015-00195, the Board denied Patent Owner's motion to authorize a request for production of the joint defense agreement (JDA) between Petitioner and GEA. IPR2015-00195, Paper 21. The Board determined that "Patent Owner does not state what useful information is to be gained from the JDA document sought, other than proving what is already acknowledged, that a JDA exists between Petitioner and GEA." *Id.* at 3.

Petitioner's new arguments and evidence proffered during trial do not demonstrate persuasively that the machines purchased as lines 1–6/7 were built to Petitioner's specification, nor has Patent Owner demonstrated persuasively that the purchase agreements otherwise created privity between GEA and Petitioner. Even if the agreements for lines 1–6/7 were similar to the line 8 agreement as Patent Owner contends, we examined the relationship created by the line 8 agreement in detail, and determined that Petitioner and GEA were not privies. *See* Inst. Dec. 7–19. Given this, Patent Owner has added nothing new of significance since our Institution Decision.

It is worth noting that after Patent Owner's Response was submitted, Patent Owner sought and was denied additional discovery relating to the agreements for lines 1–6/7. Paper 61 (Patent Owner's Motion for Discovery), Paper 65 (Opposition), Paper 71 (Decision denying discovery). Also of note, our order regarding oral argument limited the parties to present arguments related to privity only to the extent that additional evidence came of record after institution of trial. Paper 67. At oral hearing, Patent Owner did not present any arguments on the merits regarding privity; rather, Patent Owner proffered an email indicating the possibility that additional information would be obtained from the related litigation. Tr. 68–75; *see also* Paper 72 (entering the email as Board Exhibit 3002 and noting that the email contained nothing of substance). Since that time, Patent Owner has not sought to enter any such information into the record.

Accordingly, we decline to reconsider our prior decision that the Petition is not time barred under § 315(b) based on Petitioner's relationship with GEA.

B. PETITIONER'S MOTION TO EXCLUDE EVIDENCE

Petitioner moves to exclude five exhibits: (1) the deposition testimony of Stephen Spinak; (2) the declaration of Janelle Oxford; (3) the First Amended Complaint in *Gehl Foods, Inc. v. KHS AG*, No. 2:09-cv-00399 (Sept. 9, 2009); (4) the declaration of Dr. Norbert Buchner; and (5) the declaration of Andre Sharon. Paper 60, 1. Patent Owner filed an Opposition to the Motion, and Petitioner filed a Reply to the Opposition. Papers 64, 68. For the reasons that follow, Petitioner's motion is *denied*.

With the two exceptions noted in our discussion below, Petitioner made a timely objection with sufficient particularity to allow Patent Owner to correct in the form of supplemental evidence for each challenged exhibit.[18] Patent Owner makes no arguments to the contrary. *See* Paper 64.

1. Deposition of Stephen Spinak (Ex. 2036)

Petitioner moves to exclude the Spinak Deposition on the basis that it is not relevant and is hearsay. The Spinak Deposition was created by Patent Owner in another *inter partes* review (IPR2014-00054) that involved the '468 patent and GEA as the petitioner. *See* Ex. 2036, 1. Patent Owner, and its expert, cite to the Spinak Deposition in support of the contention that the underlying technology of the challenged claims is unpredictable as shown by the failure of a European equipment manufacturer to achieve FDA validation of an aseptic filling machine. Prelim. Resp. 39, 43; PO Resp. 15, 31 (referencing Ex. 2036 ¶¶ 10–14). Additionally, Dr. Sharon, Patent Owner's

[18] With regard to Exhibits 2036, 2040, and 2041, Petitioner's objections are at Paper 28, and with regard to Exhibits 2056 and 2061, Petitioner's objections are at Paper 44.

expert, provides an opinion regarding the Spinak Deposition. *See* Ex. 2061 ¶ 28 (citing Spinak Decl., Ex. 2036, ¶¶ 11–14).

The Federal Rules of Evidence apply to *inter partes* proceedings except as otherwise provided in Part 42. 37 C.F.R. § 42.62(a). Under Part 42, expert testimony that does not disclose the underlying facts or data on which an opinion is based is entitled to little or no weight. 37 C.F.R. § 42.65(a). The implication is that ordinarily the underlying facts that form the basis of an expert opinion should be considered.

Because Patent Owner's expert, Dr. Sharon, provides an opinion regarding the Spinak Deposition, the underlying data for that opinion (i.e., the cited portion of the Spinak Deposition) should be admitted so that it may be considered, as implied by § 42.65(a). Petitioner's motion is denied on that basis. Even if that is not a correct interpretation of Part 42, for the reasons that follow, we are not persuaded by Petitioner's arguments.

a) Relevance

Petitioner characterizes the Spinak Deposition as a deposition in four *inter partes* review proceedings to which Petitioner was not a party. Paper 60, 1. Petitioner contends that Patent Owner relies upon the Spinak Deposition to establish that a European Manufacturer failed to achieve FDA "aseptic" validation. *Id.* at 2. According to Petitioner, this testimony is not relevant to the proceeding at hand because Patent Owner has not tied the FDA's questions about the machine to the language of the claims of the '468 patent, and because the testimony does not relate to a fact of consequence in this proceeding. *Id.*

Patent Owner contends the Spinak Deposition is relevant to the state of the art of aseptic packaging to include the difficulty and complexity of

designing aseptic packaging equipment. Paper 64, 8. Petitioner replies that Patent Owner has not explained adequately how testimony made ten years later, or relating to different patents, is relevant. Paper 68, 4.

For the reasons that follow, Petitioner has not demonstrated that the Spinak Deposition is not relevant.

First, whether Petitioner was a party to the proceeding in which the Spinak Deposition was submitted is of no consequence in a relevance inquiry. *See* Paper 60, 1. Second, Petitioner's contention that the Spinak Deposition relates to different patents ignores that the Spinak Deposition also relates to the '468 patent. *See* Ex. 2036, 1.

Third, Petitioner is correct that the validation attempt regarding a European machine described in the Spinak Deposition occurred after the critical date of the '468 patent. *See* Ex. 2036, 11–14; Prelim. Resp. 41; Ex. 1001, 1. However, an assertion that the underlying technology remained unpredictable even after the critical date of the '468 patent has some tendency to demonstrate that the underlying technology was unpredictable up to that time. Patent Owner's contention that the underlying technology is unpredictable relates to the scope and content of the prior art, and as such, is a fact of consequence in this action. *See* Fed. R. Evid. 401.

Consequently, Petitioner has not persuaded us that the Spinak Deposition is inadmissible under FRE 402.

b) Hearsay

Petitioner argues that the Spinak Deposition is an out-of-court statement created without the opportunity for cross examination by Petitioner, and is offered to prove the truth of the matter asserted, namely,

that an unspecified manufacturer failed to achieve FDA validation.[19] Paper 60, 3–4.

Patent Owner argues that even if the Spinak Deposition is hearsay, it is admissible under Fed. R. Evid. 703. We agree. Federal Rule of Evidence 703 permits an expert to base an opinion on facts or data in the case that an expert has been made aware of if experts in the field would reasonably have relied on such facts or data in forming an opinion. Petitioner contends that Patent Owner conceded that Dr. Sharon relied upon improper expert and lay opinion. Paper 68, 3. However, Petitioner does not cite to, nor do we discern, any such concession by Patent Owner. Nor has Petitioner explained persuasively why it is unreasonable for an expert to rely upon the Spinak Deposition. Mr. Spinak testified regarding FDA validation of an aseptic bottling system, and it was reasonable for Dr. Sharon to rely upon such information. *See* Paper 64, 4–8; Ex. 2061 ¶ 28; Ex. 2036, 9:8–13:4.

Fed. R. Evid. 703 includes the caveat that if the underlying facts are inadmissible, those facts may only be disclosed to the jury if their probative value in helping evaluate the opinion substantially outweighs their prejudicial effect. Our determination is not made by a jury, so this caveat does not apply. *See* 37 C.F.R. § 42.62(b) (portions of the Federal Rules of Evidence relating to juries do not apply). For that reason, this panel should

[19] The Spinak Deposition was made during another *inter partes* review, and therefore was made while testifying in a trial. *See* 37 C.F.R. § 42.2 (trial is defined as beginning at institution). Here, and throughout, we interpret Petitioner's reference to the exhibit as an "out-of-court" statement to mean that exhibit was not made while testifying in the current trial (*inter partes* review). *See* Fed. R. Evid. 801(c)(1).

consider the data (i.e., pages 11–14 of the Spinak Deposition) underlying Dr. Sharon's opinion.

c) Conclusion

Accordingly, we deny Petitioner's Motion to Exclude the Spinak Deposition. *See* 37 C.F.R. §§ 42.20(c), 42.22.

2. Declaration of Janelle Oxford (Ex. 2040)

Petitioner moves to exclude the Oxford Declaration on the basis that it is not relevant, is improper opinion, and is hearsay. The Oxford Declaration was not created for the proceeding at hand; rather, it was created for litigation between Patent Owner and two parties other than Petitioner. *See* Paper 60, 4; Ex. 2040, 1. Patent Owner relies on the Oxford Declaration in support of the contention that a person of ordinary skill in the art would not have had a reasonable expectation of success in modifying Biewendt to reach the claimed subject matter because the underlying technology is unpredictable. Prelim. Resp. 43; PO Resp. 43. Specifically, Patent Owner asserts,

> Around 2008, Kan-Pak, LLC purchased an aseptic bottle filler from Hamba Filltec GmbH & Co., a well-established manufacturer of aseptic cup equipment. Ex. 2040 at ¶¶ 20-25. Soon after the machine was delivered to Kan-Pak, Kan-Pak determined that it did not function properly and would not receive FDA validation absent significant modifications. *Id.* at ¶¶ 22-25.

Prelim. Resp. 43 (citing Ex. 2040 ¶¶ 20–25); PO Resp. 43.

Dr. Sharon provides an opinion regarding the Oxford Declaration. Ex. 2061 ¶ 28 (citing Oxford Decl., Ex. 2040). Consequently, our analysis here parallels that of the Spinak Deposition above. Specifically, the data (i.e., the Oxford Declaration) underlying Dr. Sharon's opinion should be admitted so

that it may be considered. Even if that is not a correct interpretation of Part 42, for the reasons that follow, we are not persuaded by Petitioner's arguments.

a) Relevance

Petitioner asserts that the Oxford Declaration is not relevant for two reasons: (1) it does not support Patent Owner's assertion that a Hamba machine sold to Kan-Pak would not receive FDA validation absent significant modifications, (2) Patent Owner has not explained adequately how testimony made ten years later or relating to different patents is relevant. Paper 60, 4-5; Paper 68, 4. Patent Owner contends the Oxford Declaration is relevant to the state of the art of aseptic packaging to include the difficulty and complexity of designing aseptic packaging equipment. Paper 64, 8.

As a preliminary matter, whether the Oxford Declaration supports adequately Patent Owner's assertion goes to the weight to be afforded that assertion and not the admissibility of the underlying evidence.[20] Furthermore, Petitioner is correct that the machine problems described in the Oxford Declaration occurred well after the critical date of the '468 patent. However, an assertion that the underlying technology remained unpredictable even after the critical date of the '468 patent has some tendency to demonstrate that the underlying technology was unpredictable as of the critical date. Patent Owner's contention that the underlying

[20] *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,767 (Aug. 14, 2012) ("A motion to exclude must explain why the evidence is not admissible (*e.g.*, relevance or hearsay) but may not be used to challenge the sufficiency of the evidence to prove a particular fact.").

technology is unpredictable relates to the scope and content of the prior art, and as such, is a fact of consequence in this action. *See* Fed. R. Evid. 401.

Consequently, Petitioner has not persuaded us that the Oxford Declaration is inadmissible under FRE 402.

b) Fed. R. Evid. 701, 702

Petitioner contends that Patent Owner relies on the Oxford Declaration to show the knowledge and abilities of one of ordinary skill in the art. Paper 60, 5 (citing PO Resp. 40). According to Petitioner, Ms. Oxford has not been qualified as an expert, and for that reason such testimony is improper lay opinion under Fed. R. Evid. 701 and unqualified expert testimony under Fed. R. Evid. 702. *Id.*

Ms. Oxford did not testify as to her opinion nor did she testify as an expert. Rather, Ms. Oxford testified as a factual witness concerning operation of the aseptic bottling machine purchased by Kan-Pak. *See* Ex. 2040 ¶¶ 20–25. As such, Petitioner has not persuaded us that Ms. Oxford's testimony is inadmissible under either Fed. R. Evid. 701 or 702.

c) Hearsay

Petitioner argues that the Oxford Declaration is an out-of-court statement offered to prove the truth of the matters asserted, and as such is inadmissible hearsay. Paper 60, 6. Specifically, Petitioner contends that the matter asserted is that the Kan-Pak machine was not FDA validated and failed to operate successfully. *Id.*

Patent Owner argues that even if the Oxford Declaration is hearsay, it is admissible under Fed. R. Evid. 703. We agree. Petitioner contends that Patent Owner conceded that Dr. Sharon relied upon improper expert and lay opinion. Paper 68, 3. However, Petitioner does not cite to, nor do we

discern, any such concession by Patent Owner. Nor has Petitioner explained persuasively why it is unreasonable for an expert to rely upon the Oxford Declaration. The Oxford Declaration includes information about the operability of aseptic cup equipment, and it is reasonable for Dr. Sharon to rely upon such information. *See* Fed. R. Evid. 703; Paper 64, 4–8; Ex. 2061 ¶ 28; Ex. 2040 ¶¶ 20–25.

Fed. R. Evid. 703 includes the caveat that if the underlying facts are inadmissible, those facts may only be disclosed to the jury if their probative value in helping evaluate the opinion substantially outweighs their prejudicial effect. This caveat does not apply because our determination is not made by a jury. For that reason, this panel should consider the data (i.e., the Oxford Declaration) underlying Dr. Sharon's opinion.

d) Conclusion

Accordingly, we deny Petitioner's Motion to Exclude the Oxford Declaration. *See* 37 C.F.R. §§ 42.20(c), 42.22.

3. First Amended Complaint in Gehl Foods, Inc. v. KHS AG, No. 2:09-cv-00399 (Sept. 9, 2009) (Ex. 2041, "Gehl Complaint")

Petitioner moves to exclude the Gehl Complaint on the basis that it is not relevant and is hearsay. The Gehl Complaint was filed against KHS, a manufacturer of bottle filling machinery, on September 9, 2009, Paper 60, 7; Ex. 2041, 1; *see also* Paper 64 (Patent Owner not contesting this description of the Exhibit). Patent Owner relies on the Gehl Complaint in support of the contention that a person of ordinary skill in the art would not have had a reasonable expectation of success in modifying Biewendt to reach the claimed subject matter because the underlying technology is unpredictable. Prelim. Resp 43–44; PO Resp. 43. Specifically, Patent Owner contends that in 2009 a European aseptic equipment manufacturer,

KHS AG, was forced by a customer to abandon a five-year long unsuccessful effort to validate an aseptic sterilization and filling machine. PO Resp. 43–44 (citing Ex. 2041 ¶¶ 11, 41); *see also* PO Resp. 43 (similar contention that additionally cites Ex. 2041 ¶ 2).

Dr. Sharon provides an opinion regarding the Gehl Complaint. Ex. 2061 ¶ 28. Consequently, the underlying data for that opinion (i.e., the Gehl Complaint) should be admitted so that it may be considered. Petitioner's motion is denied on that basis. Even if that is not a correct interpretation of Part 42, for the reasons that follow, we are not persuaded by Petitioner's arguments.

a) Relevance

Petitioner contends that the Gehl Complaint is not relevant for four reasons: (1) the Gehl Complaint does not support Patent Owner's assertion that the Gehl machine did not function and did not meet FDA standards, (2) the statements occurred almost ten years after filing of the application that became the '468 patent, (3) the Gehl Complaint does not relate to the claimed subject matter, and (4) there is no evidence that KHS possessed the knowledge of one of ordinary skill in the art. Paper 60, 7–8. Patent Owner contends that the Gehl Complaint is relevant to the state of the art in aseptic packaging. Paper 64, 8.

Petitioner's contention that the Gehl Complaint does not support Patent Owner's assertion relates to the sufficiency of the evidence and not admissibility. Further, although it is true that the validation problems described in the Gehl Complaint occurred in 2009, if the underlying technology remained unpredictable even after the critical date of the '468 patent, that has some tendency to demonstrate that the underlying

technology was unpredictable as of the critical date. *See* PO Resp. 43–44; Ex. 1001, 1. Without regard for whether KHS possessed the ordinary skill in the art, Patent Owner's contention that the underlying technology is unpredictable relates to the scope and content of the prior art, and as such is a fact of consequence in this action.

Consequently, Petitioner has not persuaded us that the Gehl Complaint is inadmissible under FRE 402.

b) Hearsay

Petitioner contends that the Gehl complaint is an out of court statement offered to prove the truth of the matter asserted, namely, that the machine sold to Gehl was not FDA-validated and failed to operate successfully. Paper 60, 8 (citing PO Resp. 43).

Patent Owner argues that even if the Gehl Complaint is hearsay, it is admissible under Fed. R. Evid. 703. We agree. Petitioner contends that Patent Owner conceded that Dr. Sharon relied upon improper expert and lay opinion. Paper 68, 3. However, Petitioner does not cite to, nor do we discern, any such concession by Patent Owner. Nor has Petitioner explained persuasively why it is unreasonable for an expert to rely upon the Gehl Complaint. The Gehl Complaint includes information regarding the operation of an aseptic sterilization and filling machine, and it is reasonable for Dr. Sharon to rely upon such information. *See* Paper 64, 4–8; Ex. 2061 ¶ 28; Ex. 2041 ¶¶ 11, 41.

Fed. R. Evid. 703 includes the caveat that if the underlying facts are inadmissible, those facts may only be disclosed to the jury if their probative value in helping evaluate the opinion substantially outweighs their prejudicial effect. This caveat does not apply because our determination is

not made by a jury. For that reason, this panel should consider the underlying data (i.e., the Gehl Complaint).

c) Conclusion

Accordingly, we deny Petitioner's Motion to Exclude the Gehl Complaint (Ex. 2041). *See* 37 C.F.R. §§ 42.20(c), 42.22.

4. Declaration of Dr. Norbert Buchner (Ex. 2056)

Petitioner moves to the exclude the Buchner Declaration on the bass that it is not relevant, is improper opinion, and is hearsay. Patent Owner relies on the Buchner Declaration in support of the argument that a person of ordinary skill in the art would not have had a reasonable expectation of success in modifying Biewendt to reach the claimed subject matter. PO Resp. 39–41 (citing Buchner Declaration ¶ 18[21]). Specifically, Patent Owner relies on the Buchner Declaration to suggest that ZFL (Ex. 1012[22]) only describes the functionality of the machines at a high level, and that Biewendt (Ex. 1013[23]) similarly lacks detail. *Id.* at 40.

Petitioner contends that the Buchner Declaration is irrelevant, improper opinion testimony, and inadmissible hearsay. Paper 60, 9–11.

a) Relevance

Petitioner argues that the Buchner Declaration is not relevant under Fed. R. Evid. 401 and should be excluded under Fed. R. Evid. 402. Paper 60, 9–10. Specifically, Petitioner contends that: (1) the Buchner Declaration

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[21] Patent Owner mistakenly cites to Exhibit 2052, but based on content, Exhibit 2056 was intended. PO Resp. 40.

[22] The ZFL reference is non-patent literature by Dr. Norbert Buchner. Ex. 1012, 1.

[23] The Biewendt reference is non-patent literature by H.-G. Biewendt, et al. Ex. 1013, 1.

relates to U.S. Patent No. 6,945,013 not the '468 patent, (2) the Buchner Declaration does not describe or discuss either Biewendt (Ex. 1013) or ZFL (Ex. 1012), and (3) Dr. Buchner is not the author of Biewendt. *Id.* at 9–10.

Patent Owner contends that the Buchner Declaration is relevant to the state of the art of aseptic packaging to include the difficulty and complexity of designing aseptic packaging equipment. Paper 64, 8. Petitioner replies that Patent Owner has not explained adequately how testimony made ten years later or relating to different patents is relevant. Paper 68, 4.

Petitioner's characterization that the Buchner Declaration pertains to other patents ignores that the testimony relates to the articles written by Dr. Buchner (e.g., ZFL) that are relied upon as prior art in this proceeding. *See* Ex. 2056 ¶ 18.

Even though Biewendt is not an article by Dr. Buchner, ZFL was written by Dr. Buchner. *See* Ex. 1012, 1; Ex. 1013, 1; Ex. 2056 ¶ 18. Dr. Buchner's description of ZFL is relevant in that it relates to the scope and content of the prior art. The fact that Dr. Buchner's testimony comes after the critical date of the '468 patent is not determinative because the testimony refers to what was disclosed in ZFL, and ZFL is prior art to the '468 patent.

Consequently, Petitioner has not persuaded us that the Buchner Declaration is inadmissible under FRE 402. *See* 37 C.F.R. §§ 42.20(c), 42.22.

b) Improper Opinion Testimony

Petitioner argues that Dr. Buchner's testimony should be excluded because it is improper lay testimony under Fed. R. Evid. 701 and improper expert testimony under Fed. R. Evid. 702. Paper 60, 10–11. Such

contentions are not persuasive, because with regard to the content of ZFL, Dr. Buchner testifies as a factual witness.

c) Discovery Issue

Petitioner contends that Patent Owner violated 37 C.F.R. § 42.51(b)(1) by failing to serve "EX11" on Petitioner, and that the Buchner Declaration should be excluded on that basis.[24] Paper 60, 11. Petitioner cannot make a motion to exclude on this basis because Petitioner made no corresponding objection. *See* Paper 44, 1–3; 37 C.F.R. § 42.64. Further, Petitioner could have sought to compel production of this document as a matter of discovery, but did not. *See* 37 C.F.R. § 42.52. Consequently, Petitioner has not persuaded us that the Buchner Declaration should be excluded on this basis.

d) Hearsay

Petitioner contends that the Buchner Declaration is an out-of-court statement offered to prove the truth of the matter asserted. Paper 60, 11.

In IPR2014-01235, Petitioner filed a Declaration from Dr. Buchner from Reexam No. 90/011,072 as Exhibit 1017, and relied upon it in the Petition. *See* IPR214-01235, Paper 7, 50; Ex. 1017, 1. The Declaration in IPR2014-01235 was signed on December 19, 2011, and the Declaration in the case at hand was signed on January 20, 2011. IPR2014-01235, Ex. 1017, 7; Ex. 2056, 7. Other than this distinction, the documents have the same content. Petitioner relied on the content of the Buchner Declaration in a related *inter partes* review. Such reliance on the content of the Declaration demonstrates that the reliability concerns underlying hearsay are not present. Consequently, we will not consider Petitioner's hearsay assertion here. *See*

[24] The Buchner Declaration (Ex. 2056 ¶ 25) cites to "EX11."

37 C.F.R. §§ 42.5, 42.7; *see also* Fed. R. Evid. 102 (the rules should be construed to administer the proceeding fairly, to ascertain the truth, and to secure a just determination).

e) Conclusion

Accordingly, we deny Petitioner's Motion to Exclude the Buchner Declaration (Ex. 2056). *See* 37 C.F.R. §§ 42.20(c), 42.22.

5. Declaration of Andre Sharon (Ex. 2061)

Petitioner contends that Dr. Sharon's Declaration should be excluded because: (1) it is improper expert testimony under Fed. R. Evid. 702 in that Dr. Sharon is not qualified under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and (2) Dr. Sharon's Declaration fails to satisfy the requirements of 37 C.F.R. § 42.65 and Fed. R. Evid. 703. Paper 60, 12–15. We address these contentions in turn.

a) Fed. R. Evid. 702

Petitioner's assertions regarding *Daubert* do not persuade us. The policy considerations for excluding expert testimony, such as those implemented by the gatekeeping framework established by the Supreme Court in *Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579 (1993), are less compelling in bench proceedings such as *inter partes* reviews than in jury trials. *See, e.g.*, *Volk v. United States*, 57 F. Supp. 2d 888, 896 n.5 (N.D. Cal. 1999); *In re Bay Area Material Handling, Inc.*, No. C 95-1163 VRW, 1995 WL 729300, at *6 (N.D. Cal. Dec. 4, 1995).

To testify as an expert under FRE 702, a person need not be a person of ordinary skill in the art, but rather may be "qualified in the pertinent art." *See Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363–64 (Fed. Cir. 2008); *Mytee Prods., Inc. v. Harris Research, Inc.*, 439 F. App'x

882, 886–87 (Fed. Cir. 2011) (non-precedential) (upholding admission of the testimony of an expert who "had experience relevant to the field of the invention," despite admission that he was not a person of ordinary skill in the art). Further, there need not be a perfect match between the expert's qualifications and the patent at issue. *See SEB S.A. v. Montgomery Ward & Co. Inc.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010).

The challenged claims relate to aseptic packaging of food products. Ex. 1001, 1:14-15. Dr. Sharon is qualified to provide his opinions for this case. For example, Dr. Sharon has a Bachelor of Science in Mechanical Engineering, a Master of Science, and Ph.D. in Mechanical Engineering. Ex. 2061 ¶ 1. Dr. Sharon has experience as a research scientist, and was involved in design and fabrication of numerous automated machines. *Id.* ¶ 2; *see also* ¶¶ 3–7 (additional qualification and experience). Dr. Sharon's qualifications align with the challenged subject matter sufficiently so that his knowledge is helpful in understanding the evidence and determining facts at issue.[25]

b) 37 C.F.R. § 42.65 and Fed. R. Evid. 703

As an initial matter, Rule 42.65 addresses the weight that is given to expert testimony and says nothing with regard to the admissibility of evidence. *See* 37 C.F.R. § 42.65; *see also* Paper 60, 15 (acknowledging the rule relates to the weight to be afforded evidence). Notably, Petitioner does

[25] It is within our discretion to assign the appropriate weight to the testimony offered by Dr. Sharon. *See, e.g.*, *Yorkey v. Diab*, 601 F.3d 1279, 1284 (Fed. Cir. 2010) (holding the Board has discretion to give more weight to one item of evidence over another "unless no reasonable trier of fact could have done so").

not cite to any legal authority for excluding evidence based on failure to comply with this rule. Consequently, Petitioner's contention that this rule supports excluding the Sharon Declaration is not persuasive.

Petitioner provides two examples. In the first example, Petitioner contends that Dr. Sharon presents analyses based on information that has not been cited or fully disclosed by Dr. Sharon. Paper 60, 14 (citing Ex. 2061 ¶ 16). In the cited portion of Dr. Sharon's Declaration, Dr. Sharon opines that those involved in the design of aseptic packaging systems

> must understand principles of mechanical engineering, including the actual mechanical design of machines and other related considerations such as fluid dynamics and heat transfer. I can attest to this, as I have designed several commercial industrial machines for a variety of industries.

Ex. 2061 ¶ 16. Such testimony is proper under Fed. R. Evid. 703 because an expert may base an opinion on facts or data that the expert has personally observed.

In the second example, Petitioner contends that Dr. Sharon presents testimony regarding a dissertation that he never reviewed. Paper 60, 14–15 (citing Ex. 2061 ¶ 64; Deposition of Dr. Sharon, Ex. 1021, 81:25–82:5). Petitioner's objections to Exhibit 2061 did not provide this second example, denying Patent Owner the opportunity to correct in the form of supplemental evidence. *See* Paper 44, 3; 37 C.F.R. § 42.64(b)(1). For that reason, this example may not serve as a basis for the motion to exclude. Even considering this example, we are not persuaded for the following reasons.

In the portion of the Sharon Declaration cited by Petitioner, Dr. Sharon opines that

> the fact a dissertation that Professor Buchner oversaw in 1992 attempted and failed to achieve a 6 log reduction in *b. subtilis*,

> further suggests that Bosch systems described in the Bosch Brochure, ZFL, and Buchner references, that he authored prior to 1992, or was intimately involved in as Center Chief for Advanced Development and Director for R&D at Bosch, did not achieve a 6 log reduction, or else he would have certainly been able to achieve that same log reduction in 1992.

Ex. 2061 ¶ 64; (citing Ex. 2056 (Buchner Declaration) ¶¶ 5, 25).

Dr. Sharon is providing an opinion based on Dr. Buchner's Declaration and several of the prior art references. Dr. Sharon read these documents (i.e., the declaration and each of the references). *See* Ex. 2061 ¶¶ 9, 64. Petitioner has not explained persuasively why it is unreasonable for an expert to rely upon such documents in forming an opinion. The fact that Dr. Sharon did not also read the Buchner dissertation does not alter that analysis. Petitioner has not persuaded us that Patent Owner failed to satisfy Fed. R. Evid. 703.

c) Conclusion

Accordingly, we deny Petitioner's Motion to Exclude the Sharon Declaration (Ex. 2061). *See* 37 C.F.R. §§ 42.20(c), 42.22.

C. PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE

Patent Owner moves to exclude Exhibits 1031–1033, which are identified as terms governing sales of aseptic bottling machines from GEA to Nestlé, on the basis that the Exhibits have not been properly authenticated. Paper 58, 1. Petitioner relies on these exhibits to show that the agreements covering lines 1–6/7 do not establish privity between Petitioner and GEA, specifically that Petitioner is not obligated to fully indemnify GEA. Pet. Reply 23. Petitioner submitted an opposition to the motion, and Patent Owner submitted a reply in support of its motion. Papers 63, 69.

As discussed above, Patent Owner's contentions regarding lines 1–6/7 do not persuade us that GEA is a privy of Petitioner, and therefore, we need not consider Petitioner's response that lines1–6/7 do not obligate Petitioner to fully indemnify GEA. Pet. Reply, 23 (citing Ex. 1031–1033). Consequently, Patent Owner's motion to exclude these exhibits is *denied* as moot.

III. CLAIMED SUBJECT MATTER

A. INTRODUCTION

As background, the '468 patent explains that sterilized packaging systems in which a sterile food product is placed and sealed in a container to preserve the product for later use were "well known in the art." Ex. 1001, 1:21–23. Further, it was also known how to: sterilize incoming containers, fill containers with pasteurized product, and seal the containers in an aseptic tunnel. *Id.* at 1:23–26.

According to the '468 patent, what was not known was aseptically filling at high output processing speed: (1) containers having small openings, (2) low acid products, and (3) successfully complying with FDA standards for labeling such packaged products as aseptic. *Id.* at 2:22–29.

To overcome these shortcomings, the '468 patent discloses a method for filling aseptic containers with an aseptic food product. *Id.* at 2:39-40; Figs. 3, 22. The aseptic product is delivered to the aseptic containers through a valve and nozzle mechanism which controls the volume of aseptic product flowing into the aseptic containers. *Id.* at 14:54-15:18; Figs. 28, 30. A sterile tunnel surrounds the valve and nozzle mechanism to prevent

contaminants from being carried into the aseptic product as the product exits the nozzle and flows into the aseptic container. *Id*. at 2:13-21; 15:19-62.

B. CHALLENGED CLAIMS

Claim 1 is the sole independent challenged claim, and dependent claims 2, 3, 7, and 9 depend directly or indirectly from claim 1. The challenged claims follow.

> 1. A method comprising:
> controlling the flow of an aseptic product using a valve;
> surrounding a region where the aseptic product exits the valve with a sterile region wherein the sterile region is a sterile tunnel; and
> controlling the opening or closing of the valve with a sealed actuator, wherein the sealed actuator is surrounded with the sterile region.
>
> 2. The method of claim 1, further including providing a tank for containing a supply of pressurized aseptic product flowing to the valve.
>
> 3. The method of claim 2, further including providing a measuring device for measuring the amount of pressurized aseptic product flowing from the tank to the valve.
>
> 7. The method of claim 1, further including:
> connecting the sealed actuator to a control system with a control conduit.
>
> 9. The method of claim 1, further comprising:
> aseptically disinfecting a plurality of bottles to a level producing at least about a 6 log reduction in spore organisms.

C. CLAIM CONSTRUCTION

We interpret the claims of an unexpired patent using the broadest reasonable construction. *See* 37 C.F.R. § 42.100(b). We construe only those terms which are in controversy, and only to the extent necessary to resolve the controversy. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999).

Because Patent Owner disagrees with our interpretation of "aseptic", we provide additional analysis for this claim term. In our Institution Decision, we determined that a person of ordinary skill in the art would understand that "aseptic" means:

> aseptic to any applicable United States FDA[26] standard in the context of the claimed subject matter, and in the absence of any such standard, aseptic assumes it's ordinary meaning of "free or freed from pathogenic microorganisms."

Dec. 6–7.

An important factor in this interpretation is that the Specification explicitly states that "aseptic" means "to the FDA level of aseptic." Specifically, the '468 patent specification expressly states that "[i]n the following description of the present invention, the term 'aseptic' denotes the United States FDA level of aseptic." Ex. 1001, 1:32–34. The specification further states:

> The present invention provides an aseptic processing apparatus 10 that will meet the stringent FDA (Food and Drug Administration) requirements and 3A Sanitary Standards and Accepted Practices required to label a food product (foodstuffs) as 'aseptic'. Hereafter, *'aseptic' will refer to the FDA level of aseptic*.

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[26] United States FDA means United States Food and Drug Administration. *See* Ex. 1001, 1:48. We use "FDA" throughout.

Id. at 5:41–46 (emphasis added). In addition, the specification makes clear that the requirements that satisfy "the FDA level of aseptic" depend on the context of "aseptic"—e.g., the process, apparatus, or foodstuff involved. For example, all surfaces of the filler that come into contact with a liquid product must be sterilized. *Id*. at 1:47–50.

In other words, when construing the claims, the term "aseptic" incorporates any applicable FDA standard, and in the absence of such standard, carries its ordinary meaning. That applicable standard can vary with the foodstuff or the portion of the process involved. *See* Dec. 6–7; Ex. 1001, 2:13–22.

In its Patent Owner Response, Patent Owner disagrees with how we apply the term "aseptic" in the context of claim 1. Specifically, Patent Owner contends that the FDA standards for residual hydrogen peroxide apply to all of the challenged claims by virtue of dependence from independent claim 1. PO Resp. 11–13. According to Patent Owner, this standard applies because claim 1 requires that the filling valve is used to fill the aseptic product into a container, and a person of ordinary skill would understand that the claims implicitly require that the aseptic product is filled into aseptically sterilized containers. *Id.* at 3–6. Patent Owner elaborates that claim 1 is directed to filling because the specification only describes the steps of claim 1 in connection with filling of foodstuffs into a bottle in a bottle filling machine. *Id.* at 3–4.

Petitioner contends that the claims do not require container filling. Pet. Reply 2, 9.

The '468 patent describes the use of a valve, such as recited in claim 1, as part of an aseptic processing apparatus for filling aseptic containers

with aseptic product. *See, e.g.*, Ex. 1001, Abstract, Fig. 29. However, claim 1 is directed generally to a "method" that only covers a portion of that entire process.[27] In particular, claim 1 does not recite aseptically disinfecting containers and does not recite dispensing aseptic product into containers. Limitations not explicit or inherent in the language of a claim cannot be imported from the specification. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369 (Fed. Cir. 2003); *see also Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.").

The FDA regulation regarding residual hydrogen peroxide states in relevant part:

> (d) Limitations. No use of hydrogen peroxide solution in the sterilization of food packaging material shall be considered to be in compliance if more than 0.5 part per million of hydrogen peroxide can be determined in distilled water packaged under production conditions (assay to be performed immediately after packaging).

21 C.F.R 178.1005(d) (Ex. 2048, 1); *see also* PO Resp. 11–13 (contending this regulation applies to the challenged claims).

Based on the explicit language of the regulation, we determine that this regulation applies when hydrogen peroxide is used as a sterilant for the

[27] At oral argument Patent Owner repeatedly referred to claim 1 as "a method for filling," but claim 1 merely recites a "method." *See, e.g.*, Tr. 46:8, 50:5, 53:25.

food packaging material (containers). Claim 1, however, does not require sterilization of containers. Consequently, the FDA requirement for residual hydrogen peroxide is not applicable to the method of claim 1. Nothing in dependent claims 2, 3, and 7 alters this analysis.

We note that the ’013 patent (at issue in IPR2014-01235) is related to the ’468 patent as described above, and the claims of the ’013 patent provide contrast to the ’468 patent claims that enlightens the meaning of claim 1 of the ’468 patent.[28] Unlike claim 1 of the ’468 patent, claims 18–20 of the ’013 patent, are not directed to “[a] method;” rather, those claims are directed to “[a] method for automatically aseptically bottling aseptically sterilized foodstuffs.” Further, the ’013 patent claims explicitly include a step requiring aseptically disinfecting containers (bottles). *See* IPR 2014-01235, Paper 63, 3–4. Claim 20 explicitly recites hydrogen peroxide as the sterilant. Although claims 18 and 19 were not limited to use of a particular sterilant, because the prior art relied upon by Petitioner utilized hydrogen peroxide as the sterilant to aseptically disinfect the plurality of containers, Petitioner was required to show how the method was accomplished *in accordance with the FDA standard for residual hydrogen peroxide*. *Id.* at 23–24.

With respect to the challenged claims in this case, unlike claims 1–3 and 7, claim 9 explicitly recites a step related to containers (bottles). Specifically, claim 9 requires “aseptically disinfecting” a plurality of bottles

[28] *See NTP Inc., v. Research in Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005) (When construing claims in patents that derive from the same parent application and share common terms, “we must interpret the claims consistently across all asserted patents.”).

to a level producing at least a specified level of reduction in spore organisms. "Aseptically disinfecting" as claimed, means disinfecting the plurality of bottles in compliance with any applicable FDA regulation. As mentioned above, when hydrogen peroxide is used to sterilize food packaging material (e.g., bottles), the FDA limitation on residual hydrogen peroxide is applicable. *See* 21 C.F.R 178.1005(d) (Ex. 2048, 1).

Thus, although claim 9 does not specify the media selected to achieve sterility, when hydrogen peroxide is used to aseptically disinfect the containers, the FDA residual hydrogen peroxide limitation would apply. Consequently, in order to show that the method of claim 9 was rendered obvious by particular prior art, where Petitioner relies upon prior art that utilizes hydrogen peroxide as the sterilant, the disclosed process must be carried out in a manner that results in no great than 0.5 ppm hydrogen peroxide residue in the packaging.

Having considered the full record developed during trial, we conclude that the broadest reasonable construction of "aseptic" as would be understood by one of skill in the art in the context of the '468 patent is: aseptic to any applicable United States FDA standard in the context of the claimed subject matter, and in the absence of any such standard, aseptic assumes its ordinary meaning of "free or freed from pathogenic microorganisms." Moreover, we conclude that "aseptically disinfecting" means "disinfecting the plurality of bottles in compliance with any applicable FDA regulation."

IV. PATENTABILITY

A. INTRODUCTION

We consider Patent Owner to have admitted those aspects of these grounds of unpatentability that are uncontested by Patent Owner and are material facts. *See* Paper 26, 3 (cautioning Patent Owner that any arguments for patentability not raised in the response will be deemed waived). *See also* 37 C.F.R. § 42.23(a) (in an opposition, any material fact not specifically denied may be considered admitted); § 42.120(a) (the patent owner response is an opposition).

B. ANTICIPATION BY TAKEI – CLAIMS 1, 2, AND 7

1. Ground

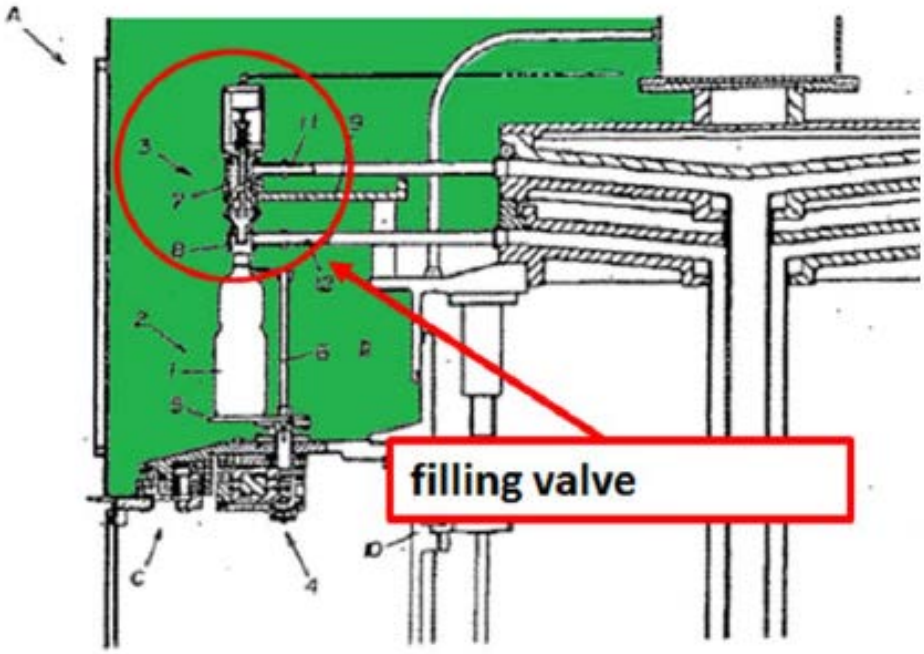
Petitioner contends that claims 1, 2, and 7 are unpatentable under 35°U.S.C. § 102(b) over Takei. *See* Pet. 12-14, 21-27. A claim is anticipated if each limitation of the claim is disclosed in a single prior art reference arranged as in the claim. *Net MoneyIN, Inc. v. VeriSign, Inc*., 545 F.3d 1359, 1369 (Fed. Cir. 2008). As recently reiterated by the Federal Circuit, "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)). We begin by analyzing independent claim 1 in accordance with the above-stated principles.

a) Takei discloses "A method comprising:"

Takei discloses a fluid filling apparatus and method of cleaning and sterilization of the flow-through fluid in a fluid filling apparatus. Ex. 1005 (Takei), 1–2; Pet. 12, 22.

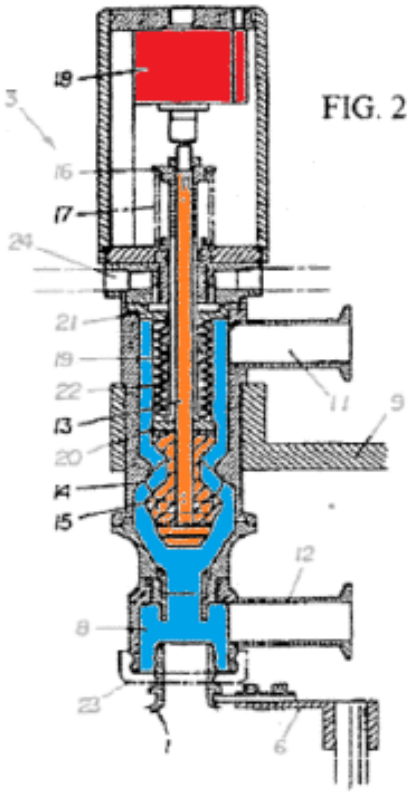
b) Takei discloses "controlling the flow of an aseptic product using a valve;"

Takei's fluid filling apparatus, A, controls the flow of an aseptic product using a valve. Ex. 1005, 4; Pet. 12–14, 22–23. An annotated version of Figure 1 of Takei's fluid filling apparatus is reproduced below.



Annotated Figure 1 of Takei is a partial vertical cross-sectional view of the fluid filling apparatus. Ex. 1005, 6. Petitioner added green to indicate "aseptic chamber b," and circled and labeled the filling valve. Pet. 12–13;

Ex. 1005, Fig. 1. The filling valve is shown in close up in annotated Figure 2 of Takei, reproduced below.



Annotated Figure 2 is a vertical cross-sectional view of Takei's fluid supply means 3. Ex. 1005, 6; Pet. 13. Petitioner added blue to indicate fluid passageway 7, orange to indicate operating rod 13 and valve member 15, and red to indicate operating means 18. Pet. 13–14.

In Takei's device, fluid (aseptic product) is pressure fed from a fluid reservoir through inflow means 11 (Fig. 1) into flow passageway 7 (Fig. 2, blue). Ex. 1005, 4; Pet. 13, 22. In the closed position, valve member 15 contacts valve seat 14 under the force of spring 17, and in the open position operating means 18 counters the force of spring 17 to allow fluid (aseptic product) to flow out of the valve and into bottles. Ex. 1005, 4; Pet. 13, 22; *see also* Ex. 1005, 1 (operating means blocks or frees up movement of

fluid). The measurement means determines when the fluid flowing into a container reaches a prescribed set value and causes the operating means to close the valve member. Ex. 1005, 3; Pet. 13–14, 22.

> *c) Takei discloses surrounding a region where the aseptic product exits the valve with a sterile region wherein the sterile region is a sterile tunnel;*

Takei's valve, to include the region where the aseptic products exits the valve (supply hole 8, Fig. 2 above), is surrounded by a sterile region (aseptic chamber b, green area, Figure 1 above) in the form of a sterile tunnel. Ex. 1005, 4; Pet. 23.

> *d) Takei discloses controlling the opening or closing the valve with a sealed actuator, wherein the sealed actuator is surrounded with the sterile region.*

Takei's valve actuator (operating means 18 and operating rod 13, orange, Fig. 2 above) is sealed and surrounded with the sterile region (aseptic chamber b). Ex. 1005, 4; Pet. 24.[29] Dr. Heldman, Petitioner's expert, explains that operating means 18 must be sealed to operate properly and prevent contaminating the aseptic chamber, and operating rod 13 is sealed by covering member 19 (diaphragm or bellows type). Ex. 1004 ¶ 25; Ex. 1005, 3–4; Pet. 24.[30]

2. Patent Owner Arguments

Patent Owner contends that the Petition is deficient in that it does not address whether Takei meets applicable FDA standards in three respects. PO Resp. 11–22.

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[29] Based on content, Petitioner's citation to page 14 of Exhibit 1005, was intended to be page 4.

[30] Based on content, Petitioner's citation to ¶ 24 of Exhibit 1004 was intended to be ¶ 25.

a) Residual Hydrogen Peroxide

Patent Owner contends that the Petition is deficient in that it does not address whether Takei meets applicable FDA standards relating to residual hydrogen peroxide. PO Resp. 11–13 (citing Ex. 2048; Ex. 1009, 60; Ex. 2046, 136; Ex. 1012, 3).

As explained above, the FDA standard for residual hydrogen peroxide does not apply to the method of claim 1. Consequently Patent Owner's argument is not persuasive because it is not commensurate in scope with claim 1. *See* Pet. Reply 9–10 (contending this argument is not commensurate in scope).

b) Maintenance of Equipment Sterility

Patent Owner contends that the Petition is deficient in that it does not address whether Takei meets applicable FDA standards relating to maintenance of equipment sterility. PO Resp. 13–16. According to Patent Owner, Takei discloses manually applying cap 23 to the mouth of the valve during the steam cleaning operation, and removal of cap 23 prior to resuming filling operations poses a risk of recontamination to the valve components due to exposure to plant atmosphere. *Id.* at 13–15. In support, Patent Owner cites to Dr. Sharon's opinion that FDA regulations require that prior to packaging operations, "both the container and closure sterilizing system and the product filling and closing system shall be brought to a

condition of commercial sterility."[31] PO Resp. 14–16; Ex. 2061 ¶¶ 35–36 (quoting 21 C.F.R. § 113.40(g)(1)(ii)(B)[32]; Ex. 2062 (21 C.F.R. § 113.40).

The FDA regulation relied upon by Patent Owner is titled, "Thermally Processed Low-Acid Foods packaged in Hermetically Sealed Containers." *See* 21 C.F.R. § 113.40 at Ex. 2062. Claim 1 is directed to a method that includes the step of controlling the flow of an "aseptic product." Claim 1 is not limited to thermally processed low-acid foods; instead, the aseptic product could, for example, be high acid food. *See* Ex. 1001, 1:56–58 (stating that packaged food products can be categorized as high acid or low acid products). For that reason this FDA regulation does not necessarily apply.

In comparison, the challenged claims in IPR2014-01235 were not limited to processing of low acid foodstuff, thus we considered Patent Owner's contention that the engineering underlying low acid foodstuffs is unpredictable. *See* IPR2014-01235, Paper 63, 19–20. We considered Patent Owner's contention in IPR2014-01235 because Petitioner relied upon references that processed low acid foodstuffs, so that a person of ordinary skill in the art seeking to modify that prior art would have to deal with associated challenges (e.g., the narrow path between using enough sterilant to sterilize the bottles without exceeding the residual sterilant requirement, the interdependence of various parameters).

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[31] Patent Owner also cites to the Spinak Deposition; however, the cited portion deals with rinsing practice during FDA validation, and not to the issue at hand. *See* PO Resp. 15 (citing Ex. 2036, 326:4–17).

[32] Based on content it appears the correct citation is § 113.40(g)(2)(ii)(B), not § 113.40(g)(1)(ii)(B). S*ee* Ex. 2062, 14 (second full paragraph).

The case at hand is distinguishable in two respects. First, the ground of unpatentability is anticipation, consequently a person of ordinary skill would *not* have been faced with the difficulties of modification of the prior art. Second, Takei's apparatus processes aseptic product in the form of alcohol, water, and the like, which would not normally include low acid products. *See* Sharon Decl., Ex. 2061 ¶ 36 (citing Ex. 1005, 4).

To the extent the cited FDA regulation is applicable to the methods of claim 1, Petitioner has demonstrated that Takei meets that limitation. The regulation requires that when sterility is lost, commercial sterility must be restored prior to resuming packaging operations. *See* Ex. 2062, 14. Takei discloses an aseptic filling apparatus that enables cleaning and sterilization of the entire apparatus so that containers may be filled in an aseptic condition. Pet. 12; Ex. 1005, 2. Takei does not disclose that removal of cap 23 prior to filling (packaging operations) contaminates aseptic chamber b; rather, Takei discloses that aseptic chamber b (corresponding to the claimed sterile tunnel) "is maintained in the aseptic condition at all times." Pet. 12; Ex. 1005, 4.

Patent Owner argues that Takei does not mention any means by which recontamination is prevented during removal of cap 23, such as a robotic mechanism, and therefore removal of cap 23 must cause contamination. PO Resp. 15 (citing Ex. 2061 ¶ 36). In support, Dr. Sharon opines that it is "possible" Takei was not concerned with this risk. Ex. 2061 ¶ 36. Patent Owner's argument does not persuade us that the express disclosure that aseptic chamber b is in aseptic condition at all times is in error. Further, the '468 patent, like Takei, includes caps (cups 198A, 198B) for the filling valve, and the '468 patent does not mention any means by which

recontamination is prevented during removal of those caps. *See* Pet. Reply 9–10; Ex. 1001, 16:31–34; Fig. 22. Therefore, if this omission demonstrates that contamination occurs, the logical inference is that the same is true of the '468 patent.

c) Sterile Region

Patent Owner contends that the Petition is deficient in that Petitioner has failed to establish that Takei's valve actuator is surrounded by a sterile region. PO Resp. 16–22. Specifically, Patent Owner contends that Takei does not explicitly describe the upper boundary of aseptic chamber b. *Id.* at 17–19 (citing Ex. 2061 ¶¶ 32–33; citing *Ex Parte Lee*, Appeal 2010-008925 (Aug. 12, 2013) for a holding regarding relying upon a reference for a dimensional limitation).

Patent Owner's argument is unpersuasive for several reasons. First, Patent Owner's argument focuses on whether the top of aseptic chamber b is the top of Figure 1 of Takei. The proper focus is whether aseptic chamber b meets the requirements of claim 1, namely, that it surrounds the region where the aseptic product exits the valve and the sealed actuator. Second, Patent Owner presents argument and evidence regarding what the extent of the aseptic chamber could or should be, rather than evidence regarding what Takei actually discloses to a person of ordinary skill. *See, e.g.*, PO Resp. 19 (citing Ex. 2057 regarding the preferred boundaries of an aseptic chamber), 21–22 (citing Ex. 2061 ¶¶ 69–70 regarding the benefits of surrounding the valve and actuator). Third, Patent Owner's citation to *Ex parte Lee* is not on point because Petitioner is not replying upon Takei's Figure 1 for a dimensional limitation; rather, Petitioner relies on Takei's Figure 1 to show the relationship between aseptic chamber b and the valve components. *See*

Pet. 23; Pet. Reply 6; *see also Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1565, (Fed. Cir. 1991) (patent drawings that are not drawn to scale may be used to establish relative sizes and relationships between the various components which are depicted).

Takei expressly states that fluid filling apparatus A is provided in aseptic chamber b as depicted in Figure 1. Ex. 1005, 4. Figure 1 identifies aseptic chamber b with the identifier "b" to the right of grabbing member 6. *Id.* at Fig. 1. Figure 1 does not include any indication that "b" (aseptic chamber b) is separated from either the region where the aseptic product exits the valve (lower end of flow passageway 7) or the actuator (operating means 18). *Id*. Patent Owner's arguments have not persuaded us to the contrary.

3. Conclusion

a) Claim 1

Having considered the full record developed during trial, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claim 1 is unpatentable under 35 U.S.C. § 102(b) as anticipated by Takei.

b) Claims 2 and 7

Claim 2 recites that the method includes providing a tank for containing a supply of pressurized aseptic product flowing to the valve. Takei includes such a tank (fluid reservoir). Ex. 1005, 4; Pet. 26.

Claim 7 depends from claim1 and adds the step of connecting the sealed actuator to a control system with a control circuit. Detection piece 27 of Takei's measurement means converts the mechanical strain induced by the weight added when filling a container into an electrical signal to operate

operating means 18. Ex. 1005, 3, 5, Fig. 2; Ex. 1004 ¶ 47 (explaining this operation); Pet. 26.

Patent Owner presents no additional arguments for claims 2 and 7. *See* 37 C.F.R. § 42.23(a).

We conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 2 and 7 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Takei.

C. OBVIOUSNESS OVER TAKEI – CLAIMS 1, 2, AND 7

As an alternative to the ground of unpatentability based on anticipation by Takei, Petitioner contends that "to the extent that *Takei*'s aseptic chamber b is not considered a 'sterile tunnel,' it would have been obvious to deploy *Takei*'s valve within a 'sterile tunnel' in view of *Takei*'s aseptic chamber b." Pet. 23[33] (citing to Ex. 1003, 14). A claim is unpatentable under § 103(a) if the differences between the claimed subject matter 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, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We also recognize that prior art references must

[33] The cited portion of Exhibit 1003, the file history of reexam application No. 95/000,686, likewise does not provide a rationale for the modification.

be "considered together with the knowledge of one of ordinary skill in the pertinent art." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (quoting *In re Samour*, 571 F.2d 559, 562 (CCPA 1978)).

The Supreme Court has held that an obviousness evaluation "cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents." *KSR*, 550 U.S. at 419. Instead, the relevant inquiry here is whether Google has set forth "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR*, 550 U.S. at 418. In its Petition, Petitioner presents the conclusion of obviousness, but provides no rationale for this proposed modification.[34] *See* PO Resp. 22.

Based on the record developed during trial, we conclude that Petitioner has not demonstrated by a preponderance of the evidence that claims 1, 2, and 7 are unpatentable under 35 U.S.C. § 103(a) as obvious over Takei.

D. OBVIOUSNESS OVER BIEWENDT, TAKEI, BEV TECH, AND DAVID – CLAIMS 1-3, AND 7

1. Ground

Petitioner contends that claims 1-3 and 7 are unpatentable under 35 U.S.C. § 103(a) over Biewendt, Takei, Bev Tech, and David. Pet. 27-32.

[34] The concept that anticipation is the epitome of obviousness does not apply here because this ground of unpatentability is premised on the interpretation that Takei does not anticipate claim 1 because Takei's aseptic chamber does not correspond to a sterile tunnel as claimed.

We begin by analyzing independent claim 1. For claim 1, Petitioner only relies only on Biewendt and Takei.

a) A method comprising:

Biewendt discloses an aseptic filling and sealing plant. Pet. 27; Biewendt, Ex. 1006 § 2 (aseptic filling process into sterilized glass bottles), § 3 (process includes filling).

b) controlling the flow of an aseptic product using a valve;

Biewendt discloses aseptically bottling Ultra High Temperature (UHT) milk, which corresponds to an aseptic product as claimed. Pet. 28; Ex. 1006 § 1. Biewendt controls the flow of UHT milk using a valve. Pet. 28; Ex. 1006, § 2.4, Fig. 5 (illustrating outlet pipe connections of filling valves); Heldman Decl., Ex. 1004 ¶ 52 (explaining how Biewendt's valve controls flow of aseptic product).

c) surrounding a region where the aseptic product exits the valve with a sterile region wherein the sterile region is a sterile tunnel;

Biewendt's bottles are filled and sealed within a housing (sterile tunnel) that is encapsulated from the atmosphere and sterilized under defined conditions so that contamination is effectively prevented. Pet. 29; Ex. 1006 § 4.1.1; *see also* § 3.1.3 (explaining aseptic conditions are maintained for the filling system until production is completed), § 2.4, Fig. 5 (illustrating view into aseptic room of the filling machine).

d) controlling the opening or closing of the valve with a sealed actuator, wherein the sealed actuator is surrounded with the sterile region.

Petitioner contends that Biewendt is silent regarding the positioning of the actuator component of the valve, implying that this is the difference

between Biewendt and the subject matter of claim 1. Thus, Petitioner refers to Takei for this limitation. Pet. 30.

As explained in the analysis of anticipation by Takei above, Takei discloses a sealed valve actuator within the sterile region, where that actuator controls the opening and closing of the valve. *See* Pet. 24, 30 (referencing earlier portion of the Petition); Ex. 1005, 4; Ex. 1004 ¶ 25. According to Petitioner, Takei's valve may be reliably cleaned and sterilized, and achieves a great improvement in that the flow passageway need not be disassembled for cleaning and sterilization. Pet. 31; Ex. 1005, 5.

Petitioner contends that it would have been obvious to use Takei's filling valve in the system of Biewendt. Pet. 30. According to Petitioner, such a modification would not change the principle of operation of either device and would achieve predictable results. *Id.* at 30–31; Ex. 1004 ¶ 61. Petitioner reasons that the combination simply arranges old elements with each performing the same function it had been known to perform. Pet. 30–31 (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. at 417; Ex. 1004 ¶ 61). Petitioner reasons that a person of ordinary skill in the art would recognize the importance of maintaining sterility, and would see the value of using a valve such as Takei's that is readily sterilized and prevents induction of contaminants into the system. Pet. 31; Ex. 1004 ¶ 55; Ex. 1005, 5. Further, according to Petitioner, a person of ordinary skill would recognize that positioning the valve and actuator within the sterile tunnel, as disclosed by Takei, would minimize risk of the actuator introducing contaminants into the system. Pet. 31–32; Ex. 1004 ¶ 55.

2. Patent Owner Arguments

a) Reasonable Expectation of Success

The prior art does not demonstrate a reasonable expectation of success where a skilled artisan would have had to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result because the prior art did not reveal which of the many possible choices was to be successful. *In re Kubin*, 561 F.3d 1351, 1360–61 (Fed. Cir. 2009).

Patent Owner contends that a person of ordinary skill in the art would not have had a reasonable expectation of success in combining Biewendt and Takei to reach the subject matter of claim 1. PO Resp. 39–46. Specifically, Patent Owner contends that Biewendt, like ZFL, only described the function of the machine at a high level, and does not contain sufficient detail to enable a competitor to build a machine with the same or higher output. PO Resp. 39–41. Patent Owner provides argument and evidence related to the difficulties of sterilizing bottles while complying with the FDA regulation on residual hydrogen peroxide. PO Resp. 41–46. Patent Owner argues that even if Biewendt is combined with ZFL, at least 39 engineering variables are not addressed by these references. PO Resp. 41 (citing Ex. 2063 ¶ 50).

Before addressing Patent Owner's argument in greater detail, we observe that Patent Owner's arguments essentially ask that Petitioner be required to demonstrate how unclaimed portions of the process of aseptic packaging of food products would have been obvious. However, the question before us is whether this ground of unpatentability renders the claimed subject matter obvious.

First, Patent Owner's contention that Biewendt does not contain sufficient detail focuses on the ability to build a machine with the same or

higher output. *See* PO Resp. 39–40[35]; *see also* Buchner Decl., Ex. 2056 ¶ 18 (testifying that his articles did not contain sufficient knowledge and details to enable a competitor to successfully build a machine "with the same or higher output."). However, such a contention is not on point, in that claim 1 does not contain any limitation regarding output rate.[36] Similarly, Patent Owner's analogy to our analysis of ZFL in IPR2015-00094 is also not on point. There, the challenged claim required filling more than 350 bottles per minute, and our analysis focused on the lack of detail regarding that specific limitation. *See* Ex. 2069, 6, 12–14.

Second, Patent Owner's arguments focus on the difficulties of bottle sterilization while complying with the FDA regulation on residual hydrogen peroxide. *See, e.g.*, PO Resp. 40 (arguing regarding bottle sterilization), 41 (arguing regarding bottle sterilization and citing Ex. 2061 ¶ 76), 42–45 (arguing regarding the difficulties of others in complying with sterilization requirements).[37] However, as explained in our claim construction above, claim 1 does not require sterilization or filling of containers, and does not trigger the FDA requirement regarding residual hydrogen peroxide.

Third, Patent Owner's contention that the combination of Biewendt and ZFL fails to address 39 engineering variables is inapposite, in that this ground of unpatentability does not propose to combine Biewendt and ZFL.

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[35] Patent Owner cites Ex. 2052, but based on content Ex. 2056 was intended.

[36] In contrast to the challenged claims in this case, claim 1 in IPR2014-01235 requires an output rate (disinfecting bottles at a rate greater than 100 bottles per minute). *See* IPR2014-01235, Paper 63, 3–4.

[37] We note that Patent Owner's argument regarding ZFL is not applicable to this ground of unpatentability. *See* PO Resp. 41–42.

See PO Resp. 41 (citing Ex. 2063 ¶ 50). Further, each of the 39 variables identified deals with unclaimed aspects of the aseptic bottling process. *See* Ex. 2063 ¶¶ 50–51.

This proposed modification must be considered in context. As detailed above, in the ground before us, Petitioner contends that it would have been obvious to replace the filling valve of Biewendt's aseptic filling plant with the filling valve of Takei's aseptic filling machine, and place that valve within Biewendt's housing (sterile tunnel), just as it is disposed within a sterile tunnel in Takei. Further, sterilized packaging systems were known to include the processes of filling containers with pasteurized product and sealing those containers in an aseptic tunnel. Ex. 1001, 1:23–26. What was not known was filling containers at a high output rate (Ex. 1001, 2:22–29), but claim 1 does not contain a limitation regarding output rate. The difference between claim 1 and the prior art was positioning a sealed valve such as Takei's in Biewendt's system.[38] Petitioner has demonstrated adequately that a person of ordinary skill in the art would have had a reasonable expectation of success in incorporating one known type of

[38] Petitioner asserts, and we agree, that, a person of ordinary skill in the art facing this challenge, would have an undergraduate scientific of engineering degree in a relevant field, at least five years of experience in the field, and an understanding of the relevant principles of microbiology and food science and technology. *See* Pet. 11; Ex. 1004 ¶ 37. Patent Owner did not challenge Petitioner's assertion of the level of ordinary skill in the art in the preliminary response or the response. *See* 37 C.F.R. § 42.23(a). Further, we note that the prior art of record in this proceeding is indicative of the level of ordinary skil in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

aseptic filling system valve into another aseptic filling system. Patent Owner's arguments do not persuade us otherwise.

b) Rationale

Patent Owner presents several contentions in support of the argument that Petitioner has not provided a sufficient rationale for the proposed modification of Biewendt. PO Resp. 35–39. Patent Owner contends that Petitioner's reasoning—that maintaining sterility in Biewendt was important— is not a reason to add Takei's valve because Biewendt already maintains sterility. *Id.* at 36 (citing Ex. 2057, 132:3–7). Patent Owner also contends that Biewendt is already sterilized with steam so that the purported advantage of Takei's valve being steam cleanable is already taught by Biewendt. *Id.* at 36–37.

Patent Owner contends that the fact that Biewendt's sterile region and Takei's valve are both sterilized with steam undermines the obviousness of the combination of the references. However, this common feature demonstrates the compatability of the references. Likewise, that Biewendt's system maintains sterility and Takei's valve may be readily sterilized, also suggests the compatibility of the combination. *See* Pet. 30–31; Heldman Decl., Ex. 1004 ¶¶ 55, 61.

Patent Owner contends that Biewendt does not disclose a risk of contamination. PO Resp. 37. To the extent this argument suggests that the reason for the modification must be found in Biewendt, we disagree. *See KSR*, 550 U.S. at 418.

Patent Owner contends that incorporation of Takei's valve actually raises rather than lowers the risk of contamination. *Id.* at 37 (citing Ex.

2057, 80:14–23, 110:12–22; Ex. 2061 ¶¶ 34, 73; Ex. 2049, 29[39]). In support of this contention, Patent Owner's expert, Dr. Sharon, testified that from a design perspective, it makes more sense to keep the valve actuator outside of the sterile region. Ex. 2061 ¶¶ 34, 73; Ex. 2049, 29.

Dr. Sharon admitted that the positioning of the valve actuator depends on the particular embodiment of the valve, and some embodiments of valves having actuators positioned outside of the sterile region can create the risk of contamination of the sterile region. Ex. 1021, 114:20–115:5. Dr. Sharon has considerable mechanical design experience and training; however, he explicitly states that he "is not an expert in the food science/sterility issues involved in aseptic processing and packaging." Sharon Decl., Ex. 2061 ¶¶ 2, 7. Further, Dr. Sharon testifies regarding valve design in general and not with regard to Takei's valve in particular.

Petitioner's expert, Dr. Heldman, testified that positioning Takei's valve within the sterile area would reduce the risk of contamination.[40] Ex. 1004 ¶ 55; Pet. 31. Dr. Heldman's subsequent testimony that, as a general matter, it is useful to limit the number of components inside of the sterile region, and that "maybe" sterility would be better ensured by placing Takei's

[39] Exhibit 2049 does not include a page with native number 29; rather, it goes from 28 to 30. *See* Ex. 2049, 2–3. The first page of this exhibit is numbered as exhibit page number 2. We are unable to locate the information Patent Owner cites.

[40] Petitioner also cites to Exhibit 1008 in support of the contention that the risk of contamination for external valves (meaning with the actuator outside the sterile region) was known. Pet. Reply 17 (citing Ex. 1008, 26). We are unable to locate information at this citation regarding filling valves positioned with the actuator outside the sterile area.

actuator outside of the sterile tunnel does not negate the earlier testimony. *See* Ex. 2057, 80:14–23, 110:12–22. Dr. Heldman has considerable training and experience in food science, and Dr. Heldman's testimony addresses Takei's valve in particular rather than valve design in general. *See, e.g.*, Ex. 1004 ¶¶ 1–8, 55, Attachment 1.

In light of this, we are persuaded by Dr. Heldman that positioning Takei's valve within the sterile area would reduce the risk of contamination.

Patent Owner contends that positioning a valve within the sterile region has the drawbacks of necessitating re-sterilization of the sterile region after maintenance of the valve, and creating air turbulence that would further complicate the design. PO Resp. 38–39 (Ex. 2061 ¶¶ 35, 73, 81). When asserting that the proposed modification could disrupt airflow in the aseptic housing, Dr. Sharon refers to the Spinak Declaration as an example that the FDA denied validation "given the improper understanding of airflows, which ran the risk of recontamination." Ex. 2061 ¶ 73 (referencing Ex. 2036, 13).

We disagree with Dr. Sharon's characterization of Mr. Spinak's testimony. Mr. Spinak was requested to assess an aseptic filler for cartons belonging to a company in a merger dispute, and the matter was settled before Mr. Spinak testified. Ex. 2036, 9:8–15, 12:12 ("[i]t's more of a box carton"). Mr. Spinak testified that there were two problems with the system: one, the underside of the carton was not sterilized, creating the risk that the environment could be contaminated; and two, the sterile air flow had little organization in the zone the cartons moved through. *Id.* at 10:14–15 (Q: "Let's go back to the merger case."), 12:15–13:4.

Mr. Spinak, on behalf of the FDA, informed the company that they must "come up with a system to prove there wasn't recontamination." *Id.* at 13:4–9. Mr. Spinak knew that the company switched to a more conventional system, but had "no idea" if that company attempted to come up with a technical solution. *Id.* at 13:14–17.

Dr. Sharon's description is incomplete in that the airflow problem was mentioned, but the failure to sterilize the bottom of cartons was not. Dr. Sharon also omits that Mr. Spinak did not know if any technical solution was attempted. To the extent that Patent Owner relies on this argument and evidence to demonstrate that air flow can be an unsurmountable problem, it is not persuasive. At most, this evidence shows that air flow in the sterile region of an aseptic system must be accounted for properly. However, that does not suggest that incorporation of Takei's valve into Biewendt's system would be an insurmountable problem, negating the reason for combing the references. As detailed above, Takei discloses an aseptic filling apparatus that enables cleaning and sterilization of the entire apparatus so that containers may be filled in an aseptic condition, and aseptic chamber b (a sterile region) "is maintained in the aseptic condition at all times." Pet. 12; Ex. 1005, 2, 4. Such disclosures suggest the ability to deal with any associated air flow problems. Beyond this, we agree with Petitioner that every modification has both advantages and disadvantages, but that does not necessarily obviate the rationale for the proposed combination. Pet. Reply 17.

Accordingly, we are persuaded by Petitioner's contention that the proposed modification arranges old elements with each performing the same function it had been known to perform with a predictable result. *See*

Leapfrog Enter. Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1161 (Fed. Cir. 2007).

3. Conclusion

a) Claim 1

We conclude that Petitioner has demonstrated by a preponderance of the evidence that claim 1 is unpatentable under 35 U.S.C. § 103 as obvious over Biewendt and Takei.

b) Claims 2, 3, and 7

Claim 2 adds that the method includes providing a tank for containing a supply of pressurized aseptic product flowing to the valve. Biewendt's tank (presetting tank) contains a supply of aseptic product, and includes a pressure sensor, suggesting the product is pressurized. Pet. 32; Ex. 1006, 6; Ex. 1004 ¶ 64. Alternatively, Petitioner explains that Takei, David, and Bev Tech each include a pressurized tank that could have been incorporated into Biewendt's device, and Petitioner provides reasons for such modification. Pet. 32–34.

Claim 3 adds that the method includes providing a measuring device for measuring the amount of pressurized aseptic product flowing from the tank to the valve. Biewendt discloses a flow volume meter that determines bottle filling volume. Pet. 34; Ex. 1006, 6. Alternatively, Petitioner explains that if the measuring device must be positioned between the tank and valve, such positioning would have been an obvious matter of design choice or would have been obvious in view of the positioning of such a device in Bev Tech. Pet. 34–36. We observe that such repositioning does not alter the function of the device. *See In re Japikse*, 181 F.2d 1019, 1023, (CCPA 1950) (holding that shifting a starting switch of the prior art to a different

position was obvious because the overall operation of the device would not be affected by such change); *In re Daily*, 357 F.2d 669, 672–73 (CCPA 1966); *In re Rice*, 341 F.2d 309, 314 (CCPA 1965).

Claim 7 adds that the method includes connecting the sealed actuator to a control system with a control conduit. Biewendt's filling cycle is "program-controlled," demonstrating that a control system is present. Pet. 36–38; Ex. 1006, 6, 11; Ex. 1004 ¶¶ 72, 74 (explaining Biewendt's filling cycle and that a control conduit was one of a limited number of known mechanisms to transmit such signals). Alternatively, Petitioner explains that modification to include such a control system would have been obvious over Takei or Bev Tech. Pet. 37–38.

Patent Owner presents no additional arguments for claims 2, 3, and 7. *See* 37 C.F.R. § 42.23(a).

We are persuaded by Petitioner's contentions. We conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 2, 3, and 7 are unpatentable under 35 U.S.C. § 103 as obvious over Biewendt, Takei, David, and Bev Tech.

E. OBVIOUSNESS OVER BIEWENDT, TAKEI, ZFL – CLAIM 9

1. Ground

As explained in our claim construction above, in order to show that the method of claim 9 was rendered obvious, where Petitioner relies upon prior art that utilizes hydrogen peroxide as the sterilant, that process must be carried out in a manner that results in no greater than 0.5 ppm hydrogen peroxide residue in the packaging.

The Petition discusses how sterilization would be carried out, utilizing hydrogen peroxide as the sterilant, to create a 6-log reduction in spore organisms, but does not address how that sterilization would comply with the residual hydrogen peroxide requirement. *See* Pet. 38–42. In Petitioner's Reply, Petitioner contends that the art recognized and achieved the FDA's residual hydrogen peroxide limit. Pet. Reply 3 (notably not citing to the Petition). This assertion does not remedy the defect in the asserted ground of unpatentability because the limitation must have been addressed in the Petition. *Intelligent Bio-Systems, Inc. v Illumina Cambridge Ltd.*, 2016 WL 2620512, *8 (Fed. Cir. 2016) ("the expedited nature of IPRs bring with it an obligation for petitioners to make their case in their petition to institute").

To the extent that we consider Petitioner's assertion that the prior art teaches sterilization in compliance with the FDA limitation on residual hydrogen peroxide, the analysis in IPR2014-01235 is applicable here. *See* IPR2014-01235, Paper 63 (analyzing a ground of unpatentability relying upon ZFL and determining that Petitioner had not demonstrated by a preponderance of the evidence that a person of ordinary skill in the art could have practiced the method of the challenged claims with a reasonable expectation of success).

We conclude that Petitioner has not demonstrated by a preponderance of the evidence that claim 9 is unpatentable under 35 U.S.C. § 103(a) as obvious over Biewendt, Takei, and ZFL.

F. OBVIOUSNESS OVER ZFL, TAKEI, AND BEV TECH – CLAIMS 1-3 AND 7

1. Ground

Petitioner contends that claims 1-3 and 7 are unpatentable under 35 U.S.C. § 103(a) over ZFL, Takei, and Bev Tech. Pet. 44–52. We begin by analyzing independent claim 1. For claim 1, Petitioner only relies only on ZFL and Takei.

a) A method comprising:

ZFL discloses an aseptic filling and sealing plant for bottling an aseptic product, such as UHT milk and UHT milk drinks. Pet. 45; ZFL, Ex. 1012, 1, 4; Ex. 1001, 2:17–20 (citing UHT treatment as a process to meet FDA aseptic standards).

b) controlling the flow of an aseptic product using a valve;

Takei discloses a valve with an actuator mechanism for controlling flow of aseptic product.[41] Pet. 46, 12–14, 22–23; Ex. 1005, 4, Figs. 1, 2. Petitioner contends it would have been obvious to incorporate Takei's valve into ZFL's sterile region and to be controlled by ZFL's flowmeters. Pet. 46–47; Ex. 1012, 4; Ex. 1004 ¶ 56.

[41] Petitioner also asserts that ZFL inherently discloses controlling the flow of aseptic product using a valve, but then when addressing whether the valve is surrounded by a sterile region, Petitioner only refers to Takei's valve as incorporated into ZFL's sterile region. *See* Pet. 45–48. For that reason, we only reply upon the version of this ground of unpatentability that incorporates Takei's valve into ZFL's sterile region.

> *c) surrounding a region where the aseptic product exits the valve with a sterile region wherein the sterile region is a sterile tunnel;*

As modified, Takei's valve would be disposed in ZFL's sterile region.[42] Pet. 48.

> *d) controlling the opening or closing of the valve with a sealed actuator, wherein the sealed actuator is surrounded with the sterile region.*

Petitioner relies on the assertions regarding Takei in the ground of unpatentability based on anticipation by Takei.[43] Pet. 48. Our analysis above is applicable here.

Petitioner contends that it would have been obvious to use Takei's filling valve in ZFL's system. Pet. 46–47. Petitioner reasons that a person of ordinary skill in the art would recognize the importance of maintaining sterility, and would see the value of using a valve such as Takei's that is readily sterilized and prevents induction of contaminants into the system. Pet. 46; Ex. 1004 ¶ 55; Ex. 1005, 5. Further, according to Petitioner, a person of ordinary skill would recognize that positioning the valve and actuator within the sterile tunnel, as disclosed by Takei, would minimize risk of the actuator introducing contaminants into the system. Pet. 46–47; Ex. 1004 ¶ 55.

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[42] Our analysis above regarding positioning Takei's valve in Biewendt's sterile region is applicable here.

[43] Petitioner alternatively asserted that Bev Tech discloses use of a programmable logic controller. *See* Pet. 47. However, we do not rely on this assertion because Petitioner only presents the conclusion that incorporation of this teaching from Bev Tech would have been obvious and does not provide a reason for that modification.

2. Patent Owner Arguments

Patent Owner's arguments are the same as those applied against the ground based on Biewendt, Takei, Bev Tech, and David discussed above. *See* PO Resp. 35–46 (treating Biewendt and ZFL similarly). Our analysis above is applicable here.

3. Conclusion

We conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1–3, and 7 are unpatentable under 35 U.S.C. § 103 as obvious over ZFL, Takei, and Bev Tech.

G. OBVIOUSNESS OVER ZFL, TAKEI, AND BEV TECH – CLAIM 9

Petitioner relies upon ZFL in the same manner for this ground of unpatentability as that of Biewendt, Takei, and ZFL analyzed above. *See* Pet. 52. For that reason, the Petition does not address how the plurality of bottles would be aseptically disinfected with hydrogen peroxide while meeting the FDA residual hydrogen peroxide limitation. Consequently, we conclude that Petitioner has not demonstrated by a preponderance of the evidence that claim 9 is unpatentable under 35 U.S.C. § 103(a) as obvious over ZFL, Takei, and Bev Tech.

V. PETITIONER'S UNOPPOSED MOTION TO SEAL

Petitioner submitted a motion to seal the Patent Owner Response (Paper 42), and Exhibit 2068. Paper 50. The Patent Owner Response addressed specific details from Petitioner's confidential documents (Exhibits 2068 and 2051), which reveal confidential business information belonging to Petitioner, including the terms of Petitioner's relationship with its supplier,

GEA, and about Petitioner's production facilities and capabilities. *Id.* at 1. Petitioner has never publicly disclosed this information, because such public disclosure would place Petitioner at a competitive disadvantage vis-à-vis competing bottling companies and other suppliers. *Id*. Petitioner submitted a redacted public version of the Patent Owner Response. Paper 51. Exhibit 2068 is the Confidential Petitioner's Reply filed under seal in case IPR2014-01235. Exhibit 2068 addresses specific details from Petitioner's confidential documents, which reveal confidential business information belonging to Petitioner, including the terms of Petitioner's relationship with its supplier, and about Petitioner's production facilities and capabilities.

Petitioner states that Patent Owner does not oppose this motion. Paper 50, 1–2.

There is a strong public policy in favor of making information filed in an *inter partes* review open to the public, especially because the proceeding determines the patentability of claims in an issued patent and, therefore, affects the rights of the public. *See Garmin International v. Cuozzo Speed Technologies, LLC,* Case IPR2012-00001 (PTAB Mar. 14, 2013) (Paper 34). Under 35 U.S.C. § 316(a)(1) and 37 C.F.R. § 42.14, the default rule is that all papers filed in an *inter partes* review are open and available for access by the public; a party, however, may file a concurrent motion to seal and the information at issue is sealed pending the outcome of the motion. It is, however, only "confidential information" that is protected from disclosure. 35 U.S.C. § 316(a)(7); *see* Trial Practice Guide, 77 Fed. Reg. at 48,760. The standard for granting a motion to seal is "for good cause." 37 C.F.R. § 42.54(a). The party moving to seal bears the burden of proof in showing entitlement to the requested relief, and must explain why

the information sought to be sealed constitutes confidential information. 37 C.F.R. § 42.20(c).

In reviewing the underlying documents that are sought to be sealed, we conclude that Paper 42 and Exhibit 2068 may contain confidential information. Accordingly, we are persuaded that good cause exists to have these documents remain under seal. In that respect, the Motion to Seal is granted, except for information that is discussed in or relied on by this decision.

The Office Patent Trial Practice Guide provides:

> *Expungement of Confidential Information*: Confidential information that is subject to a protective order ordinarily would become public 45 days after denial of a petition to institute a trial or 45 days after final judgment in a trial. There is an expectation that information will be made public where the existence of the information is referred to in a decision to grant or deny a request to institute a review or is identified in a final written decision following a trial. A party seeking to maintain the confidentiality of information, however, may file a motion to expunge the information from the record prior to the information becoming public. § 42.56. The rule balances the needs of the parties to submit confidential information with the public interest in maintaining a complete and understandable file history for public notice purposes. The rule encourages parties to redact sensitive information, where possible, rather than seeking to seal entire documents.

77 Fed. Reg. 48756, 48761 (Aug. 14, 2012).

Consequently, 45 days from entry of this decision, all information subject to a protective order will be made public by default. In the interim, a party seeking to maintain confidentiality of information that was not relied upon in this decision, may file a motion to expunge that information. *See* 37 C.F.R. § 42.56.

In accordance with prior practice, the parties may also seek to preserve the record and keep any confidential documents sealed until the outcome of any appeal of this decision. *See Nestlé USA, Inc. v. Steuben Foods, Inc.*, Case IPR2014-01235, Order Granting Request to Preserve Record Pending Appeal (Paper 68) (PTAB Feb. 9, 2016).

VI. CONCLUSION

We conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1–3 and 7 are unpatentable, but has not made such a showing with regard to claim 9.

VII. ORDER

For the reasons given, it is:

ORDERED that claims 1, 2, and 7 have been shown by a preponderance of the evidence to be unpatentable as anticipated by Takei;

FURTHER ORDERED that claims 1, 2, and 7 have not been shown by a preponderance of the evidence to be unpatentable as obvious over Takei;

FURTHER ORDERED that claims 1–3 and 7 have been shown by a preponderance of the evidence to be unpatentable over Biewendt, Takei, Bev Tech, and David;

FURTHER ORDERED that claims 1–3 and 7 have been shown by a preponderance of the evidence to be unpatentable over ZFL, Takei, and Bev Tech;

FURTHER ORDERED that claim 9 has not been shown by a preponderance of the evidence to be unpatentable over either (1) Biewendt, Takei, and ZFL, or (2) ZFL, Takei, and Bev Tech;

FURTHER ORDERED that Petitioner's Motion to Exclude is denied;

FURTHER ORDERED that Patent Owner's Motion to Exclude is dismissed as moot;

FURTHER ORDER that Petitioner's Motion to Seal is granted-in-part and denied-in-part as noted herein; and

FURTHER ORDERED that, because this is a Final Written Decision, 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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