2020-1083

United States Court of Appeals for the Federal Circuit

STEUBEN FOODS, INC.,

Appellant,

– v. –

KATHERINE K. VIDAL, Under Secretary of Commerce for Intellectual Property and Director of the Unites States Patent and Trademark Office,

Intervenor.

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, Case No. IPR2014-01235

BRIEF FOR APPELLANT

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JULY 20, 2022

COUNSEL PRESS, LLC (888) 277-3259

EXEMPLARY CLAIM FROM U.S. PATENT NO. 6,945,013

19. A method for automatically aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the bottles at a rate greater than 100 bottles per minute, wherein the aseptically disinfected plurality of bottles are sterilized to a level producing at least a 6 log reduction in spore organism; and

aseptically filling the bottles with aseptically sterilized foodstuffs.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2020-1083

Short Case Caption Steuben Foods, Inc. v. Vidal

Filing Party/Entity Steuben Foods, Inc.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 07/20/2022

Signature: /s/ W. Cook Alciati

Name: W. Cook Alciati

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☑ None/Not Applicable
Steuben Foods, Inc.		

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☑ Additional pages attached

Charles M. Avigliano	Thomas J. Fisher	Cozen O'Connor
Siddharth Fernandes	W. Blake Coblentz	Ruby J. Natnithithadha
Kenneth S. Canfield	Aaron S. Lukas	Scott A. McKeown

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☐ None/Not Applicable ☐ Additional pages attached

Steuben Foods, Inc. v. Shibuya Hoppmann Corp., et al., No. 1:19-cv-2181 (Delaware)		
USPTO Reexamination No. 95/001,452		

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

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☐ None/Not Applicable ☐ Additional pages attached

Greg H. Gardella		
Oblon McClelland Maier & Neustadt, LLP		

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☐ None/Not Applicable ☐ Additional pages attached

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☐ None/Not Applicable ☐ Additional pages attached

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STATEMENT OF RELATED CASES

This is the second appeal in this proceeding. In the first appeal, the Petitioner appealed the Board's Final Written Decision findings claims 18-20 of U.S. Patent No. 6,945,013 (the "'013 patent") not unpatentable. In a May 2017 Decision, the Court found that the Board had erred in construing the claim term "aseptic," and adopted a construction of "aseptic" that had not been proposed by either party or the Board. *See Nestlé USA, Inc. v. Steuben Foods, Inc.*, 686 Fed. App'x 917, 920 (Fed. Cir. 2017) (hereafter "*Nestlé I*"). The Court then vacated the Board's Final Written Decision and remanded for further proceedings.

There have also been two other Federal Circuit decisions involving *inter partes* review of two related Steuben patents, namely U.S. Patent Nos. 6,481,468 and 6,475,435. *See Nestle USA, Inc. v. Steuben Foods, Inc.*, 884 F.3d 1350 (Fed. Cir. 2018) and *Steuben Foods, Inc. v. Nestle USA, Inc.*, 884 F.3d 1352 (Fed. Cir. 2018), respectively.

Steuben has asserted the '013 patent along with certain related patents in the following additional District Court litigations: *Steuben Foods, Inc. v. Oystar USA, Inc. et al.*, No. 1:10-cv-780 (W.D.N.Y.); *Steuben Foods, Inc. v. Shibuya Hoppmann Corp. et al.*, No. 1:19-cv-2181 (D. Del.); and *Steuben Foods, Inc. v. Jasper Products, LLC*, No. 1:13-cv-1118 (W.D.N.Y.). Steuben settled each of the cases except for the Shibuya action, which remains pending.

The ’013 patent was subject to a prior *inter partes* review, which the Board terminated, leading the petitioner in that proceeding to seek mandamus review, which the Court denied. *See GEA Process Eng’g, Inc. v. Steuben Foods, Inc.*, Nos. 2015-1536, -1537, -1538, -1539, and -1540, where the Court denied Appellee GEA’s petition for writ of mandamus.

In addition, the ’013 patent had been subject to an ongoing *inter partes* reexamination. *See KHS USA, Inc. v. Steuben Foods, Inc.*, Reexam. Control No. 95/001,452. In a decision dated July 19, 2022, the Board reversed all rejections adopted by the examiner and found all 20 claims of the ’013 patent—including claims 18 and 19 at issue in this appeal—patentable. The prior art at issue in the ’013 patent reexamination substantially overlapped with the prior art issue in this proceeding. Additional reexamination proceedings involving certain of the Steuben Patents are pending under Control Nos. 95/000,686 and 90/013,601.

INTRODUCTION

The Court should reverse the Board’s Final Written Decision on Remand dated May 8, 2019. The two challenged claims at issue in this appeal both recite “aseptically disinfecting the bottles at a rate greater than 100 bottles per minute.” In a prior appeal in this *inter partes* review, this Court construed “aseptic” as meaning

the "FDA level of aseptic," which is confined to "regulations related to aseptic packaging."

This Court identified the FDA's "commercial sterility" regulation (21 C.F.R. § 113.3(e)(2)) as one such regulation. Accordingly, "aseptically disinfecting" as claimed requires disinfecting bottles to achieve "commercial sterility." Despite the Court's prior construction, the Remand Decision does not include a single finding that the cited prior art combination disclosed sterilizing bottles to meet the FDA's commercial sterility requirement as required under this Court's construction of "aseptic" in the prior appeal. Without such a finding, this Court should reverse the Remand Decision.

The Remand Decision also erred in finding that the cited prior art rendered obvious to claimed bottle sterilization rate of "greater than 100 bottles per minute." The Remand Decision relies on conclusory expert testimony consisting of a few thread-bare sentence fragments to find that it would be obvious to increase the primary reference's bottle sterilization rate. In so doing, the Board failed to even acknowledge certain evidence of record that demonstrates non-obviousness while attempting to reformulate the ground set forth in the Petition. In so doing, the Board committed reversible error.

The Board also violated Steuben Foods, Inc.'s rights under the Administrative Procedure Act ("APA") on remand. Specifically, the Board denied Steuben's

request to submit evidence and argument addressing the Petition's unpatentability arguments in view of this Court's claim construction in the prior appeal. The Court's prior claim construction decision articulated a new standard for determining whether an FDA regulation was "related to aseptic packaging" and therefore part of the "FDA level of aseptic." Neither the parties nor the Board had suggested such a standard in the underlying IPR. Consequently, Steuben should have been permitted to submit new argument and evidence on remand.

STATEMENT OF JURISDICTION

The Patent Trial and Appeal Board (Board) had jurisdiction over the underlying *inter partes* review pursuant to 35 U.S.C. § 6. Steuben filed a timely notice of appeal following the Board's Final Written Decision on Remand, which issued on May 8, 2019. Appx9. This Court has jurisdiction under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 329.

ISSUES ON APPEAL

1. In a prior appeal in this *inter partes* review proceeding, the Court construed "aseptic" according to "binding lexicography" to mean the "FDA level of aseptic," which the Court confined to "FDA regulations related to aseptic packaging." The Court identified the FDA's "commercial sterility" regulation (21 C.F.R. § 113.3(e)(2)) as one such regulation. Each claim at issue in this appeal recites "aseptically disinfecting the bottles." The Board's Final Written Decision on

Remand makes no finding that the Petition demonstrated that the prior art disclosed "aseptically disinfecting bottles" to achieve commercial sterility. Did the Board err in finding claims 18 and 19 of the '013 patent unpatentable in view of the Court's prior construction of "aseptic" as requiring compliance with the FDA's "commercial sterility" regulation?

2. Each challenged claim recites "aseptically disinfecting the bottles at a rate greater than 100 bottles per minute." The Petition asserts that it would be obvious to modify the primary Biewendt reference to aseptically disinfect bottles at a rate greater than 100 bottles per minute as claimed. The Board relied on conclusory expert testimony while attempting to reformulate the ground in the Petition to find the challenged claims obvious. Did the Board err in finding the challenged claims obvious?

3. In a prior appeal, this Court found that Steuben's lexicographic definition of "aseptic" as the "FDA level of aseptic," which the Court confined to FDA regulations "related to aseptic packaging." The Court then articulated a new test—not proposed by the parties or the Board—for determining whether an FDA regulation was part of the "FDA level of aseptic." According to the Court's prior decision, a regulation is "related to aseptic packaging" if it applies exclusively to aseptic packaging and is not "related to aseptic packaging" if it applies to all foods regardless of whether they are aseptically packaged. On remand, the Board denied

Steuben's request to submit evidence and argument addressing this new claim construction test. Did the Board violate Steuben's APA rights by refusing to allow Steuben to submit evidence and argument to address this Court's new test?

STATEMENT OF THE CASE

I. Steuben's patents disclosed the first high speed aseptic bottling system that would meet the FDA's regulations related to aseptic packaging, which are the most stringent in the world.

At its core, aseptic packaging involves the filling of a sterile product into a sterile package within a sterile environment. Appx3262. This sterile process allows products that would otherwise need to be refrigerated, such as milk, to be sold in a shelf stable format—meaning without refrigeration. Appx81 (1:40-47). Because products such as milk are fertile breeding grounds for bacteria when left unrefrigerated, aseptic packaging is highly regulated to ensure that consumers do not contract diseases such as botulism. *See, e.g.*, Appx3099. In the United States, the Food and Drug Administration ("FDA") regulates aseptic packaging. Appx3106. The FDA's requirements are notoriously the strictest in the world and require compliance with various requirements designed to ensure public safety. Appx3107.

In the preferred embodiment of the '013 patent, the bottles are sterilized, filled, and capped in an enclosed space kept at a pressure above atmospheric. Appx87 (13:31-39). The enclosed space is pressurized through a constant supply of

sterile air. *Id*. In that way, sterility is maintained as the elevated pressure prevents the ingress of airborne contaminants. Appx86 (12:36-40).

The preferred embodiment of the ’013 patent carefully manages airflow to ensure that air flows away from the bottle filling station of the aseptic bottling machine and toward the less critical areas. Appx85 (9:19-31). This is because the area in which the product is filled is of the utmost importance with respect to sterility. *Id*. Given these precisely designed airflows, the fluid dynamics within a sterile tunnel are of critical importance. Appx3165-3166 (¶ 20); Appx3258.

The annotated figure below demonstrates the airflow regime described in the specification of the ’013 patent.

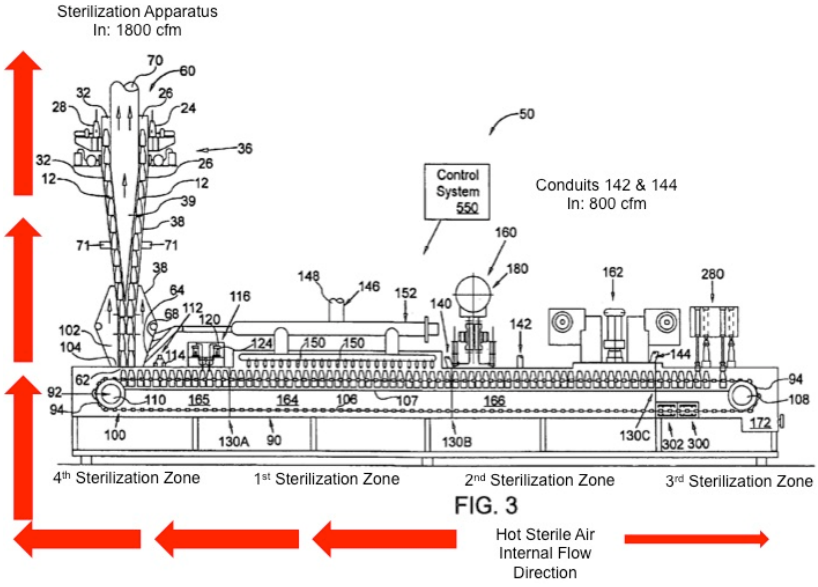

FIG. 3

Appx3214-3215 (¶ 25).

Central to the aseptic packaging process is the sterilization of the package. This generally involves the application of a chemical sterilant (e.g., hydrogen peroxide or oxonia) followed by the removal of such sterilant through a sterile fluid rinse (e.g., water or air). Appx3262. The '013 patent explains that the unique geometry of a bottle makes the application and removal of a sterilant particularly challenging. Appx85 (9:61-63; 10:9-12). For a package to be considered "aseptic" by the FDA, it must be sterilized to achieve "commercial sterility." A commercially sterile bottle is one that has been sterilized to eliminate microorganisms "having public health significance, as well as microorganisms of nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution." 21 C.F.R. § 113.3(e)(2).

The FDA, unlike the rest of the world, requires special challenge tests to demonstrate a sufficient log reduction in microorganisms. Appx3105-3106. During such a challenge test, a package is inoculated with a predetermined number of microorganisms and then exposed to a given sterilization method. *Id*. The number of surviving organisms is then determined. The amount of microbial reduction in a particular microorganism is determined on a logarithmic ("log") scale. Appx2272. One log reduction (also referred to as a D reduction) indicates that the given microbial population has been reduced by one order of magnitude. *Id*. Contrast this with other regulatory regimes that look at "spoilage" data reflecting the number of

packages that spoil after being aseptically packaged. If the number is sufficiently low, the spoilage data indicates that the product met whatever regulatory requirements of a given jurisdiction (e.g., Germany). Appx3168 at ¶ 25; Appx3135.

The FDA also requires that the sterilant be removed from the package such that less than 0.5 parts per million of residual peroxide remains in the filled package when hydrogen peroxide is used to sterilize an aseptic package. Appx2309-2310; Appx82 (3:5-8). The FDA's ultra-low residual hydrogen peroxide requirement is in tension with the FDA's commercial sterility requirement. On the one hand, the bottler must use enough sterilant at a high enough concentration to eliminate all microorganisms. On the other hand, the bottler must remove the sterilant sufficiently from the challenging bottle shape to comply with the FDA's residual peroxide requirement. This tension has been referred to in the art as the "narrow path" to successfully achieving FDA compliant packaging. Appx3111.

The '013 patent discloses methods and apparatus for navigating this narrow path at a rate greater than 100 bottles per minute. The preferred embodiment is a linear aseptic bottling system that relies on individual processing "lanes." The preferred embodiment moves bottles through the machine in two horizontal rows each with six lanes. Every two seconds, the machine outputs twelve bottles leading to a single machine throughput of 360 bottles per minute in a preferred embodiment.

In a multi-lane system, an aseptic packager must demonstrate that each lane is able to achieve sterility. Appx3272.

During the underlying IPR, Steuben submitted the declaration of Dr. Cullen Buie, a professor of Mechanical Engineering at MIT. Appx3204-3247. Dr. Buie explained that the ’013 patent contains various key design parameters not found in the cited prior art references that “enable[] a person of ordinary skill in the art to reproduce the system, process, and results described in the [’013] patent related to sterilant delivery and removal.” Appx3226-3227 (¶ 43). Based on these details taught in the ’013 patent, Dr. Buie is “confident that the [’013] Patent enable[s] a person of ordinary skill in the art to reproduce the system, process, and results described in the [’013] patent ….” Appx3226-3227 (¶ 43); Appx3210 (¶ 12); Appx3214-3220 (¶¶ 25-35); Appx3013 (251:16-252:14).

II. The cited prior art comprises promotional materials intended to generate interest in Bosch aseptic bottling equipment.

The sole IPR ground art issue relies on a primary reference referred to as Biewendt in combination with secondary references known as ZFL, Buchner, and Bosch (collectively referred to as the Bosch references). Each reference is a publication designed to generate consumer interest in Bosch’s aseptic bottling technology. For example, Bosch is a brochure of a type that would be distributed at an industry trade show. Unlike the detailed disclosure of the ’013 patent, the Bosch

references do not include detail that would allow a POSITA to recreate the system and results disclosed in the reference. Appx3173-3175 (¶¶ 33-36). In fact, Bosch's lead engineer Dr. Nobert Buchner (the author of three of the four references) testified under oath that he was under strict orders to not publish details that would allow Bosch's competitors to recreate Bosch's aseptic bottling system:

> The information in my articles, for example in the Pharma Technologie Journal, intended to inform about the achieved technical success, show what Bosch has achieved and create interest at possible customers of the machines. I avoided, however, to publish sufficient knowledge and details which could enable a competitor to successfully build a machine with the same or a higher output. All my publications were checked thoroughly before publishing by Bosch-authorities whether they were corresponding to these demands as long as I was employed by Bosch.

Appx2407 (¶ 18).

III. This Court has construed the key claim term "aseptic" in a prior appeal in this proceeding.

This is the second appeal in this IPR proceeding. The first time, the Board found claims 18-20 of the '013 not unpatentable, leading the Petitioner to appeal. Then, in *Nestlé I*, the Court held that the "specification twice defines the term 'aseptic' as the United States 'FDA level of aseptic,'" and found the definition to be "binding lexicography." *Nestlé I*, 686 F. App'x at 919. "[T]herefore, we construe aseptic to mean the 'FDA level of aseptic.'" *Id*.

The Board had construed "aseptic" to mean "aseptic to any applicable United States FDA standard, and in the absence of any such standard, aseptic assumes its

ordinary meaning of free or freed from pathogenic microorganisms." *Id*. at 918. In addressing this construction, the Court considered the "scope of the phrase 'FDA level of aseptic,'" rejecting the Board's finding that the scope would include "any applicable United States FDA standard." *Id*. at 919. Instead, the Court "confine[d] an 'FDA level of aseptic' to FDA regulations related to aseptic packaging." *Id*. In *Nestlé I*, the Court identified 21 C.F.R. § 113.3(e)(2)'s "commercial sterility" regulation as a regulation that is related to aseptic packaging. *Id*.

In doing so, the Court explained that "the scope of 'aseptic' cannot include regulations that apply to foods that are not aseptically packaged." *Id*. Under *Nestlé I*, a regulation is "related to aseptic packaging" if it applies only to aseptic packaging. If the regulation applies to foods that are not aseptically packaged, then it is not part of the "FDA level of aseptic." Neither the parties nor the Board suggested or adopted this test prior to *Nestlé I*. Having modified the Board's claim construction, the Court remanded for further proceedings.

IV. Relevant procedural history on remand.

The Court issued its mandate from *Nestlé I* on July 20, 2017. Appx3311. On July 25, 2017, the Board held a teleconference to discuss the appropriate scope of the proceeding on remand. Appx2126-2130. During that teleconference, Steuben requested the opportunity to submit briefing and evidence on the impact of *Nestlé I*'s construction of "aseptic"—and in particular the Court's new "related to" test—

on the patentability of claims 18-20. *Id.* Notwithstanding this Court's newly proposed test, the Board denied Steuben's request for further briefing. Appx2133-2134.

On July 25, 2018, the Board issued an Order citing the Supreme Court's *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018) and instituting IPR on three additional grounds that had originally been set forth in the Petition. Appx2143. Thereafter, Petitioner requested partial adverse judgment, which the Board entered, limiting the scope of this proceeding to only the original ground addressed by the Board prior to Petitioner's appeal in *Nestlé I*. Appx2146-2149.

The Remand Decision found claims 18 and 19 unpatentable and claim 20 not unpatentable. Steuben then appealed the Board's findings with respect to claims 18 and 19. Petitioner did not cross appeal with respect to the Board's finding claim 20 not unpatentable. Thereafter, this Court remanded for further proceedings following the Court's decision in *Arthrex*. Dkt. 31 at 5. Ultimately, after Steuben unsuccessfully sought Director Review, this proceeding returned to the Court's docket, leading to this Blue Brief. Appx2152.

On April 20, 2022, the Court granted Steuben's motion to dismiss Petitioner Nestlé USA, Inc. from this appeal following a settlement reached between Petitioner and Steuben. The government remains in this appeal as an intervenor.

SUMMARY OF ARGUMENT

The Board erred in three primary ways in the Remand Decision. Each error supports reversal, or at the very least remand.

First, the Board erred by failing to make findings sufficient to support its unpatentability finding under this Court's prior claim construction of "aseptic" in *Nestlé I*. As construed according to *Nestlé I*, "aseptically disinfecting" requires sterilizing bottles to achieve "commercial sterility" as set forth in 21 C.F.R. § 113.3(e)(2). This Court should reverse the Remand Decision because the Board made no finding that the prior art includes all elements of the claim as properly construed according to *Nestlé I*.

Second, the Board erred in relying on conclusory expert testimony to find that the Petitioner had demonstrated that it would have been obvious to increase Biewendt's bottle sterilization speed to sterilize more than 100 bottles per minute. Conclusory expert testimony cannot provide substantial evidence. *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1358 (Fed. Cir. 2019). Compounding the Board's error was the fact that the Board did not even acknowledge testimony of record that contradicted the Board's obviousness findings. Most notably, the Board failed to address sworn testimony from Bosch's lead engineer testifying that Bosch had a policy of deliberately concealing technical detail from publications that would

allow a competitor to reasonably expect success in increasing the throughput of Bosch's bottling equipment. The Court should reverse.

Third, and finally, the Board erred when it violated Steuben's rights under the APA. In *Nestlé I*, the Court articulated a new test for determining whether an FDA regulation was "related to aseptic packaging" and therefore part of the "FDA level of aseptic." Neither the parties nor the Board ever suggested such a test. Accordingly, Steuben requested the opportunity to submit new evidence and argument on remand to address the patentability of claims 18 and 19 in view of *Nestlé I*'s new test. The Board denied Steuben's request and in so doing violated Steuben's APA rights.

ARGUMENT

STANDARD OF REVIEW

Obviousness is a question of law based on underlying findings of fact. *In re Kubin*, 561 F.3d 1351, 1355 (Fed. Cir. 2009). This Court reviews the Board's ultimate finding of obviousness *de novo*. *Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 833 (Fed. Cir. 2015). The Court reviews the Board's factual findings for substantial evidence. *Id*. Whether or not the Board complied with the APA during *inter partes* review is reviewed *de novo*. *In re NuVasive, Inc*., 841 F.3d 966, 970–71 (Fed. Cir. 2016).

I. The Board erred by failing to find that the prior art disclosed sterilizing bottles to achieve "commercial sterility" as required by *Nestlé I*'s construction of "aseptic."

Claims 18 and 19 of the '013 patent both recite "***aseptically*** disinfecting the bottles at a rate greater than 100 bottles per minute." In *Nestlé I*, the Court construed "aseptic" to mean the "FDA level of aseptic." *Nestlé I*, 686 F. App'x at 919. The Court then addressed the "scope of the phrase 'FDA level of aseptic'" and expressly identified the FDA's commercial sterility requirement found in 21 C.F.R. § 113.3(e)(2) as being part of the "FDA level of aseptic." *Id*. As such, in view of *Nestlé I*'s construction of "aseptic," claim 18 and 19 require "aseptically disinfecting" bottles to achieve commercial sterility as required by the FDA.

In the Remand Decision, the Board acknowledged that this Court had expressly identified the FDA's commercial sterility requirement as being part of the "FDA level of aseptic." Appx20. Yet, the Remand Decision does not include a single finding that the Petitioner had demonstrated that the prior art disclosed sterilizing bottles to meet the FDA's commercial sterility requirement.

The Remand Decision discusses the claim limitation reciting "aseptically disinfecting the bottles at a rate greater than 100 bottles per minute" with reference to both claims 18 and 19. The Remand Decision's discussion of claim 18's recitation of "aseptically disinfecting" focuses entirely on increasing bottling speeds above 100 bottles per minute; it says nothing about achieving commercial sterility. *See*

Appx27-33. For its discussion of claim 19, the Remand Decision incorporates its discussion of claim 18—again saying nothing about achieving commercial sterility. Appx36. Bereft of any finding that the prior art disclosed "aseptically disinfecting" according to this Court's binding claim construction, the Remand Decision cannot be affirmed. *Personal Web Techs., Inc. v. Apple, Inc.*, 848 F.3d 987, 991 (Fed. Cir 2017); *see also PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1194 (Fed. Cir. 2014) (obviousness requires proof that "all claimed limitations are disclosed in the prior art.").

The closest the Board came to identifying a disclosure of "commercial sterility" was in discussing claim 19's requirement that the bottles be aseptically disinfected to achieve a "6 log reduction in spore organisms." There, the Board stated that "[a]ccording to Petitioner, Biewendt teaches that sterility was achieved, but does not define a specific level of spore reduction." Appx36. But that summary of the Petitioner's argument is not a finding that the prior art taught sterility. *See TRUSTID, Inc. v. Next Caller, Inc.*, No. 20-1950, 2021 WL 4427918, at *8 (Fed. Cir. Sep. 27, 2021) (unpublished) (an analysis that merely reiterates and summarily rejects arguments without adequate explanation violates APA) (citing *In re NuVasive, Inc.*, 842 F.3d 1376, 1383 (Fed. Cir. 2016)). And it certainly is not a finding that Biewendt disclosed meeting the FDA's specific definition of commercial sterility. *NuVasive*, 842 F.3d at 1383 (explaining that the Board cannot

"summarize and reject arguments without explaining why [it] accepts the prevailing argument.").

Even if the Board had intended to find that Biewendt taught commercial sterility, that finding would not be supported by any evidence at all—much less substantial evidence. *Google Inc. v. Intell. Ventures II LLC*, 701 F. App'x 946, 955 (Fed. Cir. 2017) (unpublished) ("We cannot affirm findings that lack an adequate rationale."). The Remand Decision cites to page 46 of the Petition as arguing that "Biewendt teaches that sterility was achieved." Appx33. Page 46 of the Petition refers to what Biewendt calls a "germ index." Appx2051. Biewendt discloses a German bottling plant that filled milk into brown returnable glass bottles. Appx2432. Biewendt "tested whether the UHT milk filled into brown returnable glass bottles in the aseptic filling and sealing plant meets the statutory shelf life and hygiene requirements, e.g., that it does not have any negative changes after 15 days of storage at 30°C and less than 10 germs per 0.1 cm^3." *Id*. While Biewendt's "germ index" may have met the German "shelf life and hygiene requirements," there is no evidence anywhere in the record to suggest that this disclosure meets the FDA commercial sterility requirements. *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1365 (Fed. Cir. 2016).

The Petition's paucity of evidence on this issue is particularly problematic when it is understood that the FDA differs significantly from European packaging

regulators. The Handbook of Aseptic Packaging explains that one area where the FDA is notably more stringent is in demonstrating compliance with the FDA's commercial sterility requirement. As to that issue, the Handbook explains:

> Most European regulations rely on spoilage data as a measure of how well an aseptic system works. The FDA, however, requires microbiological (challenge) and chemical tests to document whether an aseptic system provides an adequate margin of safety. Lack of understanding of this difference has hampered adoption of 'European' aseptic packing systems in the U.S.

Appx3106. Thus, the FDA would not accept Biewendt's spoilage data as demonstrating commercial sterility. Instead, challenge tests are required to demonstrate sterility.

Because the Remand Decision does not find that the prior art discloses sterilizing bottles to achieve "commercial sterility," this Court should reverse.

II. The Board erred in finding that Petitioner had carried its burden to demonstrate that the step of "aseptically disinfecting the bottles at a rate greater than 100 bottles per minute" was obvious.

A. The Remand Decision's reliance on conclusory expert testimony does not provide substantial evidence of unpatentability.

The Remand Decision finds that it would be obvious to increase Biewendt's bottle disinfecting rate to aseptically disinfect bottles at a rate greater than 100 bottles per minute in view of the disclosure of ZFL, Buchner, and Bosch. The Remand Decision points to ZFL's disclosure that a dual-line (i.e., two lines operating in tandem) was "in development" to achieve an output of 200 bottles per minute.

Notably, no evidence exists to suggest Bosch ever achieved its "development" work. Nonetheless, according to the Board, Petitioner carries its burden to show that modifying Biewendt to increase its bottling speed in view of the secondary references was obvious by relying on "supporting testimony" from Petitioner's expert, Dr. Heldman. Appx28. In paragraph 61, Dr. Heldman testifies:

> A POSITA also would have understood that the method of *Biewendt* could be modified in one or more of the specific ways disclosed by *Buchner*, *ZFL*, and *Bosch Brochure* as discussed above (i.e., **widening sterilizer, smaller bottles, or dual-line design**) to increase disinfection rates beyond 100/min. Such modifications would not require changing any of the established functions of the method and plant described in *Biewendt*. The results of such modifications, therefore, would have been predictable.

Appx2187 (¶ 61) (bold emphasis added).

This single paragraph consisting of three sentences is the sum total of Petitioner's evidence on how a POSITA could purportedly modify the Biewendt system to increase its throughput to 200 bottles per minute. The single sentence fragment supporting the Petition is that Biewendt's bottling speed could be increased by widening the sterilizer, processing smaller bottles, or using a dual-line design.

Notably absent from this single paragraph is any suggestion whatsoever as to how a POSITA would actually implement any of these techniques. Such conclusory testimony does not constitute substantial evidence to establish the required reasonable expectation of success. *See, e.g.*, *TQ Delta, LLC v. CISCO Sys., Inc.*, 942

F.3d 1352, 1358 (Fed. Cir. 2019) ("Conclusory expert testimony does not qualify as substantial evidence.").

The Remand Decision's reliance on conclusory expert testimony is particularly problematic in view of Steuben's detailed showing that a POSITA would ***not*** expect to be successful in modifying Biewendt's bottling speed in view of ZFL, Buchner, and Bosch. In fact, Steuben submitted sworn testimony from Dr. Buchner who authored the secondary references, attesting to the fact that he intentionally concealed details from his publication that would allow a POSITA to increase bottling speed. Specifically, Dr. Buchner testified:

> The information in my articles, for example in the Pharma Technologie Journal, intended to inform about the achieved technical success, show what Bosch has achieved and create interest at possible customers of the machines. ***I avoided, however, to publish sufficient knowledge and details which could enable a competitor to successfully build a machine with the same or a higher output.*** All my publications were checked thoroughly before publishing by Bosch-authorities whether they were corresponding to these demands as long as I was employed by Bosch.

Appx2407 (¶ 18) (emphasis added).[1]

Dr. Buchner was not paid by Steuben for his time, and his declaration was submitted by the Petitioner. His testimony speaks directly to the Board's finding that a POSITA would rely on Dr. Buchner's publications to obtain information that would allow the POSITA to increase Biewendt's bottling speed with the requisite

[1] Dr. Buchner originally submitted the subject declaration in connection with the *inter partes* reexamination directed to the '013 patent.

expectation of success. The testimony stands unrebutted. Yet, the Remand Decision does not even mention Dr. Buchner's testimony, much less attempt to reconcile it with the Board's finding that a POSITA would reasonably expect to be successful in modifying Biewendt in view of Bosch, ZFL, and Buchner to increase bottling speeds. "[A]n agency's refusal to consider evidence bearing on the issue before it is, by definition, arbitrary and capricious." *Aqua Products, Inc. v. Matal*, 872 F.3d 1290, 1325 (Fed. Cir. 2017). Indeed, "the agency must take account of all the evidence of record, including that which detracts from the conclusion the agency ultimately reaches." *Id*. The Board erred in failing to consider Dr. Buchner's plainly relevant testimony.

Compounding the Board's erroneous failure to even mention Dr. Buchner's testimony is the fact that the Board relied on Dr. Buchner's testimony in a different IPR to find that a POSITA would **not** expect to successfully increase bottling speed in view of ZFL. In that IPR the Board found:

> Further, the ZFL reference should be considered in context. ZFL is not a patent; rather, it is non-patent literature. We agree with Patent Owner that ZFL is promotional literature that omits the requisite technical details that would enable a person of ordinary skill in the art to replicate the ZFL apparatus. *See* Prelim. Resp. 14. This contention is supported by a declaration from the author of the ZFL reference, Dr. Buchner. *Id.*; Ex. 2027. Dr. Buchner states that in the ZFL article, he took care not to "publish sufficient knowledge and details which could enable a competitor to successfully build a machine . . ." Ex. 2027 at ¶ 18.

Appx3296. Despite this, the Board ignores Dr. Buchner's testimony in this proceeding and makes no effort to explain the plain inconsistency between these two findings. In fact, just yesterday, the Board issued its decision reversing the examiner in the reexamination directed to the '013 patent.[2] In that decision, the Board found: "We are persuaded by the Patent Owner's representations that both Bosch and Buchner lack the sufficient details to provide a POSITA with a reasonable expectation of success in meeting the challenged claims. Accordingly, we do not sustain any of the Examiner's rejections." *See KHS USA, Inc. v. Steuben Foods, Inc.*, Appeal No. 2022-002210, Decision on Appeal at 8-9, *available at* https://developer.uspto.gov/ptab-web/#/search/decisions (P.T.A.B. July 19, 2022). The Board relied on evidence that is identical in many respects to the evidence before the Board in this proceeding (and discussed *infra*).

Indeed, the Remand Decision itself is internally inconsistent in addressing the bottling speed limitation. Specifically, the Board found that "a skilled artisan would have reasonably expected that, without a residual hydrogen peroxide requirement,

[2] This Court can take judicial notice of the "adjudicative facts" of parallel reexamination proceedings, even when those proceedings post-date the decision being appealed. *Std. Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 514 n.3 (Fed. Cir. 1990); accord *St. Clair Intell. Prop. Consultants, Inc. v. Canon Inc.*, 412 Fed. Appx. 270, 275 n.1; 276 (Fed. Cir. Jan. 10, 2011) (affording "significant weight" to patent examiner statements made in reexamination, for purposes of construing the claims).

the sterilization process times disclosed in the Bosch systems could have been ***reduced***, thereby increasing the disinfection rate." Appx32 (emphasis added). At the same time, the Board cited to Dr. Heldman's testimony that it would be obvious to ***increase*** sterilization by increasing sterilant application time. Appx44. The Board's contradictory findings cannot provide substantial evidence. *See Polygroup Ltd. MCO v. Willis Elec. Co., Ltd.*, 780 F. App'x 880, 884 (Fed. Cir. 2019) (unpublished) ("We do not regard such internally inconsistent findings as supported by substantial evidence."); *Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A. De C.V.*, 865 F.3d 1348, 1354 (Fed. Cir. 2017) (finding the Board's analysis flawed due to internal inconsistencies).

Steuben also submitted voluminous expert testimony explaining in great detail that a POSITA would not reasonably expect to be successful in any attempt to increase Biewendt's bottle sterilization speed in view of the secondary references. Generally, Steuben submitted unrebutted evidence from Dr. Sharon explaining the complexities inherent in the design of an aseptic bottling machine. Appx3164-3169 (¶¶17-27). And specifically, Dr. Sharon testified that a POSITA would not expect to be successful in adding lanes to the Bosch machines:

> Adding lanes to any of the Bosch machines discussed in those references requires a massive redesign effort that will necessitate extensive experimentation to ensure that the required sterilization level is still achieved after the re-design. Based on the disclosure I have seen in the prior art, a mechanical engineer undertaking such an effort on or about February 1999 would not have a clear path to successfully constructing a functional machine

> that worked for its intended purpose of aseptically disinfecting and filling bottles, at the required throughput and sterilization level.

Appx3179 (¶ 43). Dr. Sharon then provided a specific example to the lack of expected success relating to sterilant distribution across multiple parallel processing lanes:

> Adding lanes to a machine is a complex undertaking in general, and made even more complicated in the context of a pressurized aseptic packaging system, which demands uniform sterilization conditions in all the lanes. Exhibit 2031 at 13. In a system involving parallel processing lanes, each lane experiences its own success or failure rate. Exhibit 2031 at 13. This means that maintaining yield and efficiency across all the lanes is not a trivial matter.
>
> [. . .]
>
> If maintaining uniform sterilization conditions in each lane is a goal of the machine, it is essential that each lane and/or container receive the same amount of sterilant under the same conditions. Exhibit 2031 at 13. When lanes are added, additional sterilant conduits and nozzles will need to be added to the sterilant delivery system. If using a distribution manifold, adding those additional conduits may result in a pressure drop that will manifest itself in less fluid going to the conduits dispensing sterilant to the lanes furthest away from the sterilant supply source. That is, there will be a non-uniform application of sterilant from lane to lane, which is operationally unacceptable. Exhibit 2031 at 13. To remedy this problem, an engineer would consider increasing the input fluid supply and placing additional flow regulators to achieve a uniform fluid distribution across all lanes. These will have to be experimentally adjusted as imperfections such as surface finish and other unforeseen deviations from ideal conditions will render an analytical model as only a good starting point.

Appx3179-3180 (¶¶ 44, 45).

Dr. Sharon's testimony concerning fluid distribution is consistent with Dr. Buchner's testimony explaining that in Bosch's experience, adding lanes to a machine posed issues with respect to sterilant distribution:

> In order to increase bottle-per-minute output of any machine there are many features that you need to consider.
>
> It is not possible to anticipate all the problems that may arise when expanding the size of a machine and adding additional lines.
>
> For example, in a case where we were making a machine with a number of lines we found that the air-pressure dropped from nozzle to nozzle across the first lines and at the end the pressure increased again. You have to make sure that you have at every station sufficient sterilizing agent for sterilizing and a sufficient temperature for the activity of the sterilizing medium and also sufficient air for drying with a sufficient temperature for removing the sterilizing medium in order to be below the hydrogen peroxide limit of 0.5 ppm.

Appx2408 (¶¶ 21-23). Indeed, consistent with Dr. Buchner's testimony concerning Bosch's difficulty with adding lanes to a machine, Dr. Sharon explains:

> In fact, the Bosch reference suggests that 6 lanes could be used to achieve a throughput of 100 bottles per minute. Exhibit 1009 at 2. Yet, the Biewendt reference discloses the use of 9 lanes to achieve a throughput of 100 bottles per minute. Exhibit 1008 at 2-4. This inconsistency suggests that even the highly skilled engineers at Bosch could not accurately predict throughput gains by the use of additional lanes.

Appx3180 (¶ 44).

For his part, Dr. Buie identified "roughly 39 variables" that Biewendt did not disclose concerning its aseptic bottling system. Appx3230 (¶ 50). Consistent with Dr. Sharon's testimony, Dr. Buie testified that the "ZFL/Bosch references do

not provide a person of ordinary skill with enough information to begin the design process." Appx3226-3227(¶ 43).

The foregoing evidence is unrebutted. In fact, Nestlé did not even address it with attorney argument, opting instead to assert that "a dual-line design (two separate lines operating in parallel) would avoid the 'fluid dynamic' and other challenges that PO alleges would be posed by 'adding lanes' to one of the Bosch lines." Appx2114.

Dr. Heldman did not address any of the issues identified by Dr. Sharon and Dr. Buie in his declaration. And Nestlé conspicuously did not serve any evidence at all to rebut the testimony of Drs. Sharon and Buie. The Remand Decision's reliance on conclusory expert testimony does not constitute substantial evidence of obviousness. The Court should reverse the Board's decision. The prophetic suggestion that "dual-line" embodiments were in development fails to provide the required expectation of success.

B. The Remand Decision's attempt to trivialize the proposed modification to Biewendt by reformulating the rejection set forth in the Petition must fail.

The Remand Decision attempts to trivialize the complex process of increasing bottling speed by finding that a POSITA need only increase the bottling speed to 101 bottles per minute to meet the challenged claims. Appx30-33. The Petition, however, was not premised on such a trivialization of the proposed modification.

Instead, the Petition argued that it would have been obvious to modify Biewendt "e.g., to the 200-bottle-per-minute rates disclosed in each secondary reference" by "expanding the sterilizer, including expansion up to 30 lines," "using smaller bottles" and "using a dual-line design to double the rate." Appx2049. The Board improperly deviated from the grounds set forth in the Petition. *Sirona Dental Sys GmbH v. Institut Straumann AG*, 892 F.3d 1349, 1356 (Fed. Cir. 2018).

The Board faults Steuben for allegedly failing to "explain specifically why a skilled artisan could not have modified the disclosed systems to achieve a disinfecting rate of 101 bottles per minute" and for "argui[ing] generally that a skilled artisan would not have reasonably expected to increase throughput of the disclosed Bosch systems by adding lines and/or expanding the tunnel, without identifying a specific disinfection rate that a skilled artisan would not have had a reasonable expectation of success of achieving, other than 200 bottles per minute." Appx31.

The Board's critiques are misplaced. It was Petitioner's burden to explain how a POSITA could have modified Biewendt to achieve the claimed disinfecting rate. *Google LLC v. IPA Techs. Inc.*, 34 F.4th 1081, 1085 (Fed. Cir. 2022). The Petition said nothing about modifying Biewendt to achieve 101 bottles per minute. Instead, it was premised on increasing throughput to 200 bottles per minute based on the statements in Buchner, Bosch, and ZFL. Steuben's Response addressed the

actual argument in the Petition, i.e., that bottling speed could be increased to 200 bottles per minute.

None of the Petition's arguments would result in increasing the bottling speed by a single bottle. The "dual-line" teaching of ZFL literally duplicates the 100 bottle per minute machine of ZFL. Applying that technique to Biewendt would require a duplication of Biewendt. Such a duplication would not result in 101 bottles per minute, it would result in 200 bottles per minute. The Remand Decision includes a separate infirmity on this issue. Specifically, the Remand Decision finds that "Patent Owner's declarant, Dr. Sharon, testified that Bosch engineers, presumably skilled artisans, could have duplicated a single line." Appx30. In the cited testimony, Dr. Sharon explained: "For the Bosch engineers, ***if they had one line*** and they wanted to duplicate it – and I assume they would have access to all the information they need – that they could duplicate that line." Appx2629 at 169:13-16.

In this proceeding, a POSITA does not have access to the same information as the Bosch engineers. For that reason, the Board's assertion concerning the Bosch engineers is orthogonal to the obviousness inquiry. The obviousness inquiry turns on whether a POSITA would reasonably expect to be successful in increasing the throughput of Biewendt based on prior art disclosure. *See* 35 U.S.C. § 311(b). Drs. Buie and Sharon provided **unrebutted testimony** demonstrating that a POSITA

would not expect to be successful in practicing the claimed method based on the disclosure of Biewendt. Appx3222-3227 (¶¶41-43); Appx3173-3182 (¶¶ 33-47).

The concept of "widening the sterilizer" by adding processing lanes likewise would not result in a throughput increase of a single bottle per minute. The notion of adding lanes likewise would not result in a 101 bottle per minute speed. Buchner disclosed the use of 6 lanes to achieve 70 bottles per minute where Biewendt discloses 9 lanes to achieve 100 bottles per minute. Appx22, Appx24. This suggests that each lane would increase the overall throughput of the machine by 10 bottles per minute. In order to increase the speed over 100, a lane would be added, which theoretically would result in a throughput increase to 110 bottles per minute.[3] In the lane-based system of Biewendt, there is no way to increase sterilization from 100 bottles per minute to 101 bottles per minute. To increase throughput, a lane must be added. And Steuben submitted unrebutted evidence (detailed *supra*) demonstrating the difficulty of adding lanes to a system.

C. Buchner does not disclose increasing its bottle sterilization rate by processing smaller bottles.

The Remand Decision finds that it would have been obvious to increase Biewendt's sterilization rate by processing smaller bottles in view of Buchner. Appx29-32. The Remand Decision and Petition cite to the following disclosure from

[3] Bottling speed could be increased by increasing conveyor speed, but the Petition lacks any suggestion to do so.

Buchner in an attempt to support that suggestion: "Plant output lies between 3,000 bottles per hour for the larger containers and 4,200 per hour for smaller 90mL bottles." Appx22; Appx2016; Appx3301. Buchner does not state that sterilization speed could be ***increased*** using smaller bottles. Instead, it states that the maximum line speed would ***decrease*** when larger bottles are filled. There is simply no suggestion in Buchner that processing a smaller bottle will allow a POSITA to increase sterilization speed. Processing larger bottles would slow the machine down because it would take longer to fill the bottles. But it does not follow that processing smaller bottles would allow the machine to exceed its maximum throughput. Indeed, doing so would require speeding up the bottle sterilization process, and neither the Petition nor Remand Decision explain how such a modification could be made—much less with the required reasonable expectation of success.

The only "evidence" advanced in the Petition on this issue is a single sentence fragment where Dr. Heldman states it would be obvious to process "smaller bottles." Appx28; Appx2187 (¶ 61); Appx2049. That single conclusory sentence fragment does not provide substantial evidence. *See, e.g., TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1358 (Fed. Cir. 2019) ("Conclusory expert testimony does not qualify as substantial evidence.").

The Petition's lack of substantial evidence is brought into particularly sharp focus when considered against the backdrop of the evidence from Dr. Buie and Dr.

Sharon submitted by Steuben. Dr. Sharon explains that the rate limiting step in aseptic bottling is bottle sterilization. Appx3191-3192 (¶¶70-71). In Biewendt, sterilization involves applying sterile air to the bottles, which heats the bottle and causes the sterilant to evaporate. Appx2414. For a smaller bottle to be sterilized more quickly, the bottle would need to heat up more quickly than would have been the case with a larger bottle. Dr. Buie provided a detailed modelling exercise to demonstrate that a smaller bottle will not heat up any faster than a larger bottle. Appx3222-3226 (¶¶41-42). This means that using a smaller bottle will not increase sterilization speed. The Petitioner did not even attempt to address this testimony in its Reply, much less rebut it with evidence. And the Board erred by failing to even acknowledge the testimony at all in the Remand Decision. *Aqua Products*, 872 F.3d at 1325.

The Board did acknowledge Dr. Sharon's testimony, but declined to credit it because it found that Dr. Sharon's testimony "is premised on the time it takes to remove the sterilant such that less than 0.5 ppm remains on the container," which the Board found is not required by the claims. Even if the claims do not require compliance with the FDA's residual requirement, a POSITA would be aware of it and consider it in determining whether and how to increase the bottling speed of Biewendt. Indeed, Petitioner's expert acknowledged that a POSITA would consider the FDA's residual peroxide requirement in establishing a "window of operation,"

even though claims 18 and 19 do not expressly recite compliance with that requirement. Appx2166-2167. The Board committed legal error by refusing to consider unclaimed features in connection with its consideration of a motivation to combine. *See Intelligent Bio-Sys, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1368 (Fed. Cir. 2016) (unclaimed features may be "central to a finding of no motivation to combine.") To the extent the Board intended to find that a POSITA would ignore the residual requirement because it is not expressly claimed, that would be an erroneous departure from the Petition as well. *Sirona*, 892 F.3d at 1356.

III. The Board violated Steuben's rights under the APA by refusing to allow Steuben to submit patentability evidence and argument on remand.

In *Nestlé I*, this Court construed the term "aseptic" according to "binding lexicography" to mean the "FDA level of aseptic." *Nestlé I*, 686 F. App'x at 919. The Court explained that "the question then is the scope of the phrase 'FDA level of aseptic.'" *Id.* In answering that question, the Court articulated a new test for determining whether a particular FDA regulation could be considered part of the "FDA level of aseptic." Specifically, the Court explained that the "FDA level of aseptic" "cannot include regulations that apply to foods that are not aseptically packaged. Instead, we confine an 'FDA level of aseptic' to FDA regulations related to aseptic packaging." *Id.* Thus, if a regulation applies only to aseptic packaging, it is "related to aseptic packaging" and part of the "FDA level of aseptic." If the

regulation applies to all foods regardless of whether they are aseptically packaged, it is not "related to aseptic packaging" and not part of the "FDA level of aseptic." Neither Petitioner, nor Steuben, nor the Board articulated such a test to determine whether a particular regulation could be considered part of the "FDA level of aseptic."

Following issuance of the mandate in *Nestlé I*, Steuben requested the ability to submit evidence and argument concerning the impact of the Federal Circuit's new claim construction on the patentability issues presented in the petition. Appx2126-2128. Petitioner opposed. Despite the fact that the Federal Circuit adopted a construction of "aseptic" that had not been proposed by the parties or the Board, the Board denied Steuben's request. Appx1-7. In so doing, the Board deprived Steuben of its right to be heard under the APA.

"For IPRs, the APA imposes particular requirements on the PTO. The agency must 'timely inform []' the patent owner of 'the matters of fact and law asserted.' 5 U.S.C. § 554(b)(3), must provide 'all interested parties opportunity for the submission and consideration of facts [and] arguments . . . [and] hearing and decision on notice,' *id*. § 553(c), and must allow 'a party to submit rebuttal evidence . . . as may be required for a full and true disclosure of the facts,' *id*. § 556(d)." *Qualcomm Inc. v. Intel Corp.*, 6 F.4th 1256, 1262 (Fed. Cir. 2021). The Board violated Steuben's APA rights by denying Steuben's request to submit evidence and briefing

in view of this Court's new test for determining which FDA requirements are part of the "FDA level of aseptic."

In its Order denying Steuben's request to submit evidence and argument on the patentability of the claims in view of the Federal Circuit's construction, the Board found that Steuben "was aware of the express construction of 'aseptic' because it is explicitly set forth in the '013 patent specification," pointing to the specification's lexicographic definition of "aseptic" as meaning the "FDA level of aseptic." Appx5. But that finding misses the point. Steuben was, of course, aware of its lexicography. What Steuben did not have notice of was this Court's newly-articulated test for determining whether a regulation fell within the scope of that lexicography. *See Nestlé I*, 686 F. App'x at 919. Steuben did not have notice that the Court would adopt this new test and should have been afforded its statutorily provided opportunity to submit evidence and argument on the impact of the new test on the patentability of the claims.

The Board's APA violation was not merely a matter of semantics, either. The Board assessed Steuben's arguments and evidence submitted with Steuben's Patent Owner Response in 2015 to determine whether they clairvoyantly passed muster under the Federal Circuit's 2017 articulation of a test to determine whether a particular FDA requirement was part of the "FDA level of aseptic." In so doing, the

Board repeatedly faulted Steuben for not addressing the Federal Circuit's new "FDA level of aseptic" test in its Remand Decision.

For example, with respect to the claim limitation reciting "wherein the aseptically disinfected plurality of bottles are sterilized to a level producing at least a 6 log reduction in spore organisms," the Board faulted Steuben for "not refer[ring] to any FDA regulations **related to aseptic packaging** that specifically require *bacillus subtilis* to be the 'test organism.'" Appx40-41 (citing *Nestlé I*, 686 F. App' x at 919 as "determining that the scope of the 'FDA level of aseptic' is confined to 'FDA regulations related to aseptic packaging.'") (emphasis added). Steuben had no reason to address whether the use of a spore test organism was required by a regulation "related to aseptic packaging" in its 2015 Patent Owner Response because the Federal Circuit did not announce the "related to" test until May 2017.

As another example, the Board faulted Steuben's 2015 Patent Owner Response for "not provid[ing] argument or evidence that the FDA requirement limiting the sterilant concentration to 35% H_2O_2 is applicable to the claim term 'aseptic.'" Appx43. Here, again, Steuben had no reason to assess whether the FDA's requirement to use no more than 35% H_2O_2 was a requirement "related to aseptic packaging" under *Nestlé I* because this Court issued *Nestlé I* three years after Steuben submitted its Patent Owner response.

The Board erred in violating Steuben's APA rights. Steuben respectfully submits that if the Court is not inclined to reverse for the reasons set forth, *supra*, the Court should vacate the Final Written Decision on Remand for further submission of arguments and evidence on the patentability of claims 18 and 19 under the Court's "FDA level of aseptic" test articulated in *Nestlé I*.

CONCLUSION

For the foregoing reasons, Appellant Steuben Foods, Inc. respectfully submits that the Court should reverse the Board's Remand Decision.

Respectfully submitted,

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ADDENDUM

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Paper 76
Entered: October 2, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NESTLÉ USA, INC.,
Petitioner

v.

STEUBEN FOODS, INC.,
Patent Owner

Case IPR2014-01235
Patent 6,945,013 B2

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

ELLURU, *Administrative Patent Judge*.

ORDER

Denying Patent Owner's Request for Rehearing
37 C.F.R. § 42.71

Patent Owner, Steuben Foods, Inc., requests rehearing of the Board's order dated August 14, 2017 (Paper 72, "Order"). Paper 73. With authorization, Petitioner filed a response to Patent Owner's request. Paper 75. For the following reasons, we deny Patent Owner's request for rehearing.

I. INTRODUCTION

We issued a Final Written Decision in this case. Paper 69 ("Decision" or "Dec."). The Decision construed the claim term "aseptic," as "aseptic to any applicable United States FDA standard, and in the absence of any such standard, aseptic assumes its ordinary meaning of free or freed from pathogenic microorganisms." Dec. 14. We determined that challenged claims 18–20 have not been shown to be unpatentable. Dec. 32. On appeal to the Court of Appeals for the Federal Circuit by the Petitioner, the Federal Circuit construed "aseptic," based on express disclosure in the specification, namely, as "'FDA level of aseptic.'" *Nestle USA, Inc. v. Steuben Foods, Inc.*, 686 Fed. App. 917, 919 (Fed. Cir. May 9, 2017). The Federal Circuit further determined that "the Board's construction of 'aseptic' as incorporating 'any applicable United States FDA standard' rather than only FDA regulations governing 'aseptic packaging' was erroneous." *Id*. at 920. Thus, the Federal Circuit vacated our opinion and remanded for further proceedings consistent with its opinion. *Id*.

After the Federal Circuit issued the remand mandate, we held a teleconference to inquire whether the parties had any positions or concerns regarding the remand procedure. Neither side had secured a court report to transcribe the teleconference. Petitioner indicated its position that further briefing in this case is unnecessary. We issued the Order on August 14,

2017, summarizing the teleconference. Our Order stated, in pertinent part, as follows:

> Patent Owner requested additional briefing to argue that the scope of the claim term "aseptic" includes FDA regulation, 21 C.F.R. § 178.1005(d) (as implemented at 49 Fed. Reg. 32,345 (Aug. 14, 1984)), and that the record does not contain sufficient evidence that the regulation applies to "all" foodstuffs, as decided by the Federal Circuit. Patent Owner further requested briefing to include evidence from the *Markman* hearing in the related district court case relating to "aseptic." It is Patent Owner's position that the Federal Circuit has not provided a claim construction for "aseptic," and that the regulation is encompassed by the term. Petitioner disagrees.
>
> Given the Federal Circuit's decision, we agree with Petitioner that the Federal Circuit has decided the claim construction scope of "aseptic," and thus, we deny Patent Owner' request for additional briefing on claim construction at this time.

Order 2.

Patent Owner subsequently filed the present request for rehearing asserting that "it believes that the Board misapprehended and/or overlooked certain of Patent Owner's positions and arguments presented during the July 25, 2017, teleconference." Req. 1. According to Patent Owner, it did not request further briefing to address the proper construction of "aseptic" and agreed that the Federal Circuit provided a claim construction for this term. *Id*. at 1–2. Patent Owner further asserts that its position was, and is, that "further briefing is appropriate for the parties to address whether Petitioner carried its burden to establish that the challenged claims are unpatentable under the Federal Circuit's new claim construction of the term 'aseptic.'" *Id*. at 2–3. Patent Owner argues that the Federal Circuit's "new" claim construction of "aseptic," and related statements were not previously set forth by the Board or parties, and thus, Patent Owner has not had a chance to

be heard under the Federal Circuit's claim construction and related statements. *Id*. at 3.

As an initial matter, Petitioner asserts that the rule covering rehearing requests is limited to decisions on "'petitions and motions,' of which the Order is neither." Paper 75, 1. Petitioner argues that "[t]he proper avenue to challenge the Federal Circuit's decision was via petition for rehearing to the Federal Circuit, not post-remand briefing to the Board. And Patent Owner did petition the Federal Circuit for rehearing." *Id*. at 2. In addition, Petitioner contends that "the Federal Circuit clearly and conclusively ruled that the 'aseptic' terms of the '013 patent do not require compliance with the FDA's hydrogen peroxide residue regulation, 21 C.F.R. § 178.1005(d)." *Id*. at 1.

Patent Owner also argues that we misapprehended "its argument concerning whether the Board, on remand, should consider evidence and arguments that have been developed in related proceedings." *Id*. at 3. According to Patent Owner, it did not request briefing to include evidence from the *Markman* hearing in the related district court case relating to "aseptic." *Id*. Rather, contends Patent Owner, "Patent Owner requested further briefing to bring to the Board's attention evidence and arguments that have been developed in the related proceedings that contradict Petitioner's arguments at the Federal Circuit and before the Board in this proceeding—including certain positions taken by Petitioner itself." *Id*. Specifically, Patent Owner contends that the Petitioner has taken inconsistent positions with respect to the applicability of 21 C.F.R. § 178.1005. *Id*. at 4.

Petitioner responds that "[t]he Board cannot contravene the Federal Circuit's decision and remand order regardless of subsequent statements by a petitioner, and Patent Owner cites no authority otherwise." Paper 75, 2–3.

Petitioner adds that it has "always argued that the FDA's regulation of hydrogen peroxide sterilant residue in packaged foods—21 C.F.R. § 178.1005(d)—is not limited to 'aseptic' processes and, therefore, does not limit the 'aseptic' terms in the '013 patent." *Id*. at 3; *see id*. at 3–4.

II. ANALYIS

A party requesting rehearing bears the burden of showing the decision should be modified. 37 C.F.R. § 42.71(d). The party must identify all matters it contends were misapprehended or overlooked by the Board. *Id*. Notwithstanding Petitioner's response that § 42.71 does not cover requests to rehear orders, and assuming Patent Owner's present contentions, we deny the request for rehearing.

Patent Owner argues in its request that further briefing is warranted for the parties to address whether Petitioner carried its burden to establish that the challenged claims are unpatentable under the Federal Circuit's claim construction of the term "aseptic." We deny the request for rehearing on this basis.

Patent Owner was aware of the express construction of "aseptic" because it is explicitly set forth in the '013 patent specification. Specifically, the '013 patent specification states that "[i]n the following description of the present invention, the term 'aseptic' denotes the United States FDA level of aseptic." Ex. 1001, 1:67–2:2, 4:27–28. Furthermore, in the Petition, Petitioner avers that it "accepts that the claim terms of the '013 patent assume the ordinary and customary meaning, *consistent with the specification*, that they would have to one of ordinary skill in the art at the time of the alleged invention." Petition 8 (emphasis added). Most importantly, in its Patent Owner Response, Patent Owner agreed that "[t]he term aseptic is specifically defined by the Taggart specification as '*the FDA*

level of aseptic.'" PO Resp. 31 (emphasis added). Patent Owner further argued that "the FDA level of aseptic requires that the sterilant be removed from a package such that less than 0.5 ppm remains on the package before it is filled." *Id*. at 32. The Federal Circuit resolves both of these issues—"aseptic" means the "FDA level of aseptic" and the residue regulation is inapplicable to the FDA level of aseptic. *Nestle USA*, 686 Fed. App. at 919. Thus, at the time Patent Owner filed its Patent Owner response, it was on notice of the construction of "aseptic" provided in the specification and subsequently adopted by the Federal Circuit. Because Patent Owner was on notice of the construction of "aseptic" provided by the specification and subsequently adopted by the Federal Circuit and, thus, had the opportunity to argue its positon(s) based on this construction during trial in its Patent Owner Response, we deny the request for rehearing on that basis.

Patent Owner also requests further briefing to bring to the Board's attention evidence that the Petitioner has taken inconsistent positions at the Federal Circuit and at the Board with respect to the applicability of 21 C.F.R. § 178.1005.

The Federal Circuit has resolved the issue of whether § 178.1005 is applicable to the claim term "aseptic." We do not have the authority to change that determination even if Petitioner made inconsistent statement(s) with respect to the application of the regulation. We, thus, deny the request for rehearing on this basis.

It is:

ORDERED that Patent Owner's request for rehearing of our August 14, 2017, Order is denied.

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Paper 111
Entered: May 8, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NESTLÉ USA, INC.,
Petitioner,

v.

STEUBEN FOODS, INC.
Patent Owner.

Case IPR2014-01235
Patent 6,945,013

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

ELLURU, *Administrative Patent Judge*.

FINAL WRITTEN DECISION ON REMAND
35 U.S.C. § 144 and 37 C.F.R. § 42.5(a)

I. INTRODUCTION

A. Background

This Decision addresses the United States Court of Appeals for the Federal Circuit's remand in *Nestlé USA, Inc. v. Steuben Foods, Inc.*, 686 F. App'x 917 (Fed. Cir. 2017) (non-precedential).

Nestlé USA, Inc. ("Petitioner") filed a corrected Petition requesting an *inter partes* review of claims 18–20 of U.S. Patent No. 6,945,013 (Ex. 1001, "the '013 patent"). Paper 7 ("Pet."). Steuben Foods, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 9 ("Prelim. Resp.").

On December 22, 2014, we instituted an *inter partes* review of claims 18–20 on one ground of unpatentability: Claims 18–20 as unpatentable under 35 U.S.C. § 103 over Biewendt,[1] Bosch Brochure,[2] Buchner,[3] ZFL,[4] and Chambers.[5] Paper 12 ("Inst. Dec."), 21. Subsequent to institution of

[1] H.-G. Biewendt et al., *Report on the Type Testing of the Aseptic Filling and Sealing Plant for Glass Bottles for UHT Milk*, 488 Kiel Dairy Research Reports 321 (1996) (with translation) (Ex. 1019, "Biewendt").

[2] Robert Bosch GmbH, *Aseptically Operating Filling and Closing Lines for Bottles, Jars and Wide-Mouth Containers of Glass* (May 1990) (Ex. 1009, "Bosch Brochure").

[3] N. Buchner, *Aseptic Glass in the Food Sector*, PHARMA TECH. J., at 25 (1988) (with translation) (Ex. 1006, "Buchner").

[4] N. Buchner, *Aseptic Filling of Glass and Plastic Containers*, Volume 41, Number 5, 295–298 (1990) (with translation) (Ex. 1007, "ZFL"). Although Petitioner states that ZFL was published in 1989, Ex. 1007 has a date of "1990."

[5] Principles of Aseptic Processing and Packaging (James V. Chambers & Philip E. Nelson eds., 2d ed.) (1993) (Ex. 1010, "Chambers").

trial, Patent Owner filed a Patent Owner's Response (Paper 36, "PO Resp.")[6] and Petitioner filed a Reply (Paper 46, "Pet. Reply").[7] Patent Owner filed a Sur-reply. Paper 54 ("Sur-reply").[8] An oral hearing was held on August 4, 2015, and a transcript of the hearing was entered into the record. Paper 61 ("Tr.").[9]

On December 21, 2015, we issued a Final Written Decision finding that Petitioner had not shown by a preponderance of the evidence that claims 18–20 were unpatentable over the combination of Biewendt, Bosch Brochure, Buchner, ZFL, and Chambers. Paper 69 ("Final Dec.").[10] Petitioner appealed our Decision to the Federal Circuit. Paper 67.

On May 9, 2017, the Federal Circuit issued a decision determining that "the Board's construction of 'aseptic' as incorporating 'any applicable United States FDA standard' rather than only FDA regulations governing 'aseptic packaging' was erroneous." *Nestlé*, 686 F. App'x at 920 (Paper 79). Because our decision that the claims were not shown to be unpatentable relied in part on our construction of "aseptic packaging," the Federal Circuit vacated our Final Written Decision and remanded for further proceedings. *Id.* The mandate issued on July 20, 2017. Paper 80.

On July 25, 2017, the Board held a teleconference with the parties to discuss the post-remand procedure. Paper 72, 2. Patent Owner requested

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[6] We refer to the public, redacted version of Patent Owner's Response. An unredacted version is filed at Paper 31.

[7] We refer to the public version of Petitioner's Reply.

[8] We refer to the public version of Patent Owner's Sur-reply.

[9] The transcript of the oral hearing is confidential.

[10] We refer to the public version of our Final Written Decision.

authorization to submit additional briefing, along with evidence, regarding the construction of the claim term "aseptic." *Id.* Patent Owner further requested a stay of this proceeding pending the resolution of a related case, in which construction of "aseptic" was also at issue. *Id.* We decided that the Federal Circuit had already determined the scope of "aseptic" and issued an Order denying Patent Owner's request to submit additional briefing and denying Patent Owner's request for a stay of this proceeding. *Id.* at 2–3.

On August 28, 2017, Patent Owner filed a Request for Rehearing of the Board's Order, asserting that "further briefing is appropriate for the parties to address whether Petitioner carried its burden to establish that the challenged claims are unpatentable under the Federal Circuit's new claim construction of the term 'aseptic,'" and also asserting that "Petitioner has taken positions in related proceedings that are inconsistent with its arguments to the Federal Circuit in this proceeding concerning the applicability of 21 C.F.R. § 178.1005."[11] Paper 73, 2–4. Petitioner filed a Response, arguing that Patent Owner's Request for Rehearing lacked procedural basis, that the Federal Circuit already conclusively ruled that the "aseptic" terms of the '013 patent do not require compliance with 21 C.F.R. § 178.1005(d), and that Patent Owner misrepresented Petitioner's argument. Paper 75, 1, 5. We denied Patent Owner's Request for Rehearing, determining that, "at the time Patent Owner filed its Patent Owner response, it was on notice of the construction of 'aseptic' provided in the specification and subsequently adopted by the Federal Circuit and, thus, had the

[11] The relevance of 21 C.F.R. § 178.1005 to the construction of "aseptic" is discussed below in the section relating the claim construction provided by the Federal Circuit.

opportunity to argue its position(s) based on th[at] construction during trial." Paper 76, 6. We further determined that, regardless of whether Petitioner had made inconsistent statements with respect to the application of § 178.1005, the Federal Circuit had resolved the issue of whether § 178.1005(d) is applicable to the claim term "aseptic." *Id.*

On April 2, 2018, the Board held a teleconference with the parties to hear Patent Owner's request for additional briefing after the Federal Circuit's remand decision in a related proceeding, IPR2015-00249 ("IPR '249") (*Nestle USA, Inc. v. Steuben Foods, Inc.*, 884 F.3d 1350 (Fed. Cir. 2018)).[12] Paper 78, 2; Ex. 2074. We issued an Order denying Patent Owner's request for briefing to address the impact of § 178.1005(e) on the patentability of the claims in the instant proceeding. Paper 78, 5.

On May 1, 2018, Patent Owner filed a Request for Rehearing of the Board's most recent Order (Paper 78). Paper 81. Patent Owner asserted that the Federal's Circuit's determination in the IPR '249 remand decision "that the 'aseptic' claim terms are to be construed the same in both [the present and IPR '249] proceedings requires that the patentability determinations in this proceeding take that into account Petitioner's admission that § 178.1005(e) is a regulation governing aseptic packaging." *Id.* at 4. With authorization (Paper 82), Petitioner filed a response asserting that Patent Owner's request for rehearing again argues the applicability of § 178.1005(d), and thus, is requesting that we overturn the Federal Circuit's claim construction. Paper 83. We agreed with Petitioner, and determined

[12] Although we previously indicated our intent to issue the decision at hand in conjunction with the decision on remand in IPR '249, the decision on remand in IPR '249 will be issued separately.

that Patent Owner's argument is unavailing because the Federal Circuit resolved the applicability of this regulation to the claim terms of the challenged claims. Paper 85, 4–5.

We subsequently modified our Decision on Institution to include review of all challenged claims based on all grounds presented in the Petition, but not previously instituted pursuant to *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018). Paper 87, 4. Petitioner then requested partial adverse judgment against Petitioner on all the "newly" instituted grounds. Paper 88, 1. Patent Owner requested authorization to file an opposition to Petitioner's motion for partial adverse judgment and to file briefing on the implication of the grant of a partial adverse judgment on the ground remaining in the trial. Paper 92, 3. We denied Patent Owner's request to file an opposition to Petitioner's motion for partial adverse judgment (Paper 92, 8), and granted Petitioner's motion for partial adverse judgment as to Grounds 1–3, which also addressed claims 18–20 (Paper 91). We, however, authorized Patent Owner to file briefing addressing the implication of our granting Petitioner's motion for partial adverse judgment on the ground remaining in the instant review, and Petitioner to file responsive briefing. Paper 92, 8. The parties filed their respective briefing. Papers 95, 96.

Patent Owner argues that because the adverse judgment constitutes a final written decision under 35 U.S.C. § 318(a),[13] Petitioner is estopped

[13] 35 U.S.C. § 318(a) states "[i]f an inter partes review is instituted and not dismissed under this chapter, the Patent Trial and Appeal Board shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added under section 316(d)."

under 35 U.S.C. § 315(e)[14] from maintaining the instant proceeding. Paper 95, 1. Patent Owner also argues that because partial adverse judgment has been entered that the nine references asserted under Ground 3 do not demonstrate the unpatentability of claims 18–20, Petitioner cannot prevail on its remaining ground in which only a subset of five of those nine references are asserted. *Id*. at 4. Petitioner responds that the partial adverse judgment cannot be a final written decision under § 318(a) because it does not dispose of all claims and grounds raised in the Petition. Paper 96, 1. Petitioner also argues that Patent Owner's position is contrary to Board policy and prior decisions, which uses partial adverse judgment to narrow the grounds to be addressed subsequently in a final written decision. *Id*. at 2–3 (citing Paper 91, 3–4). We agree with Petitioner that the partial adverse judgment granted to Petitioner did not constitute a Final Written Decision disposing of all issues in the proceeding. This Final Written Decision on remand in conjunction with the partial adverse judgment is consistent with the requirements under 37 C.F.R. § 42.73(a) that "[a] judgment, except in the case of a termination, disposes of all issues that were, or by motion reasonably could have been, raised and decided." *See* 37 C.F.R. § 42.2 ("A decision is final only if it disposes of all necessary issues with regard to the party seeking judicial review, and does not indicate that further action is required."). We further agree with Petitioner that its request for partial

[14] 35 U.S.C. § 315(e) states "[t]he petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that inter partes review."

adverse judgment is based on abandonment, not on the merits of any grounds. *See* 37 C.F.R. § 42.73(b)(4) ("[a]ctions construed to be a request for adverse judgment include" "[a]bandonment of the contest"). Indeed, we granted partial adverse judgment "to avoid the unnecessary time, expense, and prejudice associated with reopening IPR proceedings and to simplify the issues to be addressed in the Board's new final written decision on remand." Paper 91, 4. And, we specifically held that Ground 4 remains pending in the instant review. *Id*.

On August 31, 2018, we authorized Patent Owner to file a Motion to Terminate this proceeding, Petitioner to file an opposition, and Patent Owner to file a reply. Paper 93, 3. The parties filed their respective briefing. Papers 94, 97, 98[15].

On January 17, 2019, Patent Owner sought authorization to submit briefing construing "aseptic" under *Phillips v. AWH Corp.*, 415 F.3d 1305 (Fed. Cir. 2005) (en banc), asserting that the '013 patent will expire after we issue this Final Written Decision, but before any decision will issue by the Federal Circuit should an appeal be taken. Paper 106, 2–4. We denied Patent Owner's request because we determined there was no precedent for such briefing when, as here, the patent will expire after the Final Written Decision on remand issues. Paper 106, 4–8. We thus, on remand, decide the patentability issues remaining in the case based on the record before us at the

[15] The Motion to Terminate argues that the instant petition is time-barred under 35 U.S.C. § 314(b) because Petitioner is a privy of a time-barred entity. Paper 94. Patent Owner filed a similar motion in IPR '249. IPR2015-00249, Paper 90. We will issue a decision denying the Motion to Terminate promptly. On January 30, 2019, we held an oral hearing in IPR '249. IPR2015-00249, Paper 125.

time of our original Final Written Decision, without having granted further claim construction briefing. We have reviewed the record in light of the Federal Circuit's decision in this proceeding. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 17 and 18 of the '013 patent are unpatentable. However, we maintain our determination that Petitioner has not shown by a preponderance of the evidence that claim 20 of the '013 patent is unpatentable.

B. Related Proceedings

The parties indicate that the '013 patent is at issue in several district court cases. Pet. 54–55; Paper 71, 2–3. The '013 patent was the subject of Case IPR2014-00041, *GEA Process Eng'g, Inc. v. Steuben Foods, Inc.*, slip op. at 27 (PTAB Feb. 3, 2015) (Paper 140), which has been terminated. *See* Pet. 55; Paper 15, 4. The parties also indicate that the '013 patent is the subject of other Office proceedings. Pet. 55; Paper 71, 2. In addition, the '013 patent is related to other United States patents, which are or were the subject of various Office proceedings. Pet. 55; Paper 71, 2–3.

C. The '013 Patent (Ex. 1001)

The '013 patent is directed to a method and aseptic packaging system for the aseptic packaging of food products in containers, such as bottles. Ex. 1001, 1:10–14. The '013 patent specification discloses the steps of "providing a plurality of bottles; aseptically disinfecting the plurality of bottles; aseptically filling the aseptically disinfected plurality of bottles with the aseptically sterilized foodstuffs; and filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute." *Id.* at 3:9–18.

D. The Claims on Remand

Independent claims 18–20, on remand, are reproduced below:

18. A method for automatically aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the bottles at a rate greater than 100 bottles per minute; and

aseptically filling the bottles with aseptically sterilized foodstuffs, wherein the aseptically sterilized foodstuffs are sterilized to a level producing at least a 12 log reduction in *Clostridium botulinum.*[16]

19. A method for automatically aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the bottles at a rate greater than 100 bottles per minute, wherein the aseptically disinfected plurality of bottles are sterilized to a level producing at least a 6 log reduction in spore organisms; and

aseptically filling the bottles with aseptically sterilized foodstuffs.[17]

20. A method for automatically aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the bottles at a rate greater than 100 bottles per minute, wherein the disinfecting the bottles is with hot hydrogen peroxide spray, wherein a residual level of hydrogen peroxide is less than 0.5 PPM; and

aseptically filling the bottles with aseptically sterilized foodstuffs.

[16] *See* Certificate of Correction, deleting "*Clostridium, botulinum*" at column 16, line 41 and inserting "*Clostridium botulinum*."

[17] *See* Certificate of Correction, deleting "organism" at column 16, line 48 and inserting "organisms."

E. Grounds of Unpatentability

The following ground of unpatentability and prior art references are at issue:

Reference(s)	Basis	Claim(s)
Biewendt, Bosch Brochure, Buchner, ZFL (collectively "Bosch references"), and Chambers	§ 103	18–20

Final Dec. 4. Petitioner relies on the declarations of Dennis R. Heldman, Ph.D. (Ex. 1005) and Norbert Buchner, Ph.D. (Ex. 1017). Patent Owner relies on the declarations of Andre Sharon, Ph.D. (Ex. 2025) and Cullen Buie, Ph.D. (Ex. 2026).

II. ANALYSIS

A. Claim Construction

In our Final Written Decision, we found that the ordinary meaning of "aseptic" is "free or freed from pathogenic microorganisms."[18] Final Dec. 12 (citing Ex. 3001). We also noted, however, that the specification of the '013 patent explicitly states that "the term 'aseptic' denotes the United States FDA level of aseptic." *Id.* (citing Ex. 1001, 1:67–2:2). Thus, based on the express disclosure of the '013 patent specification, we construed "aseptic" as "aseptic to any applicable United States FDA standard, and in the absence of any such standard, aseptic assumes its ordinary meaning of free or freed

[18] In a Petition filed prior to November 18, 2018, we interpret claims of an unexpired patent using the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b). Petitioner has informed us via e-mail that the '013 patent is set to expire on May 6, 2019.

from pathogenic microorganisms." *Id.* at 14. That construction led to our determination that Petitioner had not shown by a preponderance of the evidence that claims 18–20 of the '013 patent are unpatentable. *Id.* at 32.

On appeal, the Federal Circuit determined that the specification's definition of "aseptic," as "the United States FDA level of aseptic," was "binding lexicography." *Nestle*, 686 F. App'x at 919. The Federal Circuit determined that the scope of the "FDA level of aseptic" is confined to "FDA regulations related to aseptic packaging." *Id.* The Federal Circuit further stated the following:

> Though the FDA does not define "aseptic" outright, at the time of the application, it defined "aseptic processing and packaging" as "the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms." 21 C.F.R. § 113.3(a) (1999). And "commercial sterility" was defined as "free of viable microorganisms having public health significance, as well as microorganisms of nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution." *Id*. § 113.3(e) (1999).

Id. Relevant to this case, the Federal Circuit specifically disagreed that "aseptically" packaged requires satisfaction of the regulatory requirement of 21 C.F.R. § 178.1005(d), namely that the final product has a hydrogen peroxide residue of less than 0.5 ppm. *Id.*

The Federal Circuit concluded that our construction of "aseptic" as incorporating "any applicable United States FDA standard" rather than only FDA regulations governing "aseptic packing" was erroneous. *Id.* at 920. Accordingly, as directed by the Federal Circuit, we construe "aseptic" to mean the "FDA level of aseptic," which is confined to "FDA regulations

related to aseptic packaging."

B. *Level of Ordinary Skill in the Art*

Petitioner contends that a person of ordinary skill in the art "would have an undergraduate scientific or engineering degree in a relevant field (such as microbiology or mechanical, packaging, process, or food engineering), at least five years of experience in an aseptic packaging and/or processing field (or a graduate degree conferring similar expertise), and an understanding of the relevant principles of microbiology and food science and technology." Pet. 9. Patent Owner disagrees with this contention "only in that [the level of skill] does not require a mechanical engineering degree." PO Resp. 25 (citing Ex. 1005 ¶ 12). This difference in the education levels alleged does not affect our analysis. Thus, we adopt Petitioner's proposed level of skill, at least to the extent that PO does not disagree.

C. Prior Art References

Four of the five asserted references—Biewendt, Bosch Brochure, Buchner, and ZFL (i.e., the Bosch references)—all describe aseptic bottling technology manufactured by Robert Bosch GmbH. ("Bosch"). *See* Pet. 10–14, 32. While all four Bosch references describe Bosch bottling technology, the systems and methods disclosed in each of the references are not identical. Moreover, the Bosch references do not disclose information about the same parameters of the bottling technology (e.g., sterilant temperature and application time), as discussed below.

1. Buchner (1988)

In 1988, a Bosch employee, Dr. Norbert Buchner, published Buchner as an article (Pet. 10) describing a Bosch pilot plant (Ex. 1006, 2–5), wherein preheated bottles are sprayed "with hydrogen peroxide at effective

temperatures between 50 and 70° C." Ex. 1006, 2. Buchner describes how the "bottles are sprayed on either side with hydrogen peroxide at 3 stations for approximately 15 sec." and subsequently, the bottles are "washed out externally at 1 station and internally at 3 stations with sterile water and blown out again with sterile air at a further station." *Id*. at 3. Buchner states that "[d]epending on the mode of operation of the plant and the bottle size, residual peroxide values are achieved that are below 0.5 or considerably less than 1 ppm." *Id*. at 4. According to Buchner, the disclosed method achieved *B. subtilis* bacterial count reduction "of more than 5 or more than 5.5 orders of magnitude." *Id*. at 4. With regard to output rate, the Bosch pilot plant utilized a 6-line bottle sterilizer (6-bottle-wide) and achieved output rates of "between 3,000 bottles per hour for the larger containers and 4,200 per hour for smaller" bottles, i.e., 50–70 bottles per minute. *Id*. at 2–3. Based on the experience with the Bosch pilot plant, Buchner concluded that it was *possible* to increase output "to 6,000 per hour [100 bottles per minute] with a maximum filling volume of 1 litre, a 9-line sterilizer machine being used," and that "[f]urther planning *anticipates* an increase to 12,000 per hour [200 bottles per minute]." *Id*. at 5 (emphasis added).

2. ZFL (1990)

In 1990, Dr. Buchner wrote an article describing Bosch plants that had been built. Ex. 1007, 4. The described system includes a "precleaner machine (special rinser)" not disclosed in Buchner. *Id*. at 2, Fig. 1. ZFL describes sterilizing bottles using a vaporized hydrogen peroxide sterilant applied onto all inner and outer surfaces of the containers (*id.* at 2) before filling with UHT-treated foodstuffs (*id.* at 1). ZFL, however, omits certain details provided in Buchner, such as sterilant temperature and application

time. ZFL explains that the applied hydrogen peroxide is "dried off after a certain exposure time [of hydrogen peroxide] using sterile hot air" (*id.* at 2), unlike Buchner, which used a sterile water rinse that in turn was blown off by sterile air (Ex. 1006, 3). ZFL states that the bottles have residual hydrogen peroxide levels of less than 0.5 ppm. Ex. 1007, 3. ZFL further discloses that the described Bosch plant achieves ">8D" reduction in *bacillus cereus*, a spore organism, for glass bottles." *Id*., Table 1. In addition, the Bosch plant described in ZFL has "an output of 100 [bottles]/min." *Id*. at 4. ZFL further states that "[p]lants in dual-line design for an output of 200/min are in development." *Id*.

3. Bosch Brochure (1990)

Bosch Brochure was published in 1990. Ex. 1009. Bosch Brochure describes an aseptic filling plant and method for "low-acid" products, including "applying heated hydrogen peroxide," and explains that the "[r]esidual sterilizing media is removed by drying with sterile air." *Id*. at 1. Bosch Brochure states that "[o]ur program comprises sterilization machines with 6 to 30 lines for outputs ranging from 6000 to 12000 bottles/hr [100 to 200 bottles per minute], depending on the filling volume." *Id.* at 2. Bosch Brochure further states: "Nominal throughput: up to 200 containers/min, depending on product, fill volume and neck diameter." *Id*. at 4.

4. Biewendt (1996)

In 1996, Bosch asked the German Institute for Process Technology to conduct a study of the Bosch aseptic filling and sealing plant for glass bottles for Ultra High Temperature ("UHT") milk. Pet. 13 (citing Ex. 1008,

1).[19] Biewendt describes that study, and in particular a 9-line sterilizer wherein pre-cleaned bottles are sprayed with hydrogen peroxide warm air which flows around the entire surface area of the bottles, and subsequently blow-dried with filtered, clean air on the inside and outside. Ex. 1019, 3–5. Biewendt states that "[t]he standard plant" "is designed to process 6,000 bottles per hour [100 bottles per minute]." *Id*. at 2. Biewendt provides descriptions of bottle preheating to "approx. 45 to 55°C warm" (*id*. at 3–4); sterilant concentration of "minimum 33% H_2O_2" (*id*. at 11); bottle sterilization with a "sterilizing H_2O_2 warm air mixture [that] flows around the entire surface area of the bottles" (*id*. at 4–5); bottle drying with "at least 80 °C hot air" (*id*. at 18); bottle filling and sealing wherein "2 x 5 = 10 bottles [are transported] to the lifting table in 6-second cycles, where they are lifted in cycles by the filling table, with the outlet pipe connections of the filling valves being lowered into the bottles" (*id*. at 6); descriptions of the overall process sequence (*id*. at 11–17); and descriptions of testing and results (*id*. at 17–24).

D. Principles of Law

To prevail in this *inter partes* review of the challenged claims, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A patent claim is unpatentable under 35 U.S.C. § 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

[19] Ex. 1008 was the originally filed copy of Biewendt. Petitioner subsequently filed another copy of Biewendt with a corrected Certificate of Translation, Ex. 1019. *See* Papers 26 and 27.

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). It is axiomatic that an obviousness analysis "focuses on the invention *as claimed*." *In re Huang*, 100 F.3d 135, 138 (Fed. Cir. 1996) (emphasis added).

"[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. "[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine elements in the way the claimed new invention does." *Id.* Moreover, "[i]n order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or method." *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 2010) (citing *In re Payne*, 606 F.2d 303, 314 (CCPA 1979)). In addition, a person of ordinary skill in the art must have had a reasonable expectation of success in doing so. *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1193 (Fed. Cir. 2014).

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). Similarly, if the prior art merely encourages exploration of a general approach without giving specific guidance as to how to achieve the claimed invention, there is no reasonable expectation of success. *Id.*

The ground of unpatentability before us is based on obviousness rather than anticipation. For that reason, we are not concerned with whether individual references are enabled standing alone. *Cf. Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003) (anticipatory prior art must be enabled); *Amgen Inc. v. Hoechst Marion Roussel, Inc*., 314 F.3d 1313, 1357 (Fed. Cir. 2003) (in obviousness analysis a reference need not be enabled; rather, it qualifies as prior art for what is disclosed therein). Consequently, our inquiry is whether the prior art asserted by Petitioner, as a whole, both suggest and enables the claimed methods so that a skilled artisan would have been motivated to and had a reasonable expectation of success in practicing the methods.

E. Claim 18

Petitioner contends that claim 18 is unpatentable as having been obvious over the combination of Bosch references—namely, Biewendt, Bosch Brochure, Buchner, and ZFL, and Chambers. Pet. 41–45. With respect to all the challenged claims, Petitioner argues that each recites a result without specifying particular steps to achieve that result, and that Patent Owner attempts to read into the claims unclaimed features. Pet. Reply 6, 10–14.

"providing a plurality of bottles"

Claim 18 recites "providing a plurality of bottles." For this limitation, Petitioner cites Biewendt's disclosure that the bottles are guided and conveyed to a clean room for sterilization nine at a time. Pet. 43 (citing Ex. 1019,[20]sz 3–4). Specifically, Biewendt teaches that bottles "are guided to

[20] Although Petitioner cites Exhibit 1008 in its Petition, as we noted above,

the [cleaning and drying] machine on dual tracks and conveyed further with the help of the screw conveyors" (Ex. 1019 at 3), and that nine "bottles are taken simultaneously and introduced head first into the clean room" of a sterilization machine (*id*. at 4). Patent Owner does not dispute that the asserted prior art teaches or suggests this limitation.[21] We find that Petitioner has established by a preponderance of evidence that the combination of asserted references teaches or suggests the claimed "providing a plurality of bottles."

"*aseptically disinfecting the bottles at a rate greater than 100 bottles per minute"*

Claim 18 further recites "aseptically disinfecting the bottles at a rate greater than 100 bottles per minute." Petitioner asserts that Biewendt, Bosch Brochure, Buchner, and ZFL all disclose Bosch aseptic bottling technology used to aseptically bottle aseptically sterilized UHT milk, with outputs of between 100 and 200 bottles per minute. *Id.* at 32. Petitioner specifically refers to Biewendt's disclosure that "[t]he standard plant . . . is designed to process 6,000 bottles per hour," or 100 bottles per minute. *Id.* at 43 (citing Ex. 1008, 2). Petitioner further cites Buchner's "anticipate[d]" bottling rates of up to 200 bottles per minute, as well as its disclosure that bottling rates

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this exhibit was replaced with Exhibit 1009.

[21] The scheduling order in this proceeding reminded Patent Owner that "any arguments for patentability not raised in the [Patent Owner Response] will be deemed waived." Paper 13, 3; *see also In re Nuvasive, Inc.*, 842 F.3d 1376, 1380–81 (Fed. Cir. 2016) (holding that a patentee waived an argument by presenting it only in the preliminary proceeding and not during the trial, despite the Board cautioning the patentee that arguments not briefed in the response would be deemed waived).

may be increased by using a 9-line bottle sterilizer instead of a 6-line sterilizer and/or using smaller containers. *Id.* (citing Ex. 1006, 2, 5). Petitioner also cites ZFL for its "dual-line design" to achieve an output of 200 bottles per minute. *Id.* at 43–44 (citing Ex. 1007, 4). Petitioner additionally cites Bosch Brochure's disclosure of "sterilization machines with 6 to 30 lines, for outputs ranging from 6000 to 12000 bottles/h," or 100–200 bottles per minute. *Id.* at 44 (citing Ex. 1009, 2). Petitioner argues that it would have been obvious to a skilled artisan to modify Biewendt's 100 bottle-per-minute method "to increase rates beyond 100 bottles per minute (e.g., to the 200-bottle-per-minute rates disclosed in each secondary reference) through one or more of the following modifications: (1) expanding the sterilizer, including expansion up to 30 lines; (2) using smaller containers; and (3) using a dual-line design to double the rate." *Id.* Petitioner's declarant, Dr. Heldman, provides supporting testimony to this effect. Ex. 1005 ¶ 61.

Patent Owner disputes that the asserted references teach this limitation. Patent Owner initially argues that none of the asserted references disclose Bosch bottling technology that achieved bottling speeds in excess of 100 bottles per minute, "much less the 200 bottle per minute speed projected in Bosch's 1990 promotional literature." PO Resp. 52 (citing Ex. 2025 ¶ 44). Patent Owner further argues that the disclosed systems could not be modified by adding lanes to increase throughput. For example, Patent Owner argues that "adding lanes to a system would be just as likely to reduce throughput by creating discontinuities in process conditions across the width of the line, which in turn causes excess or inadequate sterilization application or insufficient rinsing or removal of the sterilant." *Id*. at 53

(citing Ex. 2025 ¶ 43–44; Ex. 2031, 13). Further, according to Patent Owner, "expanding the [sterilization] tunnel [to add lanes] will have an effect on airflow throughout the tunnel," which would have required studying the impact of the new airflow patterns on the system. *Id*. at 53–54 (citing Ex. 2025 ¶¶ 43–44). Patent Owner also contends that the two variables are not separate because "the distribution of sterilant will be impacted both by the pressure drop resulting from the inclusion of additional manifolds as well as by the new airflow patterns in the tunnel," and thus, "figur[ing] out one issue" does not mean that the solution could have been successfully integrated into a system. *Id*.

Patent Owner also argues that the disclosed systems could not be modified by using smaller bottles to increase throughput. Patent Owner acknowledges that bottle size can affect "overall line speed" because "larger bottles take longer to fill given that it is important to avoid splashing during the fill operation, for example." *Id*. at 55. However, Patent Owner argues that "[t]here is no evidence that Bosch was able to increase its *sterilization speed* by reducing the bottle size" and that the underlying science would not have allowed for increased sterilization speed. *Id*. at 56 (emphasis added). Dr. Sharon, Patent Owner's declarant, opines that "[w]hile filling throughput is directly related to the volume of the bottle, *sterilization throughput is only minutely related* to the volume of the bottle." Ex. 2025 ¶ 70. According to Dr. Sharon, "[s]terilization throughput is directly related to the time it takes the sterilant to kill the pathogens and the time it takes to remove the sterilant such that less than 0.5 parts per million remains, as required by the FDA." *Id*. Lastly, Patent Owner contends that the "alleged relationship between bottle size and throughput would [have been] far from linear," noting that in

Buchner "the overall line speed only increased from 50 to 70 BPM when the size of the bottle [was] reduced by a factor of 5." PO Resp. 57 (citing Ex. 2025 ¶ 70; Ex. 1006, 25).

We find that Petitioner has established by a preponderance of evidence that the combination of asserted references teaches or suggests the claimed "aseptically disinfecting the bottles at a rate greater than 100 bottles per minute" for the following reasons.

Claim 18 requires disinfecting "at a rate greater than 100 bottles per minute." Thus, for example, disinfecting at a rate of 101 bottles per minute would satisfy this limitation. *See* Pet. Reply 16–17. ZFL suggests increasing aseptic bottling rates to greater than 100 bottles per minute, i.e., 200 bottles per minute, using a dual-line design, i.e., increasing the number of lines in the plant. Ex. 1007, 4; Ex. 1005 ¶ 56. ZFL indicates that plants, with a dual-line design, for an output of 200 bottles per minute were "in development." Ex. 1007, 4. Indeed, Patent Owner's declarant, Dr. Sharon, testified that Bosch engineers, presumably skilled artisans, could have duplicated a single line. Ex. 1025, 169:7–170:4. Buchner also teaches that bottling rates up to 200 bottles per minute were "anticipated," by widening the sterilizer from 6 lines to 9 lines and/or using smaller containers. Ex. 1006, 2, 5. Lastly, Bosch Brochure teaches a sterilization machine using 6 to 30 lines, depending on the filling volume, to achieve "outputs ranging from 6000 to 12000 bottles/h [i.e., 100–200 bottles per minute]." Ex. 1009, 2. It is immaterial that the Bosch references do not disclose an *operational machine* that actually surpassed 100 bottles per minute. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981) ("The test for obviousness is not whether *. . . the claimed invention must be expressly suggested in any one or all of*

the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." (emphasis added)); *see also KSR*, 550 U.S. at 421 (2007) ("A person of ordinary skill is also a person of ordinary creativity, not an automaton."). Thus, even if the projected 200 bottles per minute, as disclosed by ZFL, and 12,000 bottles per hour, as advertised by Bosch Brochure, were not yet achieved, the fact that such an increase was "in development" (Ex. 1007, 4) would have provided a skilled artisan with a reasonable expectation that a system capable of disinfecting at a rate greater than 100 bottles per minute, e.g., 101 bottles per minute, could be achieved by a dual-line system, adding lines, or using smaller containers.

Patent Owner's arguments that disinfecting at a rate greater than 100 bottles per minute could not be achieved are unavailing. Patent Owner does not explain specifically why a skilled artisan could not have modified the disclosed systems to achieve a disinfecting rate of 101 bottles per minute, sufficient to satisfy claim 18. Rather, Patent Owner argues generally that a skilled artisan would not have reasonably expected to increase throughput of the disclosed Bosch systems by adding lines and/or expanding the tunnel, without identifying a specific disinfection rate that a skilled artisan would not have had a reasonable expectation of success of achieving, other than 200 bottles per minute. *See* PO Resp. 52–55. Thus, we find that, based on the teachings of the asserted references, a skilled artisan would have reasonably expected to increase throughput of the disclosed Bosch systems to at least 101 bottles per minute by adding lanes or separate lines.

Patent Owner's argument that a skilled artisan would not have reasonably expected to increase throughput of the disclosed Bosch systems

by using smaller containers suffers from similar deficiencies. Patent Owner argues generally that sterilization speed would not increase if smaller bottles had been used. *See id*. at 55–57. Patent Owner does not explain why a minute decrease in the size of the containers would not have led to a reasonable expectation of achieving a disinfection rate of 101 bottles per minute, sufficient to satisfy claim 18. Dr. Sharon admits that there is some correlation between sterilization throughput and container size in stating that the "sterilization throughput [rate] is only *minutely related* to the volume of the bottle." Ex. 2025 ¶ 70 (emphasis added). Indeed, Dr. Sharon acknowledges that Buchner achieved a "modest 40% increase" in throughput, from 50 bottles per minute to 70 bottles per minute, by using "wide-necked containers (which are easier to sterilize)" that were "five times smaller." *Id*.; Ex. 1006, 25. Thus, despite the lack of a linear relationship between container size and throughput rate, the evidence shows that decreasing container size can increase throughput rate. Furthermore, Dr. Sharon's opinion about sterilization throughput rate is premised on the time it takes to remove the sterilant such that less than 0.5 ppm remains on the container. Ex. 2025 ¶ 70; Ex. 1007, 3 (the disclosed Bosch systems, ZFL for example, include sterilization processes that are designed to allow for less than 0.5 ppm of hydrogen peroxide in the containers). Claim 18, however, does not have a residual requirement, as discussed above in the construction of "aseptic." We find that a skilled artisan would have reasonably expected that, without a residual hydrogen peroxide requirement, the sterilization process times disclosed in the Bosch systems could have been reduced, thereby increasing the disinfection rate. Thus, we find that, based on the teachings of the asserted references, a skilled artisan would have reasonably

expected the throughput of the disclosed Bosch systems to increase to at least 101 bottles per minute by reducing the size of the containers.

Accordingly, we find that Petitioner has established by a preponderance of evidence that the combination of asserted references teaches or suggests the claimed "aseptically disinfecting the bottles at a rate greater than 100 bottles per minute."

"*aseptically filling the bottles with aseptically sterilized foodstuffs, wherein the aseptically sterilized foodstuffs are sterilized to a level producing at least a 12 log reduction in Clostridium botulinum*"

Claim 18 further recites "aseptically filling the bottles with aseptically sterilized foodstuffs, wherein the aseptically sterilized foodstuffs are sterilized to a level producing at least a 12 log reduction in *Clostridium botulinum*."[22] For this limitation, Petitioner cites Biewendt's disclosure of aseptic filling of "UHT milk." Pet. 44 (citing Ex. 1008, 1). Biewendt discloses that "UHT milk is filled under aseptic conditions into sterilized brown returnable glass bottles." Ex. 1019, 1. Biewendt further discloses that bottles of UHT milk packaged according to its process "[did] not have any negative changes after 15 days of storage at 30 °C and [had] less than 10 germs per 0.1 cm^3." *Id*. at 23. Specifically, 897 bottles tested after 15 days of storage showed "zero" germs. *Id.* at 23–24. Thus, based on the cited passages, we agree with Petitioner that Biewendt teaches that sterility was achieved. *See* Pet. 46. Petitioner additionally cites Buchner for its disclosure of UHT sterilization of foodstuffs. Pet. 20 (citing Ex. 1006, 3). Petitioner also cites ZFL for its disclosure of filling of "UHT milk" and

[22] At times, we refer to *Clostridium Botulinum* as "*C. botulinum*."

foods sterilized in the "UHT presterilization process." *Id*. at 26 (citing Ex. 1007, 1).

With respect to the specific level of spore reduction, Petitioner explains, "[b]y definition, UHT-sterilized foodstuffs are processed to achieve a 12-log reduction in *C. botulinum* spores." Pet. 44 (citing Ex. 1010, 48[23]; Ex. 1005 ¶¶ 18, 62). In support, Petitioner cites Chambers, a book titled *Principles of Aseptic Processing and Packaging*, which discloses that "[p]rocesses for commercial sterility of low-acid foods and UHT milk, in contrast to acid foods, require a greater thermal process to reduce the level of *C. botulinum* spores by 10^{12}." Ex. 1010, 48. Dr. Heldman, Petitioner's declarant, testifies in further support that, "[a]s demonstrated by *Chambers*, milk classified as 'UHT' sterilized has necessarily been processed to a level producing at least a 12-log reduction in *C. botulinum* spores," and that "[t]he system of *Biewendt* is used to package UHT milk . . . an 'aseptically sterilized foodstuff,' which is necessarily processed to a level producing at least a 12 log reduction in *C. botulinum* spores." Ex. 1005 ¶¶ 18, 62. Petitioner further asserts that a 12 log reduction in *Clostridium botulinum* spores is inherently disclosed by Biewendt's teaching of UHT sterilization and that, "if UHT sterilization achieves a 12-log reduction in *C. botulinum* in the '013 patent, it must necessarily achieve the same reduction in *Biewendt*." Pet. 44–45; *see* Ex. 1001, 1:52–55; 10:31–34. Lastly, Petitioner asserts that if Biewendt is not determined to inherently disclose the claimed reduction in *C. botulinum*, a skilled artisan would have found it obvious to provide that

[23] For Exhibit 1010, we refer to the numbering found at the bottom left of each page (e.g. "48 of 80") rather than the native numbering found on the bottom middle of each page.

feature in view of Chambers's disclosure and/or FDA aseptic standards as disclosed by the '013 patent. Pet. 45; *see id.* at 36 (citing Ex. 1001, 1:52–55).

Patent Owner does not dispute that the combination of asserted references teaches or suggests this limitation. *See* PO Resp. 33–58. Based on Petitioner's evidence, for example, Biewendt's disclosure of aseptic filling of bottles with "UHT milk" (Ex. 1008, 1), and Dr. Heldman's testimony that milk classified as "UHT sterilized" has necessarily been processed to a level producing at least a 12 log reduction in *C. botulinum* spores (Ex. 1005 ¶¶ 18, 62), we find that Petitioner has established by a preponderance of evidence that the combination of asserted references teaches or suggests the claimed "aseptically filling the bottles with aseptically sterilized foodstuffs, wherein the aseptically sterilized foodstuffs are sterilized to a level producing at least a 12 log reduction in *Clostridium botulinum*."

F. Claim 19

Petitioner contends that claim 19 is unpatentable as having been obvious over the combination of Biewendt, Bosch Brochure, Buchner, ZFL, and Chambers. Pet. 41–42, 45–48.

"providing a plurality of bottles"

Claim 19 recites "providing a plurality of bottles." For the reasons discussed above with respect to claim 18, we find that Petitioner has established by a preponderance of the evidence that the combination of asserted references teaches or suggests the claimed "providing a plurality of bottles." *See* Pet. 45 (relying on the ground asserted against this similar limitation in claim 18).

"aseptically disinfecting the bottles at a rate greater than 100 bottles per minute"

Claim 19 further recites "aseptically disinfecting the bottles at a rate greater than 100 bottles per minute." For the reasons discussed above with respect to claim 18, we find that Petitioner has established by a preponderance of evidence that the combination of asserted references teaches or suggests the claimed "aseptically disinfecting the bottles at a rate greater than 100 bottles per minute." *See* Pet. 45 (relying on the ground asserted against this similar limitation in claim 18).

"wherein the aseptically disinfected plurality of bottles are sterilized to a level producing a least a 6 log reduction in spore organisms"

Claim 19 further recites "wherein the aseptically disinfected plurality of bottles are sterilized to a level producing a least a 6 log reduction in spore organisms." For this limitation, Petitioner refers to Biewendt's disclosure that bottles of UHT milk packaged according to its process "[did] not have any negative changes after 15 days of storage at 30 °C and [had] less than 10 germs per 0.1 cm^3." Pet. 46 (citing Ex. 1008, 23). According to Petitioner, Biewendt teaches that sterility was achieved, but does not define a specific level of spore reduction. *Id*. For the specific level of spore reduction, Petitioner refers to Buchner's teaching of a 12 log reduction in *C. botulinum*, which Petitioner asserts is a "spore organism" according to the broadest reasonable interpretation. *Id*. (citing Ex. 1006, 4). Petitioner also refers to ZFL's teaching of greater than a 6 log reduction in *B. cereus*, which Petitioner also asserts is a "spore organism." *Id*. (citing Ex. 1007, 2). Petitioner concludes that it would have been obvious to modify the method of Biewendt in view of Buchner and/or ZFL to achieve at least a 6 log

reduction in "spore organisms" as required by claim 19. *Id*. (citing Ex. 1005 ¶ 63).

Patent Owner explains that "[t]o achieve FDA levels of sterility for low-acid food packaging, an applicant must demonstrate that . . . the system achieves a certain log reduction of the spore organism, which is most resistant to the sterilant being used" and that for hydrogen peroxide, the sterilant used in the asserted prior art references, the test organism is *bacillus subtilis*. PO Resp. 40–41. Patent Owner asserts, without citing evidentiary support, that "[a] skilled artisan would also have been aware that hydrogen peroxide was the only FDA-approved sterilant at the time of filing and, as such, that the target organism was *bacillus subtilis* in light of the discussion above." *Id*. at 41. Patent Owner further contends that "a person of ordinary skill in the art would understand that the hydrogen peroxide treatment itself could only achieve about a 4 log or less reduction of *bacillus subtilis*." *Id*. at 45 (emphasis omitted) (citing Ex. 2025 ¶ 59). Patent Owner concludes that none of the asserted Bosch references "achieve FDA levels of aseptic as they do not demonstrate a 6 log reduction of any spore organism, much less of *bacillus subtilis*." *Id*.

Patent Owner also argues that each of Buchner and ZFL individually do not teach the claimed "6 log reduction in spore organisms." Patent Owner acknowledges that Buchner mentions a 5 log reduction in *bacillus subtilis*, but argues that Buchner does not explain how it is achieved and that a 5 log reduction falls an entire order of magnitude short of the claimed 6 log reduction. *Id*. at 42 (citing Ex. 2025 ¶¶ 3, 68–69). Patent Owner also acknowledges that ZFL teaches greater than a 6 log reduction in spore organisms, but argues that ZFL "discloses only a 5.1 log reduction as it

would be measured by the FDA (which is in turn required by the claims)." *Id*. at 42. Specifically, Patent Owner asserts that according to ZFL's Table 1, the rinser in combination with the hydrogen peroxide treatment achieved an 8 log reduction in *bacillus cereus*, but the rinser itself achieved a 2.9 log reduction. *Id.* Patent Owner thus contends that "the FDA would not consider the results of the precleaner/rinser step in determining whether LAASF [low acid aseptic sterilization and filling] equipment was able to achieve the FDA level of aseptic," and that when the steam rinser in ZFL is not applied, only a 5.1 log reduction in *bacillus cereus* is achieved. *Id*. at 42–43 (citations omitted) (emphasis omitted). Thus, concludes Patent Owner, "for FDA purposes, the ZFL system obtained only a 5.1 log reduction of *b. cereus* through the use of hydrogen peroxide." *Id*. at 44.

Patent Owner further disputes that a skilled artisan could have modified the disclosed systems to increase sterilization by using sequential sterilizers to sterilize the bottles twice in order to achieve a 6 log reduction in spore organisms. Patent Owner argues that there would have been a "tailing effect" on the use of multiple sequential sterilizers such that the result would not necessarily have been an "additive sterilization effect." *Id*. at 49 (citing Ex. 2025 ¶¶ 51–53; Ex. 2023; Ex. 2038, 12). According to Patent Owner, the "[t]he literature reveals a tailing effect that demonstrates that assumptions cannot be made about the ability of an additional sequential sterilizer to achieve further log reductions." *Id*. at 50 (citing Ex. 2037, 1; Ex. 2038, 11–12; Ex. 2025 ¶ 52). Relying on Cerf,[24] Patent Owner contends

[24] O. Cerf, *A Review: Tailing of Survival Curves of Bacterial Spores*, J. APPLIED BACTERIOLOGY, 1977, 42, 1–19 (Ex. 2039); O. Cerf et al., *Tailing*

that in a given colony of microorganisms, there may be certain organisms that are more resistant to a given treatment than others, which creates a tailing effect such that after a given treatment time, the treatment is ineffective on the more resistant microorganisms. *Id*. (citing Ex. 2039, 3, 11–12, Fig. 3; Ex. 2023, 1; Ex. 2025 ¶¶ 52–53). According to Patent Owner, "[t]his creates a tailing effect such that after a given treatment time, the treatment is ineffective on the more resistant microorganisms." *Id*. (citations omitted). Patent Owner concludes that "[w]hile a sequential sterilization treatment might have some increased sporicidal effect, there is no reason to believe that such an effect would result in an increase of sterilization efficacy by two to three orders of magnitude (as would be required to enable the [ZFL] Bosch systems, which only achieved a 3-4 log reduction in *b. subtilis*, to meet claim 19's recitation of a 6 log reduction)." *Id*. (citing Ex. 2025 ¶ 51).

As an initial matter, we find that Petitioner has established by a preponderance of evidence that the asserted references teach this claim limitation. Claim 19 recites a sterilization level of "at least a 6 log reduction in *spore organisms*," without specifying a particular spore organism. Buchner teaches a 12 log reduction in *C. botulinum*, which Patent Owner has not disputed is a "spore organism." *See* Pet. 45 (citing Ex. 1006, 4). In addition, ZFL discloses reduction of >8D *bacillus cereus*, which Patent Owner also does not dispute is a "spore organism." Ex. 1007, 3.

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of Survival Curves of Bacillus licheniformis Spores Treated with Hydrogen Peroxide, J. APPLIED BACTERIOLOGY, 1977, 42, 405–415 (Ex. 2023); O. Cerf et al., *Diversity in the Resistance of Bacillus Spores to Hydrogen Peroxide*, 1972 (with translation) (Ex. 2038).

Patent Owner's contentions that ZFL fails to teach this limitation are unavailing because they are premised on requirements that are not claimed. Patent Owner mistakenly conflates "FDA level of aseptic" with FDA approval and/or validation.[25] Patent Owner's argument that hydrogen peroxide was the only FDA-approved sterilant at the time of filing, and that to achieve FDA levels of sterility for this sterilant, the test organism is *bacillus subtilis*, is not sufficiently persuasive. As an initial matter, claim 19 does not require the use of hydrogen peroxide or FDA approval. Similarly, Patent Owner has not sufficiently shown why we must interpret claim 19's recitation of "spore organism" as *bacillus subtilis* under our construction of "aseptic" as the "FDA level of aseptic." Although Patent Owner argues that *bacillus subtilis* is the relevant "test organism," Patent Owner does not refer to any FDA regulations related to aseptic packaging that specifically require *bacillus subtilis* to be the "test organism." *See* PO Resp. 40–41; *Nestle*, 686 F. App'x at 919 (determining that the scope of the "FDA level of aseptic" is

[25] Patent Owner argues that "the specification makes clear that the methods of the invention are FDA compliant." PO Resp. 32. Patent Owner identifies some of the requirements for FDA compliance, including no greater than 0.5 ppm hydrogen peroxide residue in the sterilized bottles under 21 C.F.R. § 178.1005(d). *Id.* at 31–33; Ex. 1005 ¶ 22. The Federal Circuit's determination that § 178.1005(d) compliance is not required by the claim term "aseptic" indicates that the claims do not require compliance with all FDA regulations by the recitation of "aseptic." Indeed, the Federal Circuit stated that the "FDA level of aseptic" is confined to "FDA regulations related to aseptic packaging," and that "the FDA's hydrogen peroxide residue standard applies to *all* foodstuffs, regardless of whether they are aseptically packaged" (emphasis in original), and "[a]ccordingly, the scope of 'aseptic' cannot include regulations that apply to foods that are not aseptically packaged." *Nestle*, 686 F. App'x at 919.

confined to "FDA regulations related to aseptic packaging"). In other words, merely asserting that *bacillus subtilis* is the test organism is insufficient. Patent Owner does not discuss whether that is merely a requirement for FDA approval, which is not claimed, or whether there is a relevant regulation dealing with aseptic packaging, as required by the construction of "aseptic." Moreover, even if such a regulation existed, Patent Owner has not reconciled such a regulation with the express claim language that recites "spore organisms" without specifying a particular spore organism. For example, Patent Owner did not propose a construction of "spore organisms." *See* PO Resp. 30–33. Moreover, Patent Owner's argument that ZFL's disclosure of a reduction of >8D *bacillus cereus* does not satisfy this limitation because the result was obtained with the use of both hydrogen peroxide and an upstream bottle rinser is equally unavailing because it is premised on FDA validation, which is not a requirement of claim 19. *See* PO Resp. 43 (relying on testimony that "[t]he OSITAs at the time would not consider the rinsing practice in the validation") (citing Ex. 2020, 326 ll. 4–17).

We also find that Petitioner has established by a preponderance of the evidence that a skilled artisan would have had reason to modify the Bosch references with a reasonable expectation of success to achieve at least a 6 log reduction of *bacillus subtilis*. Patent Owner's declarant, Dr. Sharon, agreed that a skilled artisan would have been motivated to achieve a 6 log reduction in microbial spores. Ex. 1025, 35:5–12. We are further persuaded by Petitioner's arguments and evidence that a skilled artisan would have understood how to modify processing parameters to increase the level of sterilization. *See* Pet. 19. As Petitioner contends (*id*. at 19–20), ZFL

discloses that "the sterilizing conditions such as flow rate, temperature and peroxide concentration may be adapted to the requirement for different containers."[26] Ex. 1007, 2–3; *see* Ex. 1005 ¶¶ 19–22, 50, 60, 63. Furthermore, Dr. Heldman testifies, based on prior art references,[27] that "increasing sterilant temperature, concentration, and/or exposure time generally increase levels of disinfection." Ex. 1005 ¶ 21; *see also* Ex. 1025, 44:18–45:2, 49:19–50:8 (Dr. Sharon testifying that the prior art disclosed that increasing sterilant concentration or temperature would increase the effectiveness on sterilization). Dr. Heldman explains further that the only constraints on modifying these disinfection parameters would have been the material of the container being disinfected and the FDA requirements. *Id.* ¶ 22. For example, Dr. Heldman explains that a plastic bottle could not be

[26] Our analysis does not rely upon Petitioner's argument that ZFL alone teaches a 6 log reduction in *bacillus subtilis*. *See* Pet. Reply 17–19.

[27] Dr. Heldman refers to P. Elliott et al., *Microbiological Evaluation of Low-Acid Aseptic Fillers*, J. FOOD TECH. (May 1992) (Ex. 1013, "Elliott") and R.T. Toledo, *Sporicidal Properties of Hydrogen Peroxide Against Food Spoilage Organisms*, 26 APPLIED MICROBIOLOGY 595 (1973) (Ex. 1014, "Toledo"). Ex. 1005 ¶¶ 17, 19–22. Elliott discusses adjusting peroxide dosage and heated air temperature to maintain parameters within a "window of operation" for container sterilization that accounts for maximum permitted container temperature and peroxide residue. Ex. 1013, 4, Fig. 2. Toledo discloses that "[i]ncreasing the concentration of H_2O_2 increased its sporicidal properties . . . . reduced the exposure time, and also increased the 'D' value." Ex. 1014, 4, Fig. 3. As explained by Dr. Heldman, the "D" value" is the log reduction value, or sometimes also refers to the time for spore population to decrease by a factor of 10 at a given temperature or in response to a particular microbicide. Ex. 1005 ¶ 16. Toledo also discloses that "[t]he temperature at which H_2O_2 was incorporated has a very marked effect on spore inactivation. Figure 4 shows that the rate of inactivation in 25.8% H_2O_2 increased with increasing temperature." Ex. 1014, 4.

subjected to sterilant temperatures that would melt or deform the bottle, the FDA required no greater than 0.5 ppm H_2O_2 residue in the sterilized bottles, and the FDA required sterilant concentration not to exceed 35% H_2O_2. *Id*.

The requirements Patent Owner relies on to support its position are not recited by claim 19. Specifically, the Federal Circuit disagreed that the claim term "aseptic" of the challenged claims required compliance with the regulatory requirement of 21 C.F.R. § 178.1005(d) that the final product have a hydrogen peroxide residue of less than 0.5 ppm. *Nestle*, 686 F. App'x at 919. Moreover, Patent Owner has not provided argument or evidence that the FDA requirement limiting the sterilant concentration to 35% H_2O_2 is applicable to the claim term "aseptic." Without these constraints, as is the case with claim 19, a skilled artisan would have had more freedom to modify the parameters that led to increased levels of disinfection, such as by increasing sterilant temperature, concentration, and/or exposure time, with a reasonable expectation of success. *See* Ex. 1025, 44:18–45:2, 49:19–50:8; Ex. 1005 ¶¶ 19–22. Likewise, that Patent Owner's supplier, GEA Procomac, could not achieve more than a 5 log reduction of hydrogen peroxide resistant microorganisms is not informative because the parameters under which this system was built are not commensurate with the scope of claims 18 and 19. *See* Ex. 2021, 10. For example, GEA Procomac concluded that an increase in hydrogen peroxide resistant microorganisms was not possible with "reasonable block footprints" (Ex. 2021, 6) on plastic bottles (*id*. at 5; Ex. 2025 ¶¶ 29, 57), both of which are not claimed elements of claims 18 and 19.

In addition, Dr. Heldman provides sufficiently persuasive opinion evidence of other known solutions that would have increased sterilization

levels, including extending the length of the sterilizer or providing a second sterilizer. Ex. 1005 ¶ 50. Dr. Heldman explains the following:

> To adjust application time, a POSITA would know, for example, to extend the length of the sterilizer (to allow longer sterilant application, drying and/or removal times) or to provide a second sterilizer (in series) to sterilize the bottles *twice*. Such adjustments would not change the established functions of the sterilant or the sterilizer, and the results of such modifications, therefore, would have been predictable.

Id. Patent Owner's argument disputing increased sterilization from sequential sterilizers because of concerns about "tailing," a phenomenon whereby after a given treatment time, the treatment is ineffective on the more resistant microorganisms (PO Resp. 50), thereby preventing a 6 log reduction in spore organisms, are unavailing. Patent Owner's argument relies on disclosure in Cerf that the "tail" "may reflect a distribution of the degrees of resistance within a genetically homogenous spore population." Ex. 2023, 1; *see* Ex. 2025 ¶ 52 (According to Dr. Sharon, Cerf explains that "in a given colony of microorganisms, there may be certain organisms that are more resistant to a given treatment than others," which "creates a tailing effect such that after a given treatment time, the treatment is ineffective on the more resistant microorganisms." (citing Ex. 2023)). Petitioner, however, has provided sufficiently persuasive evidence that contradicts Cerf's conclusion. *See* Pet. Reply 20–21. For example, Toledo concluded that "[t]he presence of the tail in Cerf . . . could be due to decomposition of H_2O_2, resulting in decreased activity at the later stages of exposure." Ex. 1014, 3. Furthermore, Petitioner argues persuasively that "tailing" would not prevent sequential sterilizers from increasing the reduction of *bacillus subtilis* to 6-log unless the "tail" flattens to the point that microbial kill stops

before a 6 log reduction is achieved. *See* Pet. Reply 21. Petitioner notes, however, that Cerf observed "tailing" to the point where microbial kill stopped in "only one set of conditions (15% hydrogen peroxide applied at 25˚ C." Pet. Reply 21. The Bosch references teach using a minimum 33% H_2O_2 at 70°C. Ex. 1019, 11; Ex. 1006, 2. Cerf discloses testing H_2O_2 at other conditions that did not result in a tailing effect through a 6 log reduction of *bacillus subtilis*. Ex. 2038, 23 ("survivor curve at pH 2.9 is straight at least for the first 6 decimal reductions"). We thus are persuaded by Petitioner that a skilled artisan would have understood, based on Cerf, which conditions to use to increase the sterilization effects of H_2O_2 and *avoid* tailing through at least a 6 log reduction of spore organisms. Therefore, we conclude that a skilled artisan would have had reason for, and would have had a reasonable expectation of success in, modifying the Bosch references to achieve a 6 log reduction in *bacillus subtilis*.

Accordingly, we find that Petitioner has established by a preponderance of evidence that the combination of asserted references teach or suggest the claimed "wherein the aseptically disinfected plurality of bottles are sterilized to a level producing a least a 6 log reduction in spore organisms."

"*aseptically filling the bottles with aseptically sterilized foodstuffs*"

As discussed above with respect to claim 18, Biewendt discloses that "UHT milk is filled under aseptic conditions into sterilized brown returnable glass bottles." Pet. 48 (relying on the ground asserted against this similar limitation in claim 18); Ex. 1008, 1. Furthermore, as discussed above, we find that the asserted references, in combination, teach aseptically sterilizing bottles to a level producing a least a 6 log reduction in spore organisms.

Accordingly, we find that Petitioner has established by a preponderance of evidence that the combination of asserted references teach or suggest the claimed "aseptically filling the bottles with aseptically sterilized foodstuffs."

G. Combinability of the Sterilization Process of the Bosch References with Respect to Claims 18 and 19

Petitioner asserts that Biewendt, Bosch Brochure, Buchner, and ZFL ("the Bosch references") all disclose Bosch aseptic bottling technology used to aseptically bottle aseptically sterilized UHT milk, with outputs of between 100 and 200 bottles per minute. Pet. 32.

Patent Owner argues that the sterilization process of Buchner cannot be combined with ZFL, Bosch Brochure, and Biewendt. PO Resp. 58–60. Specifically, Patent Owner contends that the sterilization processes disclosed in the Bosch references are not the same. *Id*. at 58. For example, according to Patent Owner, ZFL and Biewendt describe "peroxide treatment followed by sterile air rinsing" (*id*. (citing Ex. 1005 ¶ 30)), whereas "the Buchner process includes six stations which are used in connection with the application of a sterile water rinse" (*id*. (citing Ex. 2024, 96:1–97:1)). Patent Owner reasons:

> Given that the sterile water rinse is necessary to achieve both the microbial reduction (5 log) and the residual peroxide levels (0.5ppm) disclosed by Buchner, it is not reasonable to simply assume that any skilled artisan could achieve the sterilization levels described in the Buchner reference by using the sterilization processes described in ZFL, Bosch, or Biewendt (which describe only an air rinse).

Id. at 59. Patent Owner explains "Procomac in 2006 explained that a sterile water rinse provides the clearest path to reaching the FDA requirement of

less than 0.5ppm on the bottle." *Id.* (citing Ex. 2021, 11). Patent Owner concludes:

> In order to come anywhere close to meeting FDA levels of aseptic with the ZFL, Bosch [Brochure], or Biewendt systems it appears that one would have to modify the process to include some form of sterile water rinse as described in Buchner. However, Bosch [Brochure] did not go that route and neither Petitioner nor Dr. Heldman even suggest that such a modification would be made.

Id.

We find that a skilled artisan would have combined the Bosch references and are not sufficiently persuaded by Patent Owner's argument to the contrary. As an initial matter, Patent Owner's argument that a skilled artisan would not have modified Buchner's sterile water rinse with any of the other sterilization processes described in ZFL, Bosch Brochure, or Biewendt because a sterile water rinse was necessary to achieve both the microbial reduction (5 log) and the residual peroxide levels (0.5 ppm) is unavailing because "aseptic" does not include a 0.5 ppm residual hydrogen peroxide requirement. We further agree with Petitioner that any variations between the references, for example between Buchner and the other references, are design options, the selection of which is within the skill of a skilled artisan. *See* Ex. 1006, 2 (water rinsing and drying are alternatives), 4 ("preliminary cleaning" or "washing system" is an option to "achieve a very low contamination level"); *see also* Pet. Reply 9–10.

In addition, as Petitioner contends (Pet. Reply 9–10), "[t]he references concern the same subject matter, describe bottling systems from the same company [Bosch], and depict sterilization machines having substantially similar designs." *See*, *e.g.*, Ex. 1006, Fig. 2; Ex. 1007, Fig. 3; Ex. 1008, Fig.

2. "All four references disclose disinfecting bottles with hydrogen peroxide, describe using sterilizers having between 6 and 9 lines (or more), and describe bottle output rates of between 100 and 200 bottles/min." Ex. 1005 ¶ 37. For these reasons, we find that a skilled artisan reading one Bosch reference would have had reason to use the other Bosch references to learn and implement additional details of the method not disclosed in the originally reviewed reference. *See* Pet. 33; Ex. 1005 ¶ 37. *See KSR*, 550 U.S. at 418 (a holding of obviousness may be based on a showing that "there was an apparent reason to combine the known elements in the fashion claimed"). Also, the reason to combine does not need to come from the references. *KSR*, 550 U.S. at 418 (a reason to combine may be found in "interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art"). We are further persuaded by Petitioner's argument, as supported by the testimony of Dr. Heldman, that given the similarities in teachings amongst the Bosch references, a skilled artisan would have reasonably expected to succeed in applying teachings from one Bosch reference to another. Ex. 1005 ¶ 37.

Thus, we find that a skilled artisan could have combined the asserted references with a reasonable expectation of success to arrive at the limitations in claims 18 and 19.

H. Enablement of Prior Art with Respect to Claims 18 and 19

Patent Owner further argues that the cited prior art is non-enabling while, in contrast, the '013 patent specification discloses key design parameters that "'enable a person of ordinary skill in the art to reproduce the system, process, and results described in the '013 patent related to sterilant

delivery and removal.'" PO Resp. 26 (citing Ex. 2026 ¶ 43), 33–34. Patent Owner's declarant, Dr. Buie, testifies that the '013 patent specification would have enabled a person of ordinary skill in the art to construct and use or perform the disclosed atomization system, airflow regime, and air-rinsing for sterilant delivery and removal. *See id.* at 27–28, 30 (citing Ex. 2026 ¶¶ 12–20, 25–41, 43). Patent Owner argues that, rather than disclosing key operational details, Bosch purposely avoided publishing enabling details in order to keep its machines a trade secret, and that the asserted references omit the key details necessary to replicate the Bosch machines. *Id*. at 34–38.

Patent Owner's arguments are misplaced. As an initial matter, the enablement or lack thereof for the '013 patent does not support Patent Owner's assertion that the prior art is not enabled. Moreover, it is irrelevant that the asserted references would not have enabled a skilled artisan to make a Bosch machine. *See In re Antor Media Corp.*, 689 F.3d 1282, 1290 (Fed. Cir. 2012) (the prior art "only needs to enable the portions of its disclosure alleged to [invalidate] the *claimed* invention" (emphasis added)). It is likewise irrelevant that the asserted references omit variables that are not claimed. *See* PO Resp. 38 (Patent Owner arguing that "at least 39 variables necessary to construct the aseptic bottling apparatus disclosed therein are missing"). For example, Patent Owner alleges that the asserted references disclose using "sterilant, and us[ing] enough to get a desired kill, but not too much so that it cannot be adequately removed in order to meet the FDA residual peroxide requirement of 0.5ppm," without quantifying the necessary parameters. *Id.* at 39 (citing Ex. 2025 ¶ 30). However, as noted repeatedly, claims 18 and 19 do not include an FDA residual peroxide requirement of

0.5 ppm. As discussed with respect to each limitation of claims 18 and 19, the prior art provides sufficient disclosure for a skilled artisan to have practiced these claims.

I. Claim 20

Petitioner contends that claim 20 is unpatentable as having been obvious over the combination of Biewendt, Bosch Brochure, Buchner, ZFL, and Chambers. Pet. 41–42, 48–50.

"*wherein a residual level of hydrogen peroxide is less than 0.5 PPM"*

Claim 20 is narrower than claims 18 and 19 because claim 20 requires disinfection of bottles with "hot hydrogen peroxide" and "wherein a residual level of hydrogen peroxide is less than 0.5 PPM." It is undisputed that the prior art teaches the use of hydrogen peroxide to disinfect bottles. *See* Ex. 1019, 5, 18; Pet. 49 (Petitioner also refers to the teachings of Buchner and ZFL for this limitation). In our initial Final Written Decision, we determined that the asserted prior art references did not teach the limitation "wherein a residual level of hydrogen peroxide is less than 0.5 PPM" and we incorporate that analysis here. Paper 69.

The question before us now is whether the asserted prior art, as a whole, was enabling such that a skilled artisan would have had a reasonable expectation of success in practicing a method that would have "aseptically" disinfected bottles at a rate greater than 100 bottles per minute and also met the claimed maximum 0.5 ppm residual hydrogen peroxide requirement. *See In re Antor Media Corp.*, 689 F.3d at 1290 (the prior art "only needs to enable the portions of its disclosure alleged to [invalidate] the *claimed* invention" (emphasis added)). We are cognizant, as Patent Owner argues (PO Resp. 16–17), that the parameters of sterilization technology are

interdependent, and specifically that sufficient sterilant must be applied to sterilize the bottles, while being able to remove the sterilant sufficiently to satisfy the 0.5 ppm residual hydrogen peroxide requirement claimed. *See* Ex. 2025 ¶¶ 26, 40. In other words, there is a "sweet spot"—sufficient sterilant to sterilize, but only so much that it can be removed sufficiently to meet the FDA requirement. *See* Tr. 47:18–21 (Patent Owner arguing that "if you hit the right time and temperature you don't have to use as much sterilant. If you don't use as much sterilant, you can evacuate it much more easily and you can process it much more quickly."). Petitioner disagrees that this tension would have existed, arguing that "any such problems presuppose that the claims require both a minimum disinfection level and a maximum 0.5 ppm residue," and "they do not." Pet. Reply 22. We are not persuaded by Petitioner's argument.

The parties dispute the level of sterilization required by the challenged claims, but both agree that some degree of sterilization is required. Patent Owner argues that the "FDA level of aseptic" required "demonstrating that a 6 log reduction of spore organisms was achieved on the packing material," and that "the target organism was *bacillus subtilis*" when hydrogen peroxide was the sterilant.[28] PO Resp. 41, 44–46. Petitioner argues that although "[t]he FDA regulations . . . do not define a 'level' of 'aseptic,'" the regulations do state that "'aseptic processing and packaging' is the filling of containers 'in *an atmosphere free of microorganisms* . . . having public

[28] We note that subsequent to the Federal Circuit's remand decision, Patent Owner requested additional briefing to argue that 21 C.F.R. § 178.1005(d) and § 178.1005(e) were applicable to the claim term "aseptic," but did not argue that regulations requiring a 6 log reduction in spore organisms or a 6 log reduction in *bacillus subtilis* were applicable. *See* Papers 72, 73, 78, 81.

health significance.'" Pet. Reply 8 (emphasis added) (citing 21 C.F.R. § 113); Tr. 12:17–20, 13:22–24. Petitioner further asserts that claim 20 does not require a "minimum disinfection level [like claim 19] and a maximum 0.5 ppm residue." Pet. Reply 22. Petitioner concludes that because "claim 20 recites 0.5 ppm H_2O_2 residue with *no* specific disinfection level," "any difficulty achieving *both* objectives is immaterial to the invention *as claimed*." *Id*. at 22. We disagree.

By virtue of reciting "aseptic," as in "aseptically disinfecting," claim 20 requires an "FDA level of aseptic." As the Federal Circuit stated, at the time of the application, the FDA defined "'aseptic processing and packaging' as 'the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms.'" *Nestle*, 686 F. App'x at 919. However, we need not decide precisely what level of sterilization is required by claim 20's recitation of "aseptic," as it is not disputed that some level is required. Thus, we disagree with Petitioner's contention that "any difficulty" with using enough sterilant to sterilize and not too much to meet the 0.5 ppm residual level is "immaterial." *See* Pet. Reply 22. We find that the evidence of record establishes that the interdependence between using a sufficient sterilant amount and being able to remove it to a sufficient level is relevant to whether the skilled artisan would have had a reasonable expectation of success in practicing claim 20.

For this limitation, Petitioner refers to the disclosures in Biewendt, Buchner, and ZFL. Although referring to Biewendt's disclosure of hot hydrogen peroxide to sterilize bottles, Petitioner admits that Biewendt "does not . . . specify that residual H_2O_2 is 'less than 0.5 PPM,' as claimed." Pet.

49. Petitioner, however, refers to Buchner and ZFL, each of which discloses a residual hydrogen peroxide level of not greater than 0.5 ppm. Pet. 49–50 (citing Ex. 1006, 4; Ex. 1007, 3). Petitioner has not sufficiently persuaded us that the combination of these disclosures teaches "wherein a residual level of hydrogen peroxide is less than 0.5 PPM."

Specifically, Petitioner has not persuaded us that the prior art taught a skilled artisan how to reach the sweet spot identified above (i.e., the balance between enough sterilant to aseptically disinfect without exceeding the specified 0.5 ppm residual level) with a reasonable expectation of success. Although Petitioner refers to disclosure in both Buchner and ZFL indicating that such a residual requirement of less than 0.5 ppm was achieved, Petitioner has not shown how the asserted references enable a skilled artisan to practice this requirement. In particular, Petitioner does not sufficiently explain how a skilled artisan would have modified Biewendt with the teachings of Buchner and/or ZFL to practice the 0.5 ppm residual hydrogen peroxide requirement. The Petition merely asserts that "it would have been obvious to ensure that the process disclosed in Biewendt would have a residual requirement of 'less than 0.5 PPM,' as claimed." Pet. 49–50. In its Reply, Petitioner asserts the following:

> The Bosch references teach two methods of sterilant removal: "rinsing on either side with sterile water" or "drying using hot sterile air." Ex. 1006 at 2, 3 ("bottles are then washed out externally at 1 station and internally at 3 stations [15 s] with sterile water"); Ex. 1019 at 18 ("drying effect of said H_2O_2 with at least 80°C hot air"). PO offered no evidence that residual levels of < 0.5 ppm *would not* be achieved by rinsing the bottles with water for > 15 s or applying > 80°C hot air as taught by the Bosch references.

Pet. Reply 22. Petitioner mistakenly shifts the burden to Patent Owner to disprove that the asserted references taught this limitation. Petitioner, however, has the burden to show by a preponderance of the evidence how either method of sterilant removal would have achieved the "wherein a residual level of hydrogen peroxide is less than 0.5 PPM" limitation.

Petitioner has not carried this burden. Petitioner argues that "the alleged difficulties balancing disinfection and residue arise when removing H_2O_2 with air," and that "[w]ater rinsing taught by *Buchner*, as PO's [declarant] acknowledged, is *more effective* than air in removing H_2O_2." *Id*. at 22–23 (citing Ex. 1025 (Dr. Sharon testimony), 63:6–23). Dr. Sharon testified, in response to the question, "how effective is using a sterile water rinse at removing residual hydrogen peroxide in an aseptic processing system?," that "I could not quantify that for you. It has some effect, but I could not quantify that for you." Ex. 1025, 63:6–13. Dr. Sharon further testified, in response to the question, "Is [a sterile water rinse] more or less effective than using an air rinse?," that "I believe that it would be – I couldn't quantify it, but I believe that it would be more effective, or at least it would – it would aid the process certainly if you were doing both. And I couldn't quantify, you know, exactly . . . ." *Id.* at 63:15–23. Although Dr. Sharon acknowledges that a sterile water rinse is more effective than an air rinse, Petitioner does not identify the parameters of a sterile water rinse that would be more effective. For example, Petitioner does not refer to temperature and time of the water rinse used in Buchner that achieved the maximum hydrogen peroxide requirement. Petitioner contends Buchner

discloses a sterile water rinse of "5s out[side], 15s in[side]."[29] Pet. Reply 12 (citing Ex. 1006, 3). Buchner, however, discloses spraying with hydrogen peroxide for approximately 15 seconds, but does not disclose the amount of time that bottles are rinsed with sterile water. *See* Ex. 1006, 3. Buchner only states that "[t]he bottles are then washed out externally at 1 station and internally at 3 stations with sterile water and blown out again with sterile air at another station." *Id.* at 3.

Even accepting Petitioner's assertions regarding Buchner, Petitioner does not provide persuasive argument or evidence that a skilled artisan would have incorporated Buchner's sterile water rinse into Biewendt, which teaches removing the sterilant by drying the bottles with hot air (Ex. 1019, 18), to achieve the FDA required residual hydrogen peroxide level.[30] *See* Pet. 49–50; Pet. Reply 9. For example, Petitioner does not sufficiently persuade us that a skilled artisan would have modified the Biewendt apparatus—by substituting in a water rinse, with the associated parameters taught by Buchner, for drying the bottles with hot air at 80 °C— because the

[29] Petitioner seems to assume that in Buchner's aseptic bottling system, bottles spend 5 seconds at each station. However, Buchner does not provide disclosure to this effect (Ex. 1006, 3), nor does Petitioner explain how it arrived at this number. *See* Pet. 37–38 (Petitioner contending that Buchner's statement "[t]he sterilant is sprayed onto the bottles "at 3 stations for approximately 15 sec" means "5 seconds per station").

[30] This finding is not inconsistent with our finding that a skilled artisan would have had reason to combine the asserted references in practicing claims 18 and 19, despite design differences in the references. Here, the design differences between a sterile water rinse in Buchner and drying the bottles with hot air in Biewendt might affect the amount of hydrogen peroxide residue remaining on the bottles and the ability to disinfectgreater than 100 bottles per minute.

proposed modification would necessitate changing other parameters disclosed in Biewendt in order to still achieve the FDA required maximum residual level of 0.5 ppm hydrogen peroxide at a sterilization rate of greater than 100 bottles per minute, as required by claim 20. Thus, Petitioner does not sufficiently persuade us that a skilled artisan would have known how to successfully modify the sterilant parameters taught by Biewendt to include the Buchner water rinse, and still achieve the required maximum residual level of 0.5 ppm hydrogen peroxide at a sterilization rate greater than 100 bottles per minute.[31]

Petitioner also has not sufficiently persuaded us that merely knowing which parameters are relevant in a sterilization process would have enabled a skilled artisan to modify the teachings of the asserted references to arrive at claim 20 with a reasonable expectation of success. Specifically, Petitioner argues that "one skilled in the art would look at [the asserted] references as a whole and would look at the various parameters they have there and [they] would certainly give them a limited choice of parameters that could be used to achieve the results that are disclosed in the patent[]." Tr. 87:13–18; *see* Ex. 1005 ¶ 21 (Petitioner's declarant opining that "the relationships between sterilant temperature, concentration, and exposure time has been known for decades"); *see also* Ex. 1005 ¶¶ 19, 20, 22. Patent Owner, however, has

[31] Regarding ZFL, we agree that ZFL discloses residual sterilant levels of less than 0.5 ppm. Ex. 1007, 3. However, ZFL does not provide sterilant temperature and sterilant application time, even though it states that the disclosed apparatus achieved the FDA required residual level of hydrogen peroxide. *See* Pet. 12, 49–50; Ex. 1007, 3; *see also* Pet. Reply 12 (relying on Buchner regarding residual sterilant, and not addressing ZFL).

provided persuasive argument and evidence that there are complexities in modifying these parameters, especially given the narrow scope of claim 20's requirements. In response to Petitioner's reference to background technology, Patent Owner's declarant stated:

> [I]t simply tells a mechanical engineer that all of the parameters for designing an aseptic sterilization and filling machines are interdependent and need to be balanced. It does not quantify the parameters, and even if it did, it does not provide any guidance as to how to ensure that the actual bottle in a machine is exposed to these same theoretical conditions.

Ex. 2025 ¶ 30; *see also* Ex. 2025 ¶ 40 (Patent Owner's declarant stating that "[t]he interdependent nature of such variables in an aseptic packaging machine requires guidance in order to converge on a working process. The Bosch references do not provide a POSITA with any such guidance."); Ex. 1025, 35:5–14, 44:18–45:6; Ex. 1025, 109:25–110:14; PO Resp. 38–40, 49–58. Therefore, considering the evidence of record, Petitioner has not provided sufficient arguments and evidence to support a finding that the prior art discloses sufficient teachings to allow a skilled artisan to modify the sterilization parameters to arrive at the method of claim 20 with a reasonable expectation of success.

Petitioner also contends that the prior art enables the claimed methods because the "Bosch references" disclose "at least as much information as the '013 patent" and "actually provide more information than the '013 patent about parameters." Pet. Reply 12. Specifically, Petitioner argues that the combination of Biewendt and Buchner teaches a greater rate of sterilization than the process described by the '013 patent because the combination teaches the application of the sterilant, hydrogen peroxide, at a greater temperature and for an increased time compared to those disclosed in the

’013 patent. Pet 47–48; Ex. 1005 ¶¶ 66–67. Whether the ’013 patent is enabling is not the issue here. At issue here is whether Petitioner has shown that the asserted references would have led a person of ordinary skill in the art to the method of claim 20. *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1310 (Fed. Cir. 2015) (“The obviousness inquiry turns on what the prior art would have taught a person of ordinary skill in the art and whether the claimed invention would have been obvious in view of the *prior art*.” (emphasis in original)). Furthermore, Petitioner cites to two Federal Circuit decisions (Pet. 13–14), neither of which is instructive to our analysis. *Sri Int’l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008) relates to the enablement standard for prior art under 35 U.S.C. § 102(b), not at issue here. In *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1471 (Fed. Cir. 1997), the Federal Circuit reviewed the district court’s denial of JMOL and stated that “the record was sufficient to entitle the jury to conclude that the reference was enabling.” We find these facts are not relevant to our analysis because the issue is whether the body of prior art asserted enables the claimed method

Therefore, we find that Petitioner has not shown by a preponderance of the evidence that the asserted references teach a skilled artisan how to achieve the limitation “wherein a residual level of hydrogen peroxide is less than 0.5 PPM” with a reasonable expectation of success. Accordingly, we find that Petitioner has not shown by a preponderance of evidence that claim 20 is unpatentable as having been obvious.

J. Unpredictability of the Art

Patent Owner does not explicitly argue that there are secondary considerations of nonobviousness. *ZUP, LLC v. Nash Mfg.*, Inc., 896 F.3d

1365, 1373 (Fed. Cir. 2018) ("While [the] burden of persuasion remains with the challenger, a patentee bears the burden of production with respect to evidence of secondary considerations of nonobviousness."). However, with respect to all the challenged claims, Patent Owner argues that arriving at the challenged claims based on the asserted references was highly unpredictable, and that many failed in their attempts to build aseptic bottling systems that could meet FDA standards. PO Resp. 2.

Although claim 20 is not limited to processes involving low acid foodstuffs, Petitioner's asserted ground of unpatentability is based upon references that include processing of low acid foodstuffs. *See* Ex. 1006, 5 (Buchner stating that the "[t]he following products, inter alia, are of interest for aseptic packing in the pH range above 5.5; milk products . . ."); Ex. 1007, 1 (ZFL stating that "[t]here is a whole array of filling goods in the neutral or low-acid pH-range, such as UHT milk and UHT milk drink"); Ex. 1009, 1 (Bosch Brochure stating that "[f]or low-acid and neutral products (pH>4.5), a special process is used, applying heated hydrogen peroxide"); Ex. 1019, 1 (Biewendt disclosing aseptic filling and sealing plant for bottles for UHT milk). *See* Tr. 23:10–12 (Petitioner agrees that the Bosch references are about low acid foodstuffs). Patent Owner argues that the engineering underlying LAASF is unpredictable. PO Resp. 16–17. For example, Patent Owner contends that "[d]evelopment of LAASF processes usually requires half a decade or more of experimental trial and error due to the competing and conflicting design parameters and the inherent complexity of both the fluid dynamics in a bottling system and the related sterilization chemistry." *Id*. at 17 (citing Ex. 2025 ¶ 16; Ex. 2018, 1). Relying on Dr. Sharon's declaration, Patent Owner asserts:

> Of particular importance is the tension between using enough sterilant to kill the relevant microorganism of greatest concern on the one hand, while on the other the hand ensuring that less than 0.5 parts per million residual peroxide remains on the interior of the package before it is filled (which is required by the FDA).

Id. (citing Ex. 2017, 47; Ex. 2025, ¶ 26). Specifically relevant to claim 20, Dr. Sharon states:

> The narrow path between using enough sterilant to sterilize the bottles on the one hand while being able to remove the sterilant sufficiently such that the residual requirement for the FDA is met on the other, largely drives the design process of a low acid sterilization and filling machine that will meet FDA levels of aseptic.

Ex. 2025 ¶ 26. "The narrow path," explains Dr. Sharon, "makes the design of low acid sterilization and filling systems for FDA approval particularly difficult and complex." *Id*. ¶ 24. Relying on the declarations of Drs. Sharon and Buie, Patent Owner contends:

> [T]he unpredictability in LAASF processes arises from the fact that the design of such processes requires delicate balancing of interdependent variables such as temperature of the sterilant, temperature of the rinsing fluid, concentration of sterilant, any structure limitations on the packaging materials, the temperature of the bottle when the fluids (both sterilizing and rinsing) are applied to the bottle, airflow through the system, sterilant drop size, and sterilant flow rates.

PO Resp. 21 (citing Ex. 2025 ¶¶ 20, 30, 39–40, 45–47; Ex. 2026 ¶¶ 7–11). Patent Owner further asserts that "[e]ach of these parameters is non-linear and oftentimes cannot be adjusted without having an adverse effect on another parameter." *Id*. As an example, Patent Owner explains that "increasing the dose of sterilant can improve disinfection but may create exponential difficulties in removing the sterilant before filling." *Id*. (citing

Ex. 2027, 62; Ex. 2025 ¶¶ 24, 26).

Patent Owner also contends that the failures of others, after the filing date of the '013 patent, in their attempts to design aseptic bottling machines that met FDA requirements, demonstrate the unpredictability of the art. PO Resp. 17–20, 48. Patent Owner asserts that "[t]here is every reason to believe that the manufacturers were fully aware of the Bosch machines, as those machines were being advertised by one of the leading companies in the industry," but yet "many failed in their attempts to develop a peroxide-based bottling systems (as in Bosch) which met FDA standards." *Id*. at 17–18. Patent Owner identifies multiple alleged failures of manufacturers' attempts to design an aseptic bottling system that satisfied FDA standards. *Id*. at 18–19. For example, Patent Owner presents evidence that an aseptic equipment manufacturer in 2009 was forced to abandon a five-year long effort to install a functioning aseptic sterilization and filling machine. *Id.* at 19 (citing Ex. 2019 ¶¶ 11, 41). The customer filed suit against the manufacturer alleging, for example, that "after years of modifications and tests, the bottling system still [did] not work" and could not consistently or reliably sterilize bottles or produce products that could meet FDA requirements, specifically asserting that excessive peroxide residual levels exceeded the FDA requirement to be saleable. Ex. 2019 ¶¶ 2, 41. We acknowledge, as Petitioner argues (Tr. 18:13–22), that Patent Owner's evidence of all the identified failures, is not specific as to whether these failures were due to the fact that the parties could not practice the claimed limitations of claim 20, or for other reasons. Despite this shortcoming, however, these failures are some evidence of the unpredictability of the art.

Nonetheless, we do not find Patent Owner's arguments regarding the

unpredictability of the prior art to be sufficiently persuasive with respect to claims 18 and 19. As a preliminary matter, Patent Owner's arguments with respect to unpredictability of the prior art focuses on FDA approval/validation, which is not a recited element of claims 19 and 20. *See* PO Resp. 17–20. For example, as discussed above with respect to the construction of the claim term "aseptic," the requirement of a maximum 0.5 ppm residual hydrogen peroxide level is not relevant to these claims. Thus, Patent Owner's argument that there is unpredictability given the "inherent tension" between using enough sterilant to kill the relevant microorganism and, at the same time, meeting FDA requirements on the amount of residual peroxide remaining on the interior of the package, is unavailing. To the extent Patent Owner argues that the fluid dynamics associated with LAASF would have led to unpredictability in practicing the methods of claims 18 and 19 (*see* PO Resp. 21–23), Patent Owner has not sufficiently shown how fluid dynamics associated with LAASF would have prevented a skilled artisan from arriving at the limitations of claims 18 and 19.

Weighing the evidence for obviousness analyzed above with respect to claims 18 and 19 along with Patent Owner's evidence with respect to the failure of others, we conclude that the weight of the evidence demonstrates the obviousness of claims 18 and 19. Here, again, Patent Owner refers to failed attempts in achieving FDA approval/validation of aseptic bottling systems, which is not a recited element of claims 18 and 19. *See* PO Resp. 17–19. For example, Patent Owner asserts that "many manufacturers failed in their attempts to develop FDA-compliant aseptic sterilization and filling processes" (*id*. at 17); "many failed in their attempts to develop a peroxide-based bottling systems (as in Bosch) which met FDA standards)" (*id*. at 18);

"a European equipment manufacturer requested FDA validation of an aseptic sterilization and filling apparatus and that application was rejected" (*id*.); GEA Procomac abandoned its efforts to develop a peroxide-based aseptic sterilization and filling machine and switched to a different design because it could not achieve FDA validation for systems that used hydrogen peroxide to sterilize plastic bottles (*id*. at 18; Ex. 2025 ¶¶ 29, 57); an aseptic cup equipment manufacturer's aseptic bottle filler "would not receive FDA validation absent significant modifications" (PO Resp. 18–19); and a European aseptic equipment manufacturer abandoned a five-year long effort to install a functioning aseptic sterilization and filling machine because it did not meet FDA standards (*id*. at 19).

However, weighing the evidence for obviousness analyzed above with respect to claim 20 along with Patent Owner's evidence with respect to the failure of others, we conclude that the weight of the evidence does not demonstrate the obviousness of claim 20. Unlike claims 18 and 19, claim 20 is much narrower, requiring sterilization at a rate greater than 100 bottles per minute, while maintaining the residual hydrogen peroxide on the bottles at less than 0.5 ppm. The opinion evidence provided by Drs. Sharon and Buie supports a finding that there was unpredictability of aseptic bottling in finding that sweet spot requiring the use of enough sterilant to kill the relevant microorganism of greatest concern, while meeting the residual hydrogen peroxide requirement of claim 20. *See* Ex. 2017, 47; Ex. 2025 ¶ 26. As Patent Owner's declarants explain, the interdependence of certain sterilization parameters (e.g., the temperature of the rinsing agent, the time it takes to apply the rinsing agent, and the temperature of the bottles during rinsing) make reaching this sweet spot, at a rate greater than 100 bottles per

minute, unpredictable. The failure of others to build aseptic bottling machines that satisfied FDA approval bears out this fact. *See* PO Resp. 17–20. Although it is unclear that all the identified failures were related to the inability to build an aseptic bottling machine that satisfied the hydrogen peroxide residual requirement, at least one identified failure relates to this requirement. *See* Ex. 2019 ¶¶ 2, 41 (complaint by customer against equipment manufacturer alleging that "excess peroxide residual levels in the 8 ounce bottles exceed the FDA requirement to be saleable"). Therefore, we find the evidence of the unpredictability and failure of others in the prior art further supports our determination that Petitioner has not carried its burden with respect to claim 20.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has shown by a preponderance of the evidence that claims 18 and 19 of the '013 patent are unpatentable. However, Petitioner has not shown by a preponderance of the evidence that claim 20 of the '013 patent is unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby

ORDERED that claims 18 and 19 have been shown to be unpatentable;

FURTHER ORDERED that claim 20 has not been shown to be unpatentable; and

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

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US006945013B2

(12) **United States Patent**
Taggart

(10) **Patent No.: US 6,945,013 B2**
(45) **Date of Patent: Sep. 20, 2005**

(54) **METHOD AND APPARATUS FOR ASEPTIC PACKAGING**

(75) Inventor: **Thomas D. Taggart**, South Wales, NY (US)

(73) Assignee: **Steuben Foods Incorporated**, Jamaica, NY (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/871,078**

(22) Filed: **May 31, 2001**

(65) **Prior Publication Data**

US 2002/0029543 A1 Mar. 14, 2002

Related U.S. Application Data

(62) Division of application No. 09/306,552, filed on May 6, 1999, now Pat. No. 6,536,188.
(60) Provisional application No. 60/118,404, filed on Feb. 2, 1999.

(51) **Int. Cl.**[7] **B67B 1/03**
(52) **U.S. Cl.** **53/426**; 53/425; 53/49
(58) **Field of Search** 53/426, 425, 49, 53/79; 422/28, 302, 292

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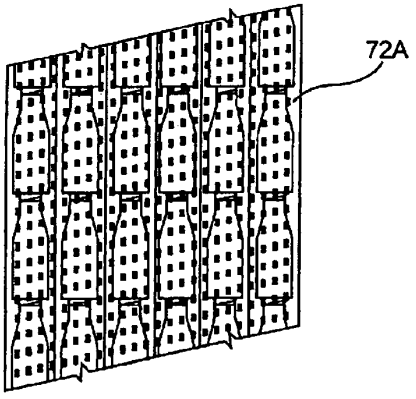
Primary Examiner—Sameh H. Tawfik
(74) *Attorney, Agent, or Firm*—Schmeiser, Olsen & Watts

(57) **ABSTRACT**

A method and apparatus for providing aseptically processed low acid products in a container having a small opening, such as a glass or plastic bottle or jar, at a high output processing speed.

20 Claims, 14 Drawing Sheets



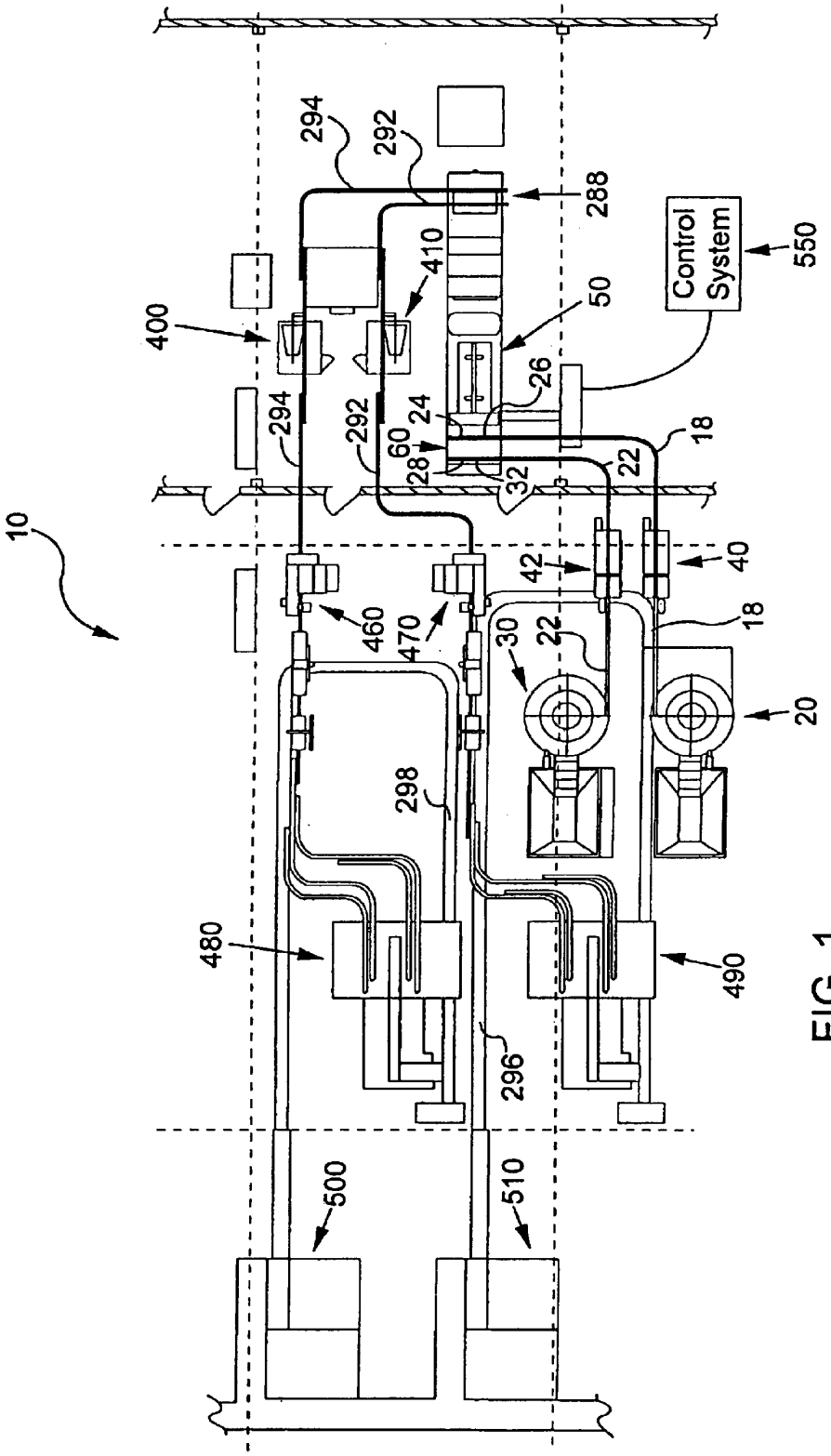

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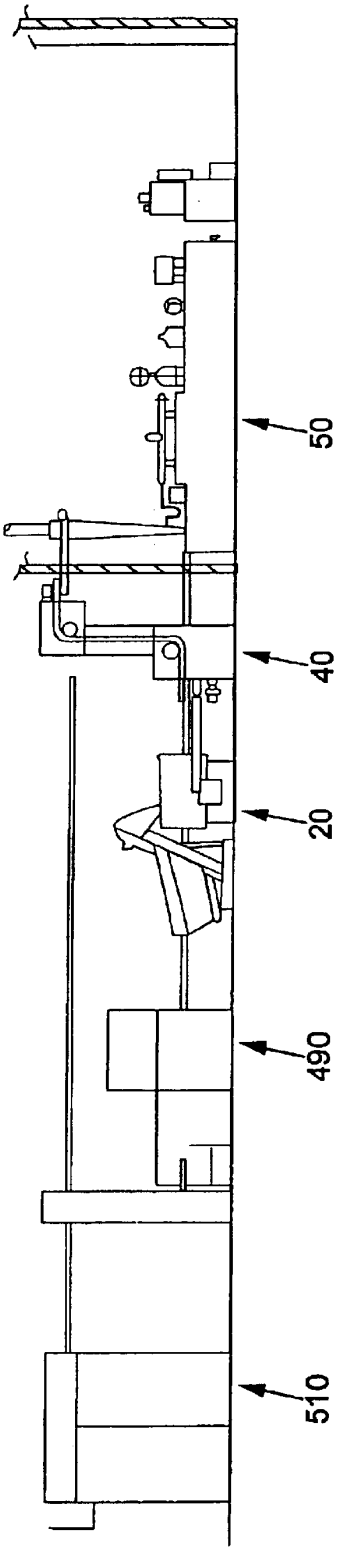
FIG. 1



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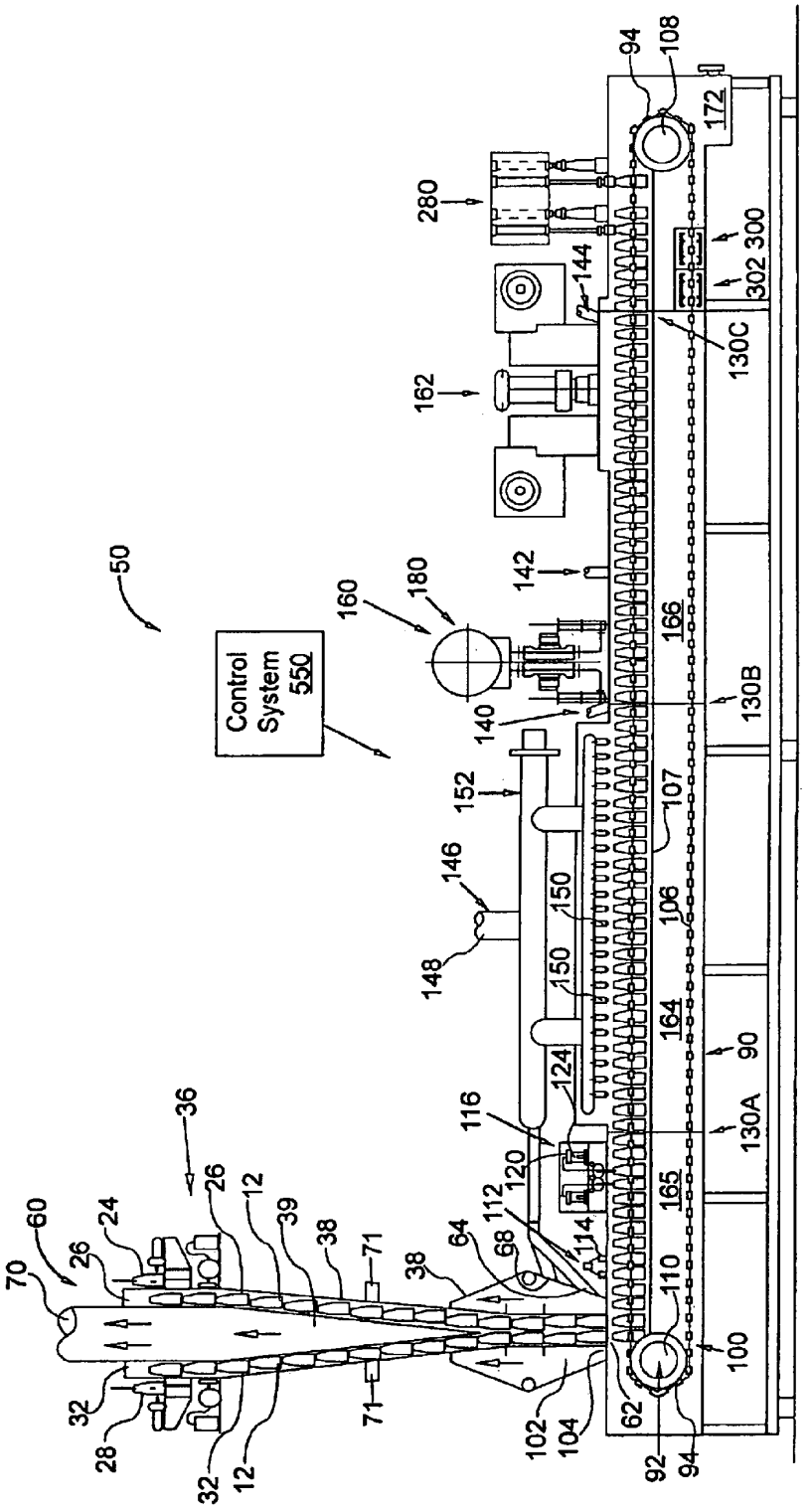
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FIG. 3

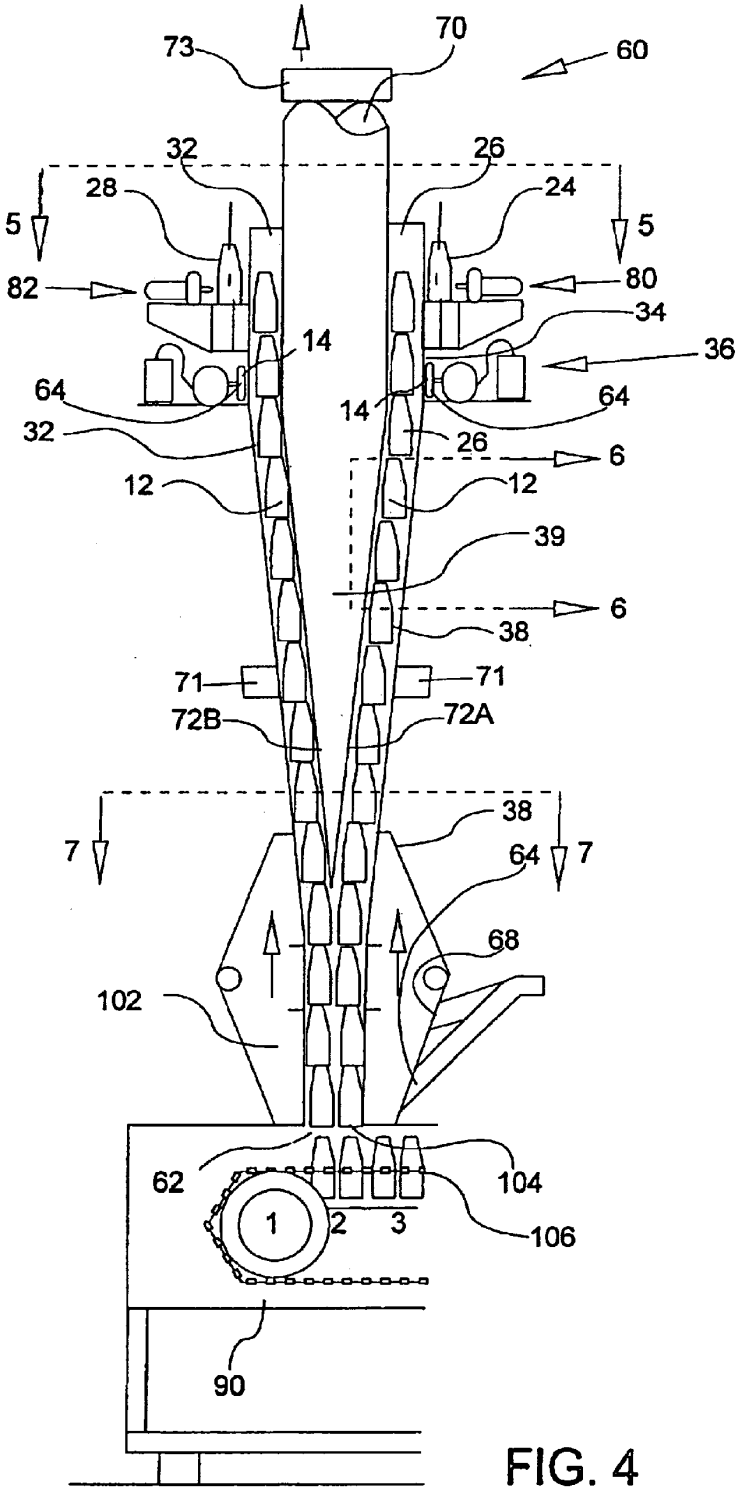
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FIG. 4

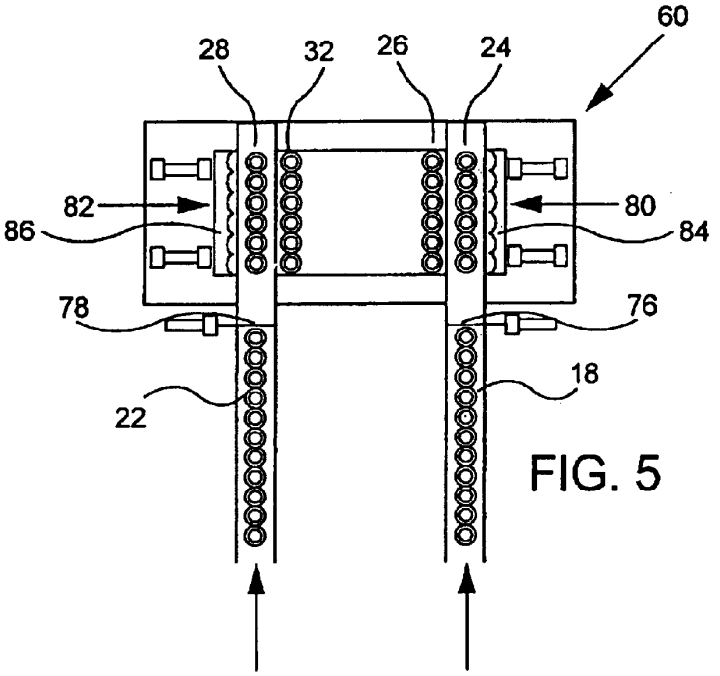

FIG. 5

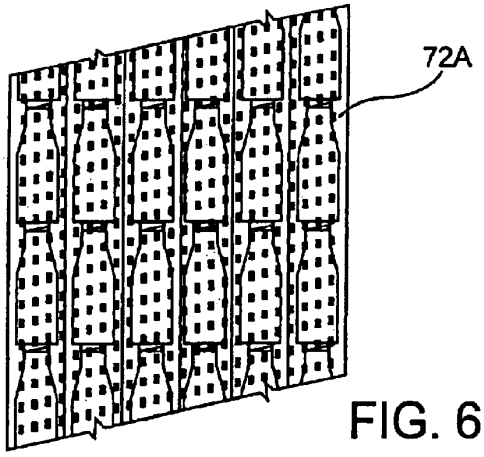

FIG. 6

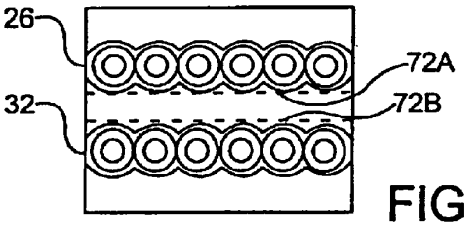

FIG. 7

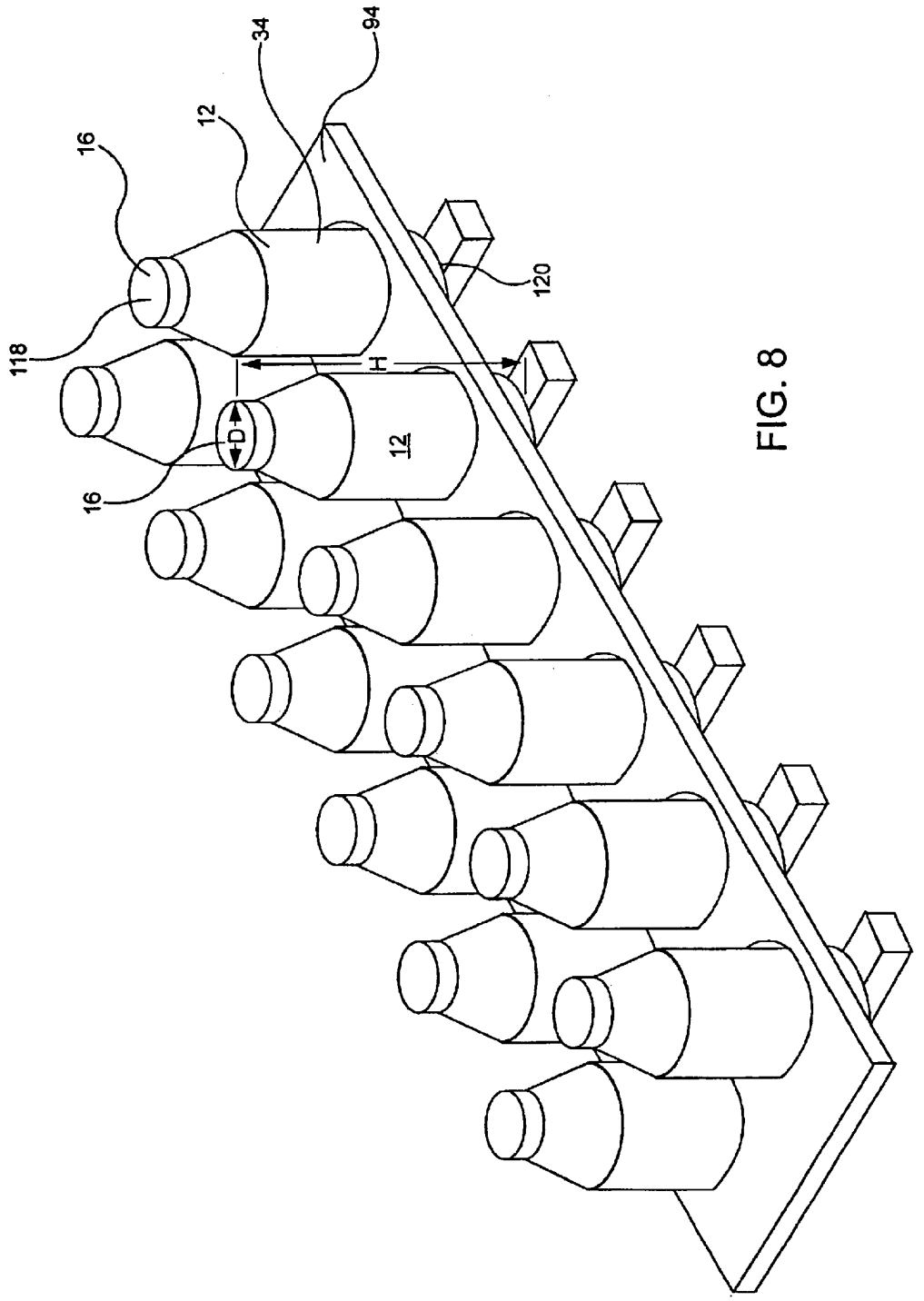

FIG. 8

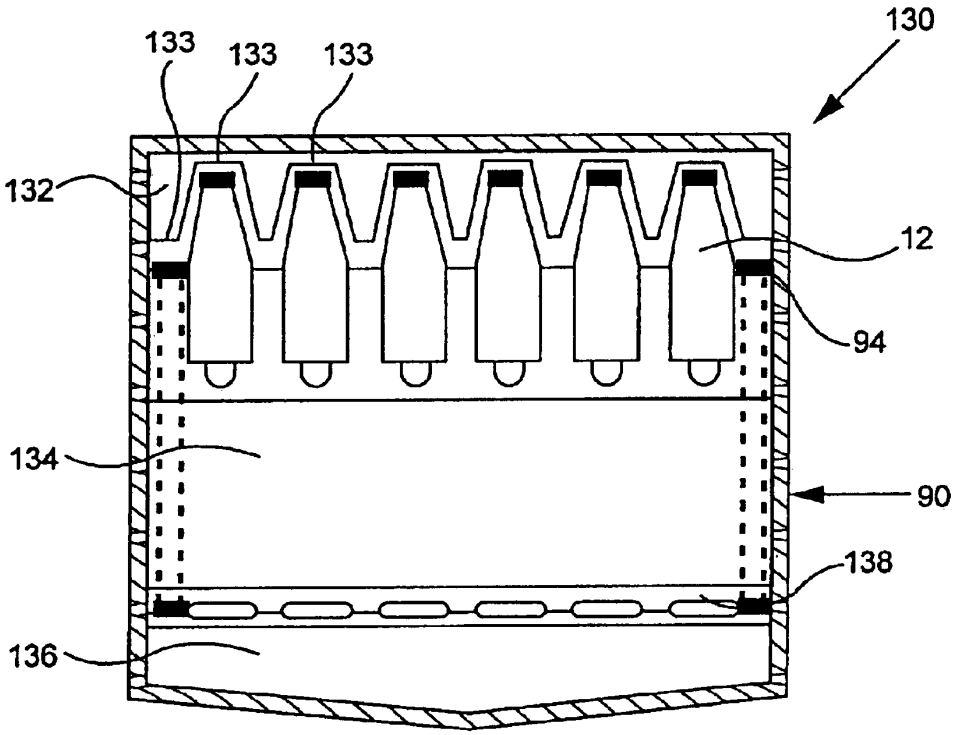

FIG. 9

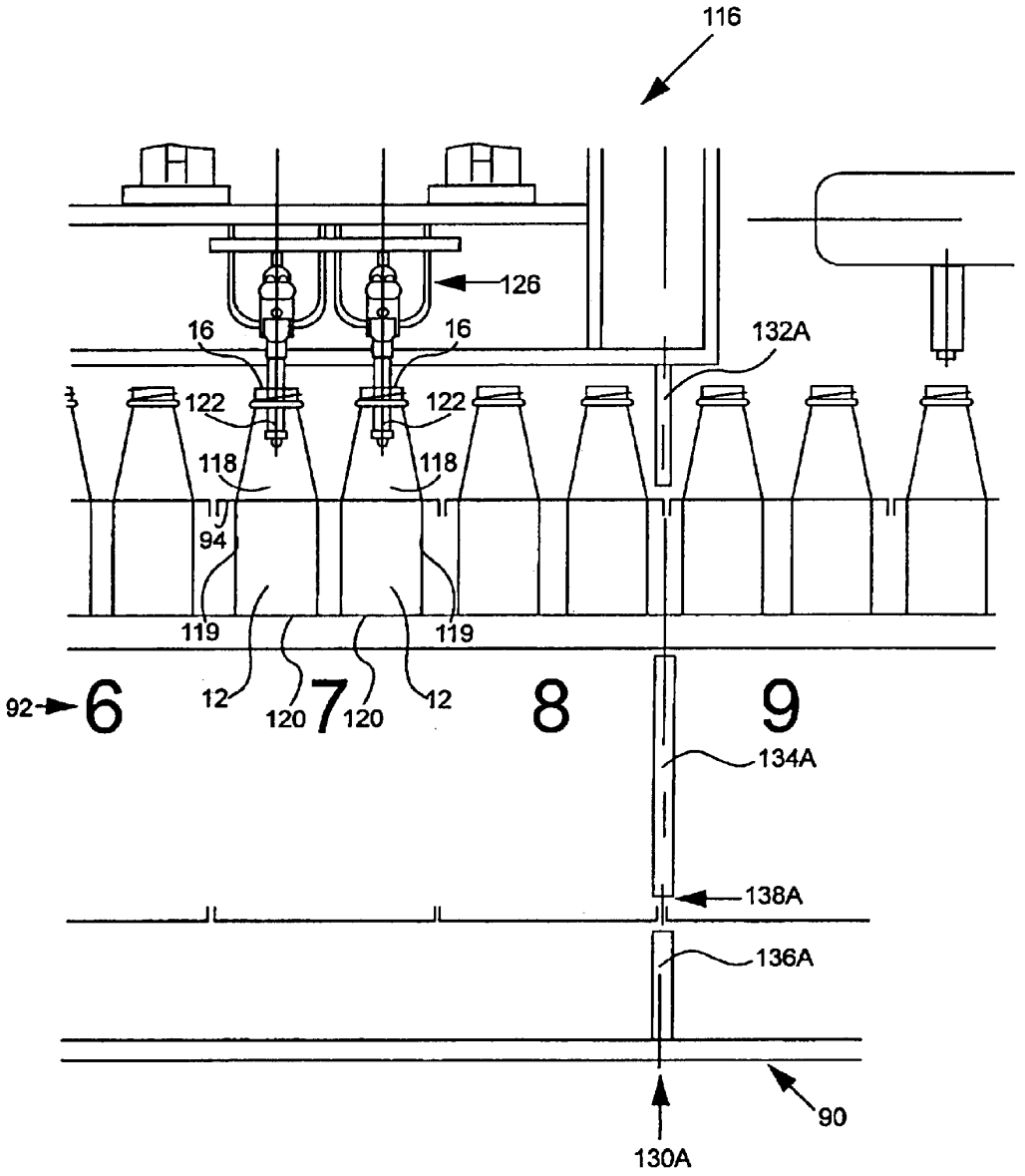
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FIG. 10

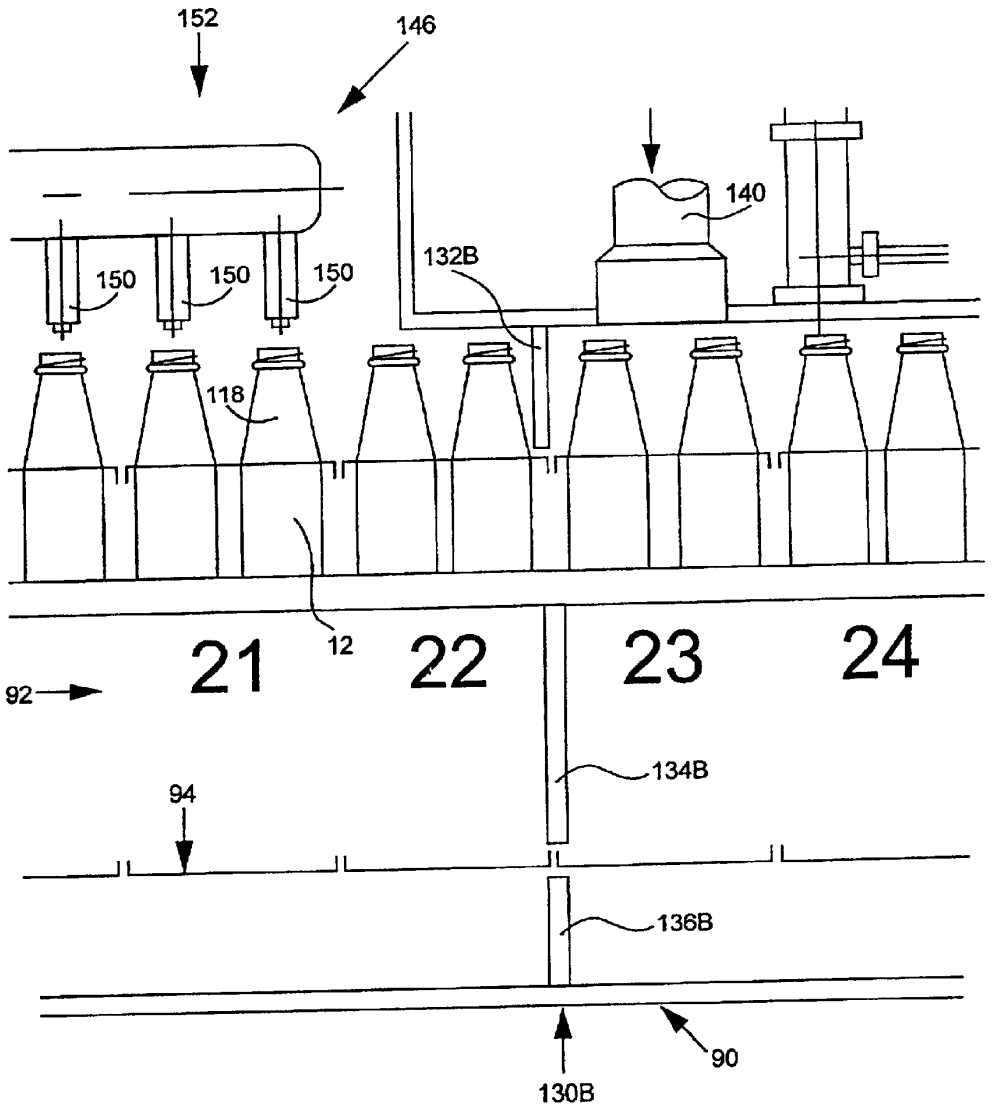
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FIG. 11

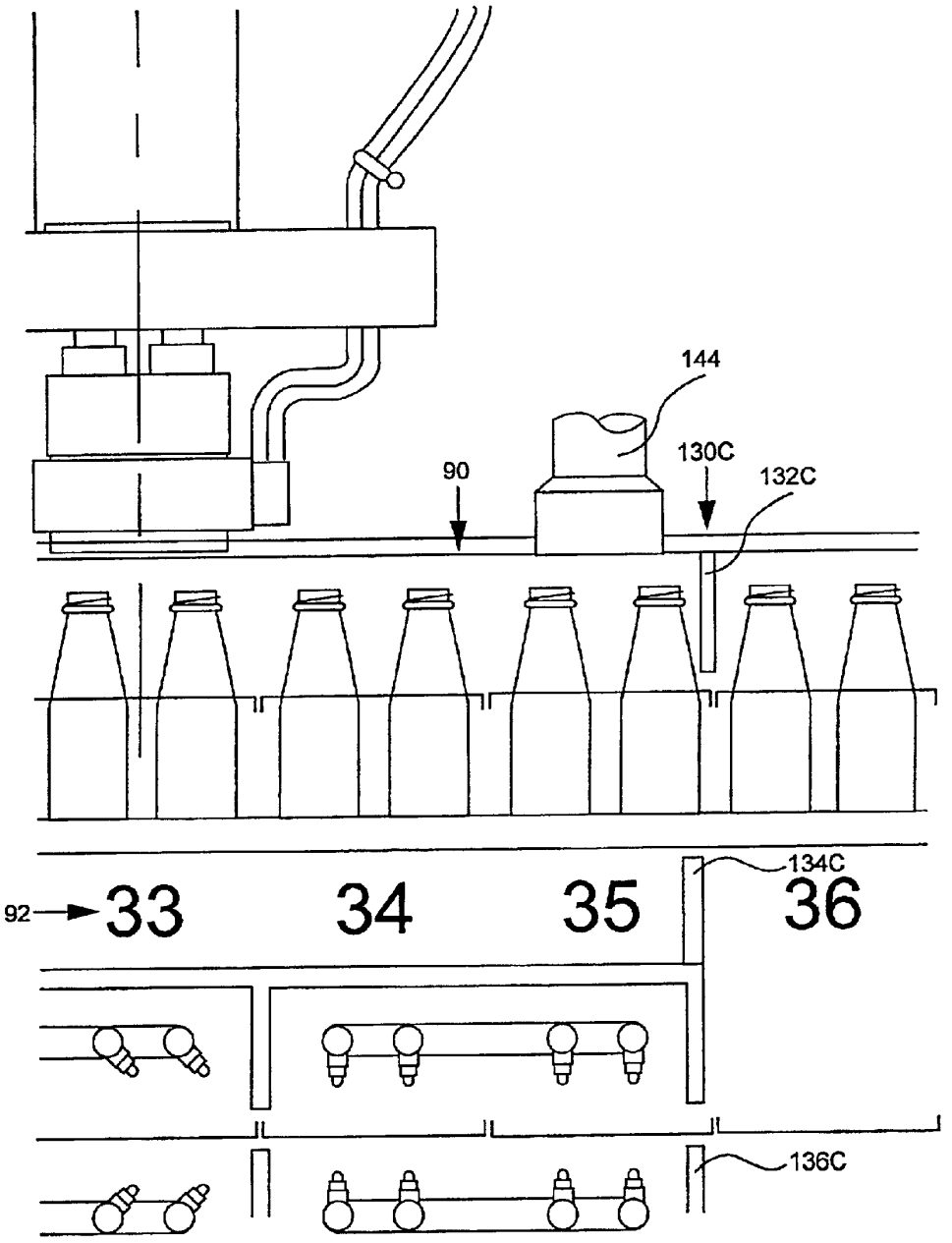
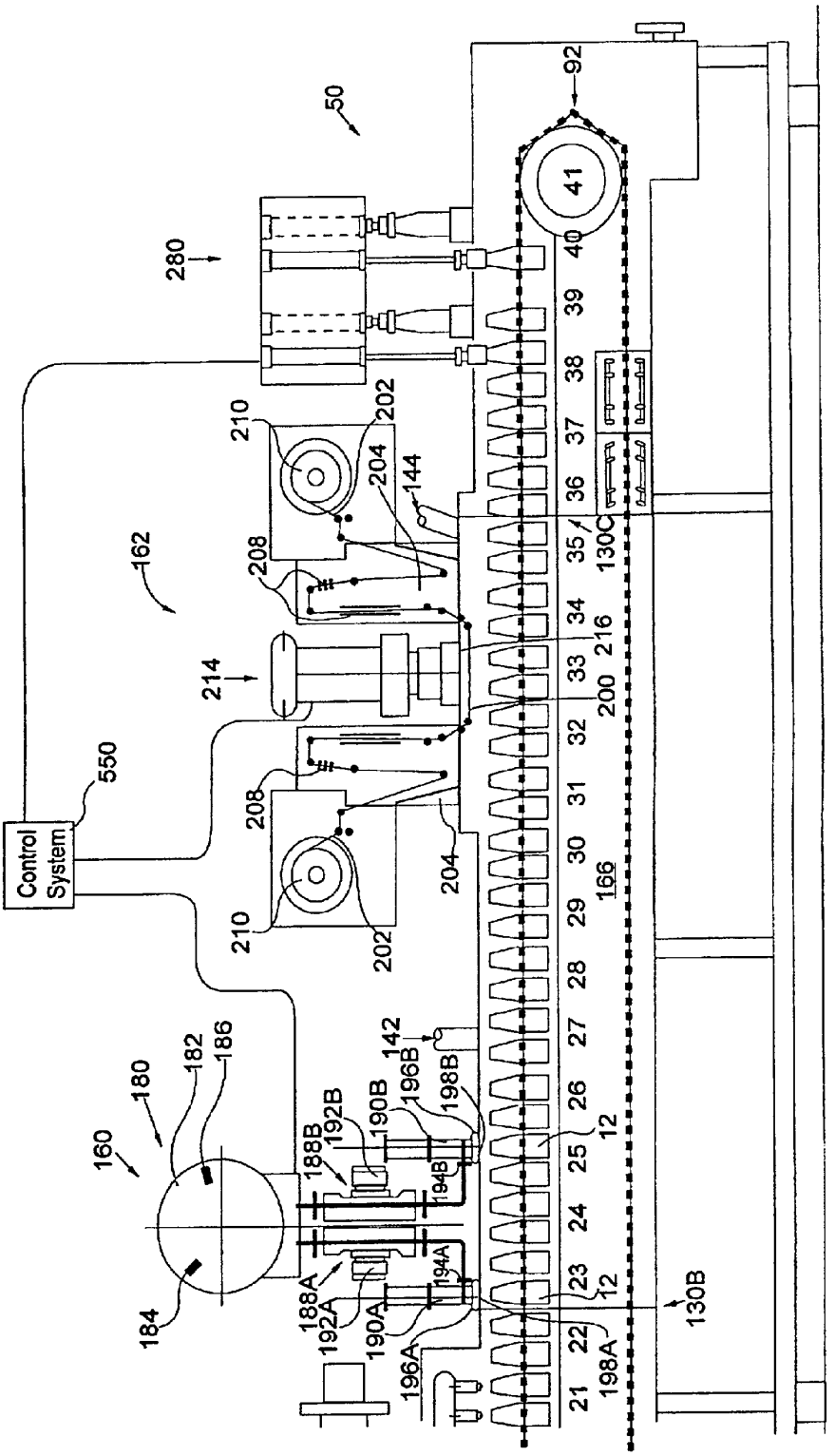


FIG. 12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Control System
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FIG. 13

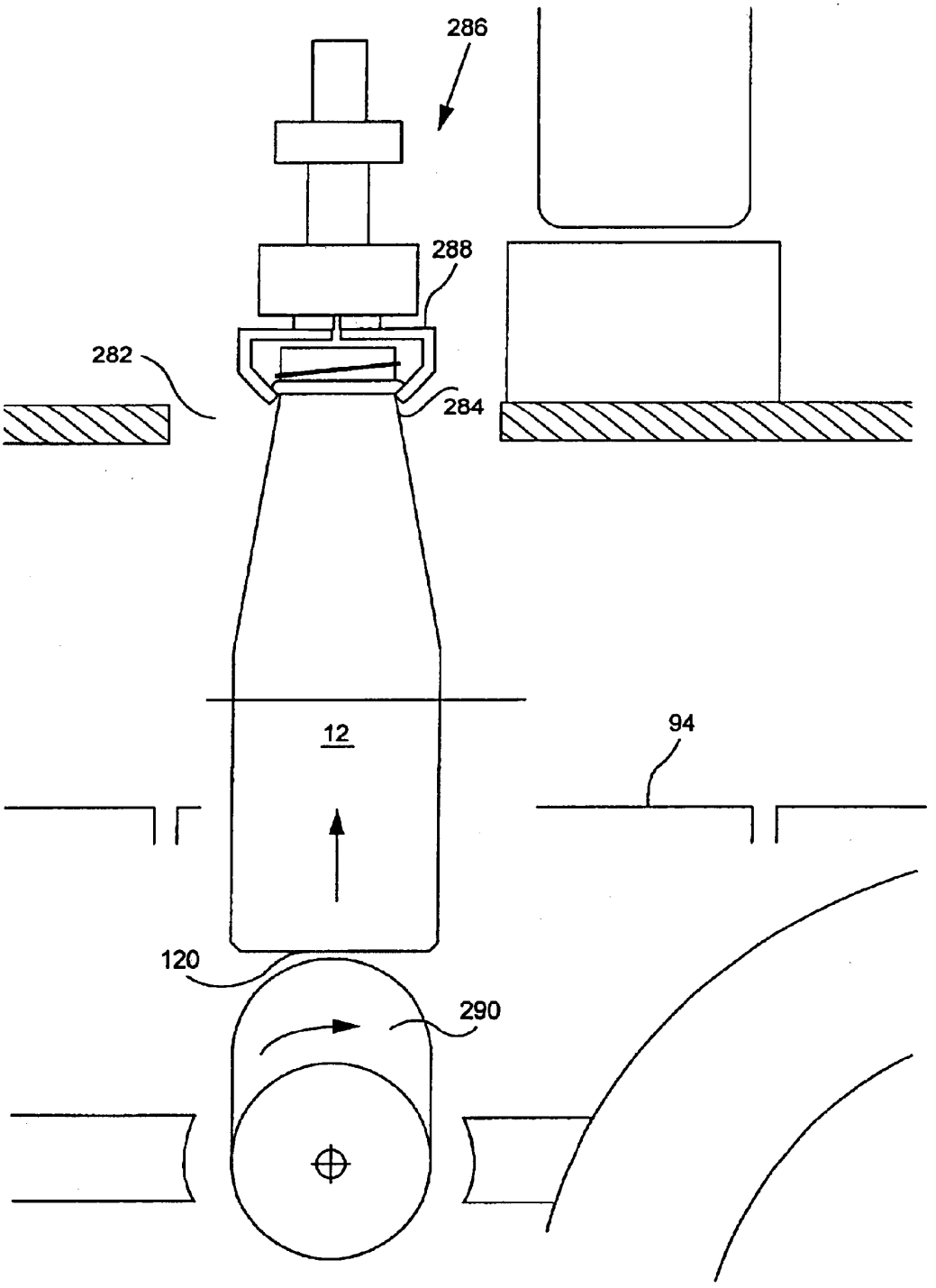

FIG. 14

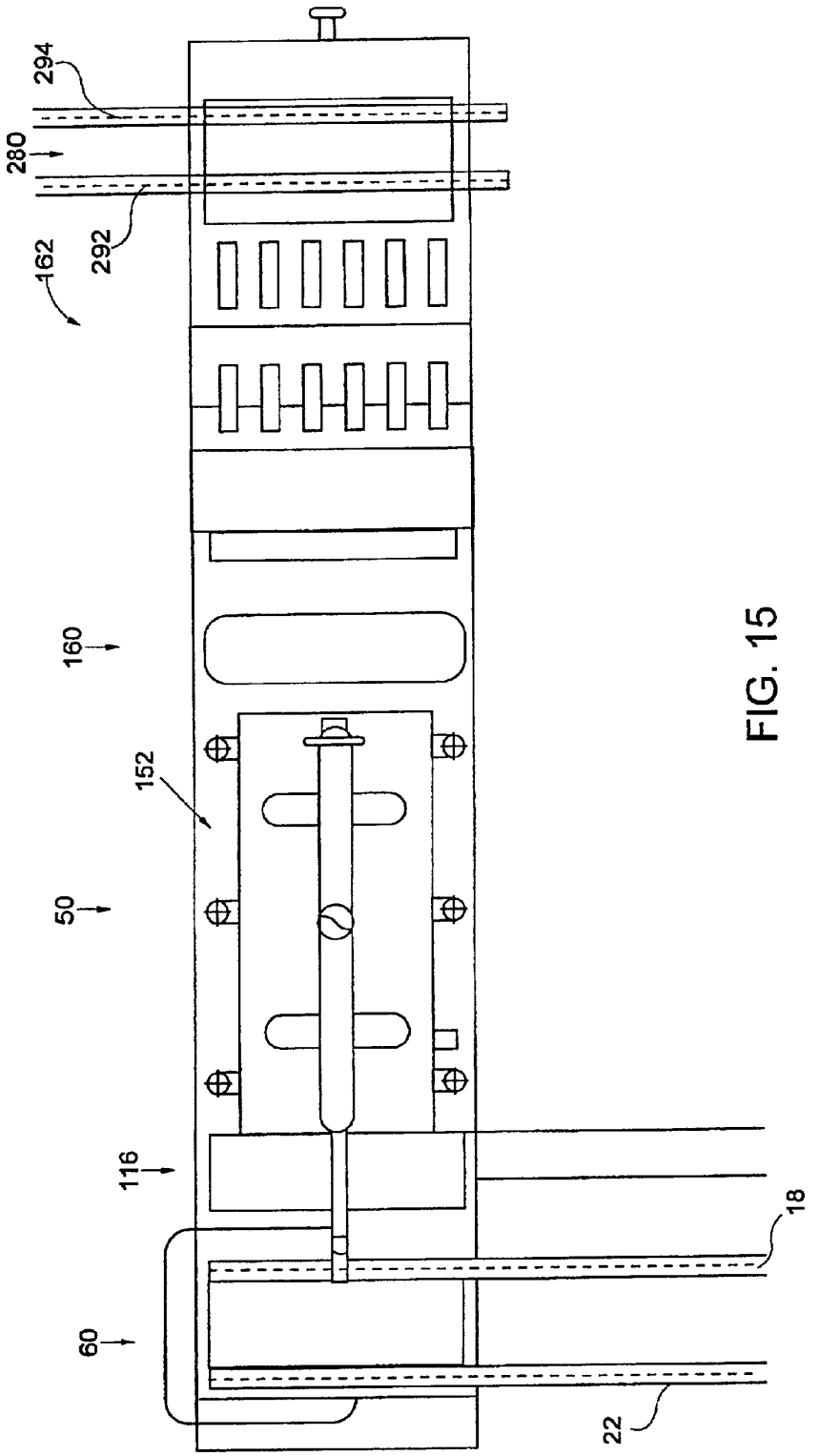

FIG. 15

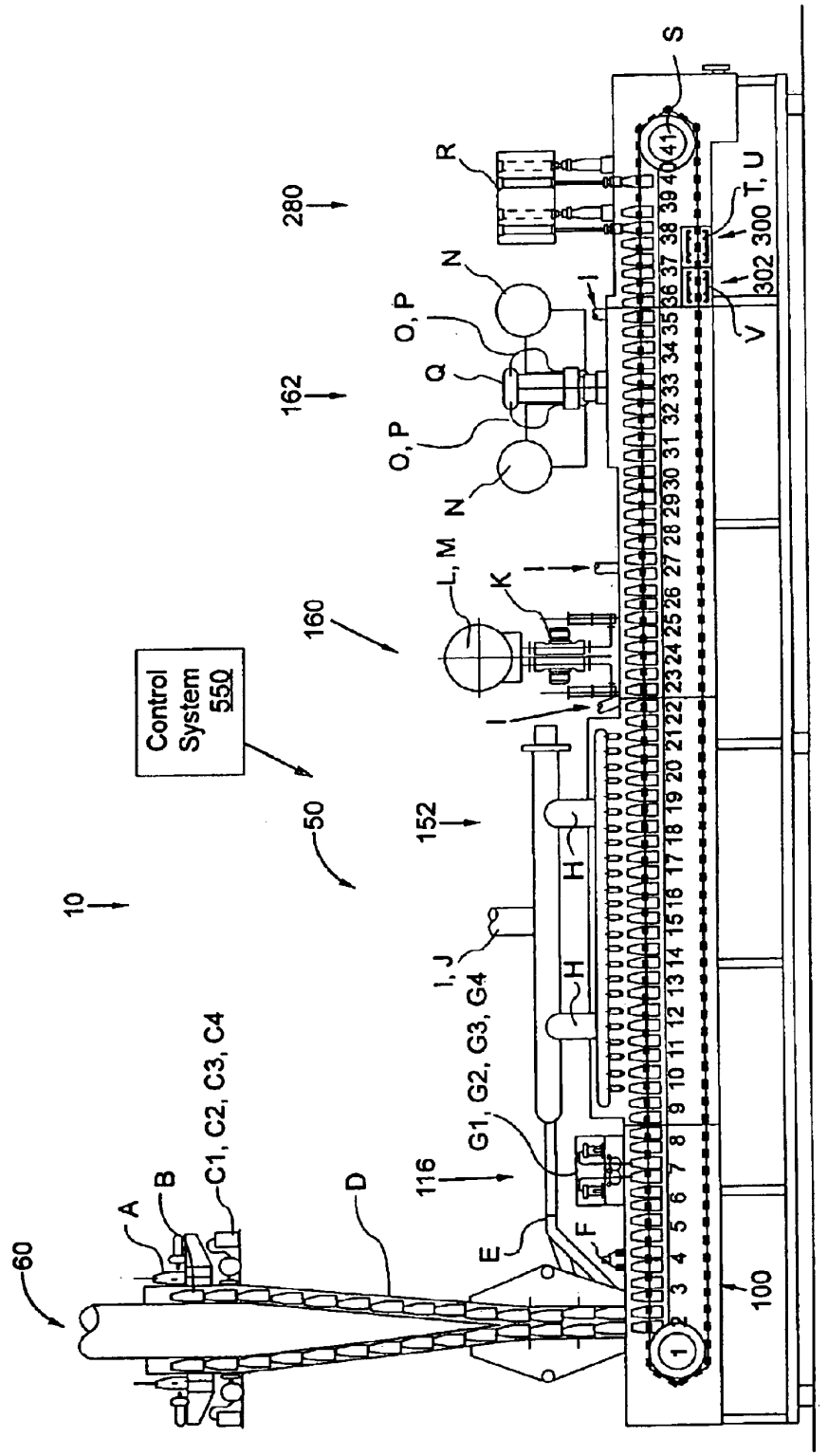
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FIG. 16

METHOD AND APPARATUS FOR ASEPTIC PACKAGING

This application is a divisional of Ser. No. 09/306,552, filed on May 6, 1999, now U.S. Pat. No. 6,536,188, which is a non-provisional of Ser. No. 60/118,404, filed on Feb. 2, 1999.

FIELD OF THE INVENTION

The present invention relates generally to systems for the aseptic packaging of food products. More particularly, the present invention relates to an aseptic packaging system for the aseptic packaging of food products in containers such as bottles or jars.

BACKGROUND OF THE INVENTION

Sterilized packaging systems in which a sterile food product is placed and sealed in a container to preserve the product for later use are well known in the art. Methods of sterilizing incoming containers, filling the containers with pasteurized product, and sealing the containers in an aseptic tunnel are also known.

Packaged food products can generally be categorized as high acid products (Ph below 4.5) or low acid products (Ph of 4.5 and above). The high acid content of a high acid product helps to reduce bacteria growth in the product, thereby increasing the shelf life of the product. The low acid content of a low acid product, however, necessitates the use of more stringent packaging techniques, and often requires refrigeration of the product at the point of sale.

Several packaging techniques, including extended shelf life (ESL) and aseptic packaging, have been developed to increase the shelf life of low acid products. During ESL packaging, for example, the packaging material is commonly sanitized and filled with a product in a presterilized tunnel under "ultra-clean" conditions. By using such ESL packaging techniques, the shelf life of an ESL packaged product is commonly extended from about 10 to 15 days to about 90 days. Aseptic packaging techniques, however, which require that the packaging take place in a sterile environment, using presterilized containers, etc., are capable of providing a packaged product having an even longer shelf life of 150 days or more. In fact, with aseptic packaging, the shelf life limitation is often determined by the quality of the taste of the packaged product, rather than by a limitation caused by bacterial growth.

For the aseptic packaging of food products, an aseptic filler must, for example, use an FDA (Food and Drug Administration) approved sterilant, meet FDA quality control standards, use a sterile tunnel or clean room, and must aseptically treat all packaging material. The food product must also be processed using an "Ultra High Temperature" (UHT) pasteurization process to meet FDA aseptic standards. The packaging material must remain in a sterile environment during filling, closure, and sealing operations.

Many attempts have been made, albeit unsuccessfully, to aseptically fill containers, such as bottles or jars having small openings, at a high output processing speed. In addition, previous attempts for aseptically packaging a low acid product in plastic bottles or jars (e.g., formed of polyethylene terepthalate (PET) or high density polyethylene (HDPE)), at a high output processing speed, have also failed. Furthermore, the prior art has not been successful in providing a high output aseptic filler that complies with the stringent United States FDA standards for labeling a packaged product as "aseptic." In the following description of the present invention, the term "aseptic" denotes the United States FDA level of aseptic.

SUMMARY OF THE INVENTION

In order to overcome the above deficiencies, the present invention provides a method and apparatus for providing aseptically processed low acid products in a container having a small opening, such as a glass or plastic bottle or jar, at a high output processing speed.

Many features are incorporated into the aseptic processing apparatus of the present invention in order to meet the various United States FDA aseptic standards and the 3A Sanitary Standards and Accepted Practices.

The aseptic processing apparatus of the present invention uses filtered air to maintain a positive pressure within a filler apparatus. The filler apparatus includes a sterile tunnel that is pressurized to a level greater than atomospheric pressure using filtered sterile air. The filler apparatus includes three interfaces with the ambient environment, each of which eliminates the possibility of external contamination. The first interface is where containers first enter the sterile tunnel through a bottle infeed and sterilization apparatus. In accordance with the present invention, there is always an outflow of aseptic sterilant (e.g., hydrogen peroxide) enriched sterile air from the first interface to prevent contaminants from entering the sterile tunnel. The second interface with the sterile tunnel is the path where incoming lid stock enters a lid sealing and heat sealing apparatus. To prevent contamination, the lid stock passes through a hydrogen peroxide bath that provides an aseptic barrier for any contaminants that enter the sterile tunnel through the second interface. The third interface with the sterile tunnel is at an exit opening of a discharge apparatus where sealed containers leave the sterile tunnel. Positive sterile air pressure within the sterile tunnel ensures that sterile air is continuously flowing out of the exit opening of the discharge apparatus, thereby preventing contaminants from entering the sterile tunnel through this interface.

The aseptic processing apparatus includes a conveying apparatus for transporting the containers through a plurality of processing stations located within the sterile tunnel. The entire conveying apparatus is enclosed within the sterile tunnel, and is never is exposed to unsterile conditions.

The interior surface of a container such as a bottle or jar is much more difficult to aseptically sterilize than the interior surface of a cup. A cup generally has a large opening compared to its height, whereas a bottle or jar generally has a small opening compared to its height and its greatest width (e.g., the ratio of the opening diameter to the height of the container is less than 1.0). A sterilant can be introduced, activated, and removed in a cup much more rapidly than in a bottle or jar. The processing speed when using a bottle or jar is limited, in part, by the time required to aseptically sterilize the interior surface of the bottle or jar. The aseptic processing apparatus of the present invention overcomes the processing speed limitations associated with the use of containers such as bottles or jars.

A high output processing speed is achieved in the present invention by applying a hot atomized sterilant, such as a hydrogen peroxide spray onto the interior surface of each container, and by subsequently activating and removing the sterilant in a plurality of drying stations using hot sterile air. For example hydrogen peroxide breaks down into water and oxygen, and thus oxidizes and kills bacteria within the container. To achieve aseptic sterilization, a minimum container temperature is developed and held for a predetermined

period of time (e.g., 131° F. for 5 seconds) after application of the sterilant. Hot sterile air is delivered at a high volume and a relatively low temperature to dry the container and to prevent the container (if formed of plastic) from being heated to its softening temperature. After container drying, the residual hydrogen peroxide in the container is below a predetermined level (e.g., about 0.5 PPM (parts per million)).

The present invention generally provides a method for aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the plurality of bottles;

aseptically filling the aseptically disinfected plurality of bottles with the aseptically sterilized foodstuffs; and

filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute.

The present invention additionally provides a method for aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the bottles at a rate greater than 100 bottles per minute; and

aseptically filling the bottles with aseptically sterilized foodstuffs.

BRIEF DESCRIPTION OF THE DRAWINGS

The features of the present invention will best be understood from a detailed description of the invention and a preferred embodiment, thereof selected for the purposes of illustration, and shown in the accompanying drawings in which:

FIG. **1** is a plan view of an aseptic processing apparatus in accordance with a preferred embodiment of the present invention;

FIG. **2** is a side view of the aseptic processing apparatus of FIG. **1**;

FIG. **3** is a partial cross-sectional side view of the aseptic processing apparatus of FIG. **1**;

FIG. **4** is a cross-sectional side view of a bottle infeed and sterilization apparatus;

FIG. **5** illustrates a cross-sectional top view of the bottle infeed and sterilization apparatus taken along line **5**—**5** of FIG. **4**;

FIG. **6** is an interior sectional view of an interior wall taken along line **6**—**6** of FIG. **4**;

FIG. **7** is a cross-sectional view of the bottle infeed and sterilization apparatus taken along line **7**—**7** of FIG. **4**;

FIG. **8** is a perspective view of a conveying plate for use in the aseptic processing apparatus of the present invention;

FIG. **9** is a perspective view of a partition in a sterile tunnel;

FIG. **10** is a cross-sectional side view of an interior bottle sterilization apparatus and the partition located between stations **8** and **9**;

FIG. **11** is a cross-sectional side view of the partition located between stations **22** and **23**;

FIG. **12** is a cross-sectional side view of the partition located between stations **35** and **36**;

FIG. **13** is a cross-sectional side view of a lid sterilization and heat sealing apparatus;

FIG. **14** is a side view of a lifting apparatus with a gripper mechanism for lifting the bottles from the sterile tunnel;

FIG. **15** is a top view of the aseptic processing apparatus; and

FIG. **16** is a side view of the aseptic processing apparatus indicating the control and monitoring locations that are interfaced with a control system.

DETAILED DESCRIPTION OF THE INVENTION

Although certain preferred embodiments of the present invention will be shown and described in detail, it should be understood that various changes and modifications may be made without departing from the scope of the appended claims. The scope of the present invention will in no way be limited to the number of constituting components, the materials thereof, the shapes thereof, the relative arrangement thereof, etc., and are disclosed simply as an example of the preferred embodiment. The features and advantages of the present invention are illustrated in detail in the accompanying drawings, wherein like reference numerals refer to like elements throughout the drawings. Although the drawings are intended to illustrate the present invention, the drawings are not necessarily drawn to scale.

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. The present invention provides a method and apparatus for producing at least about a 12 log reduction of *Clostridium botulinum* in food products. In addition, the present invention produces packaging material with at least about a 6 log reduction of spores. Actual testing of the aseptic processing apparatus is accomplished with spore test organisms. These test organisms are selected on their resistance to the media selected used to achieve sterility. For example, when steam is the media, the test organism is *Bacillus stearothermophilus*. When hydrogen peroxide is the media, then the test organism is *Bacillus subtilis* var. globigii.

The present invention processes containers such as bottles or jars that have a small opening compared to its height and its greatest width (e.g., the ratio of the opening diameter to the height of the container is less than 1.0). In the preferred embodiment, a bottle **12** (see, e.g., FIG. **8**) is illustrated as the container. The container may alternately comprise a jar. The bottle **12** is preferably formed of a plastic such as polyethylene terepthalate (PET) or high density polyethylene (HDPE), although other materials such as glass may also be used. The present invention uses an aseptic sterilant such as hydrogen peroxide (H_2O_2) or oxonia to sterilize the bottles **12**. In the preferred embodiment of the present invention, hydrogen peroxide is used as the sterilant. The present invention uses hydrogen peroxide with a concentration of less than about 35% and ensures that the bottles **12** have less than about 0.5 ppm of residual hydrogen peroxide after each bottle **12** is sterilized.

FIGS. **1–3** illustrate several views of an aseptic processing apparatus **10** in accordance with a preferred embodiment of the present invention. As shown, the aseptic processing apparatus **10** includes a first bottle unscrambler **20**, a second bottle unscramble **30**, and a bottle lifter **40** for providing a supply of properly oriented empty bottles. The empty bottles are delivered to a filler apparatus **50** after passing through a bottle infeed and sterilization apparatus **60** for aseptic sterilization. The filled bottles are sealed at a first capping apparatus **400** or a second capping apparatus **410**. A control

system **550** monitors and controls the operation of the aseptic processing apparatus **10**. The filled and sealed bottles are packed and palletized using a first case packing apparatus **480**, a second case packing apparatus **490**, a first palletizer **500**, and a second palletizer **510**.

The bottles **12** arrive at a first bottle unscrambler **20** with a random orientation, such that an opening **16** (see FIG. **8**) of each bottle **12** can be oriented in any direction. The first bottle unscrambler **20** manipulates the bottles **12** until the opening **16** of each bottle **12** is in a top vertical position. The bottles **12** leave the first bottle unscrambler **20** in a series formation with the opening **16** of each bottle **12** oriented vertically. The bottles **12** travel in single file in a first lane **18** to a first bottle lifter **40**. The first bottle lifter **40** lifts and transports the bottles **12** to a bottle infeed and sterilization apparatus **60**. A second bottle unscrambler **30** may also used to provide a supply of vertically oriented bottles **12**. The bottles **12** output from the second bottle unscrambler **30** travel in single file in a second lane **22** to a second bottle lifter **42**, which lifts and transports the bottles **12** to the bottle infeed and sterilization apparatus **60**.

FIG. **3** illustrates the bottle infeed, sterilization, and conveying apparatus **60** attached to the filler apparatus **50**. FIG. **4** illustrates a cross-sectional side view of the bottle infeed, sterilization, and conveying apparatus **60**. FIG. **5** illustrates a cross-sectional top view of the bottle infeed, sterilization, and conveying apparatus **60** taken along line **5**—**5** of FIG. **4**. The bottle infeed and sterilization apparatus **60** preferably inputs six bottles **12** in a horizontal direction from the first lane **18** and six bottles in a horizontal direction from the second lane **22** (FIG. **5**). A gate **76** in the first lane **18** selectively groups six bottles **12** at a time in first horizontal row **24**. A gate **78** in the second lane **22** selectively groups six bottles **12** at a time in a second horizontal row **28**. An infeed apparatus **80** includes a pushing element **84** for pushing the bottles **12** in the first horizontal row **24** into a first vertical lane **26**. A corresponding infeed apparatus **80** includes a pushing element **86** for pushing the bottles **12** in the second horizontal row **28** into a second vertical lane **32**. The six bottles **12** in the first vertical lane **26** and the six bottles **12** in the second vertical lane **32** are directed downward into the bottle infeed and sterilization apparatus **60**.

Referring to FIG. **4**, as the bottles **12** move downward in the first vertical lane **26** and the second vertical lane **32**, a sterilant **14**, such as heated hydrogen peroxide, oxonia, or other aseptic sterilant, is applied to an outside surface **34** of each bottle **12** by a sterilant application apparatus **36**. The outside surface **34** of a bottle **12** is illustrated in greater detail in FIG. **8**. The bottles **12** may move downward in the first vertical lane **26** and the second vertical lane **32** by the force of gravity. Alternatively, controlled downward movement of the bottles **12** can be created by the use of a conveying device such as a moving conveying chain. A plurality of pins are attached to the conveying chain. Each bottle **12** rests on one of the pins attached to the conveying chain. Therefore, the motion of each bottle is controlled by the speed of the moving conveying chain.

A sterilant such as hydrogen peroxide may be provided to the sterilant application apparatus **36** in many ways. For example, liquid hydrogen peroxide may be provided in a reservoir at a level maintained by a pump and overflow pipe. A plurality of measuring cups (e.g., approximately 0.5 ml each) connected by an air cylinder are submerged into the reservoir and are lifted above the liquid level. Thus, a measured volume of liquid hydrogen peroxide is contained in each measuring cup.

Each measuring cup may include a conductivity probe that is configured to send a signal to the control system **550** indicating that the measuring cup is full. A tube (e.g., having a diameter of about 1/16") is positioned in the center of the measuring cup. A first end of the tube is positioned near the bottom of the measuring cup. A second end of the tube is connected to the sterilant application apparatus **36**. The sterilant application apparatus **36** includes a venturi and a heated double tube heat exchanger. When the measuring cup is full, and a signal is received from the control system **550**, a valve is opened allowing pressurized sterile air to enter the venturi. The pressurized air flow causes a vacuum to be generated in second end of the tube causing liquid hydrogen peroxide to be pulled out of the measuring cup. The liquid hydrogen peroxide is sprayed into a sterile air stream which atomizes the hydrogen peroxide into a spray. The atomized hydrogen peroxide enters the double tube heat exchanger in order to heat the atomized hydrogen peroxide to its vaporization phase. The double tube heat exchanger is heated with steam and the temperature is monitored and controlled by the control system **550**. In FIG. **4**, the application of the sterilant **14** by the sterilant application apparatus **36** is accomplished through the use of spray nozzles **64** that produce a sterilant fog which is directed to the outside surface **34** of each bottle **12**.

Alternatively, a direct spray of heated hydrogen peroxide may be continuously applied to the outside surface **34** of each bottle **12**. For producing the direct spray, a metering pump regulates the amount of hydrogen peroxide, a flow meter continuously measures and records the quantity of hydrogen peroxide being dispensed, a spray nozzle produces a fine mist, and a heat exchanger heats the hydrogen peroxide above the vaporization point.

FIGS. **3** and **4** illustrate the sterilization chamber **38** for activation and drying of bottles **12** which is included in the bottle infeed, sterilization, and conveying apparatus **60**. The sterilization chamber **38** sterilizes the outside surface **34** of each bottle **12**. The sterilization chamber **38** encloses a conduit **39**. Sterile heated air, which is generated by a sterile air supply system **146** (FIG. **3**), enters the conduit **39** of the sterilization chamber **38** through ports **64** and **68** located at the bottom of the sterilization chamber **38**. The sterile heated air also enters through a bottom opening **62** of the bottle infeed and sterilization apparatus **60**. The sterile heated air travels up through the conduit **39** of the sterilization chamber **38**, and exits the top of the sterilization chamber **38** through an exhaust conduit **70**. The sterile heated air continuously flows in an upward direction through the sterilization chamber **38**, thus preventing any contaminants from entering the bottle infeed and sterilization apparatus **60**. To create the sterile heated air, the air is first passed through a filtering system (e.g., a group of double sterile air filters) to sterilize the air. The air is then heated in a heating system (e.g., an electric heater) to about 230° F. The air temperature is regulated by the control system **550**. Other techniques for providing the sterile heated air may also be used. The control system **550** monitors the air pressure and flow rate of the sterile heated air to ensure that an adequate flow of the hot sterile air is maintained in the bottle sterilization chamber **38** of the bottle infeed and sterilization apparatus **60**.

As illustrated in FIGS. **4**, **6**, and **7**, the sterilization chamber **38** includes two opposing, interior, perforated walls **72**A, **72**B. The perforated walls **72**A and **72**B guide the bottles **12** downward in the first vertical lane **26** and the second vertical lane **32**, respectively. The perforated walls **72**A, **72**B also allow the complete circulation of hot sterile air around the outside surface **34** of each bottle **12** in the sterilization chamber **38**. The sterilization chamber **38** supplies hot sterile air to the outside surface **34** of each bottle

12 between the sterilant application apparatus **36** and the bottom opening **62** of the bottle infeed and sterilization apparatus **60**. This sterilant may be hydrogen peroxide or oxonia (hydrogen peroxide and peroxyacetic acid).

In accordance with the preferred embodiment of the present invention, twelve drying positions are provided in the sterilization chamber **38**. Each bottle **12** is exposed to the hot sterile air in the sterilization chamber **38** for about at least 24 seconds. This provides time sufficient time for the hydrogen peroxide sterilant to break down into water and oxygen, to kill any bacteria on the bottles **12**, and to evaporate from the outside surface **34** of the bottles **12**.

An exhaust fan **73** is located at a top of the exhaust conduit **70** to provide an outlet from a sterile tunnel **90**, and to control the sterile air flow rate through the sterilization chamber **38**. The exhaust fan **73** is controlled by the control system **550**. The control system **550** controls the sterile air temperature preferably to about 230° F., and controls the sterile air flow rate through the sterilization chamber **38**. The flow rate is preferably about 1800 scfm through the sterilization chamber **38**. The bottles **12** leave the sterilization chamber **38** with a hydrogen peroxide concentration of less than 0.5 PPM.

As shown in FIGS. **3** and **4**, a plurality of proximity sensors **71** located along the sides of the vertical lanes **26**, **32** detect any bottle **12** jams that occur within the sterilization chamber **38**. The proximity sensors **71** transmit an alarm signal to the control system **550**. The bottles **12** leave the bottle infeed and sterilization apparatus **60** through the bottom opening **62**, and enter the sterile tunnel **90** of the filler apparatus **50**.

In the preferred embodiment of the present invention, the filler apparatus **50** includes forty-one (41) index stations **92**, hereafter referred to as "stations." Various index stations **92** are illustrated in FIGS. **3**, **4**, and **11–15**. The conveying motion of the bottles **12** to the various stations **92** through the filler apparatus **50** is based on an indexing motion. The filler apparatus **50** is designed to convey the bottles **12** through the various operations of the filler **50** in a two by six matrix. The twelve bottles **12** in the two by six matrix are positioned in, and displaced by, a conveying plate **94** as illustrated in FIG. **8**. Therefore, twelve bottles **12** are exposed to a particular station **92** at the same time. A conveying apparatus **100** moves the set of twelve bottles **12** in each conveying plate **94** sequentially through each station **92**.

Referring to FIGS. **3** and **4**, the bottles **12** are supplied from an infeed chamber **102** to station **2** of the filler apparatus **50** through the bottom opening **62** of the bottle infeed and sterilization apparatus **60**. The infeed chamber **102** is enclosed to direct heated hydrogen peroxide laden air completely around the outer surface **34** of the bottles **12**. A mechanical scissors mechanism and a vacuum "pick and place" apparatus **104** position twelve bottles **12** at a time (in a two by six matrix, FIG. **8**) into one of the conveying plates **94**.

A plurality of conveying plates **94** are attached to a main conveyor **106**. The main conveyor **106** forms a continuous element around conveyor pulleys **108** and **110** as illustrated in FIG. **3**. A bottle support plate **107** supports a bottom **120** of each bottle **12** as the bottles **12** are conveyed from station to station through the filler apparatus **50**. Each conveying plate **94** passes through stations **1** through **41**, around pulley **108**, and returns around pulley **110** to repeat the process. The main conveyor **106**, conveying plates **94**, and pulleys **108** and **110** are enclosed in the sterile tunnel **90**.

At station **4**, the bottles **12** in the conveying plate **94** enter a bottle detection apparatus **112**. The bottle detection apparatus **112** determines whether all twelve bottles **12** are actually present and correctly positioned in the conveying plate **94**. Proximity sensors **114** detect the presence and the alignment of each bottle **12**. In the present invention, a bottle **12** with correct alignment is in an upright position with the opening **16** of the bottle **12** located in an upward position. Information regarding the location of any misaligned or missing bottles **12** is relayed to the control system **550**. The control system **550** uses this location information to ensure that, at future stations **92**, bottle filling or sealing will not occur at the locations corresponding to the misaligned or missing bottles **12**.

At station **7**, as illustrated in FIGS. **3** and **10**, the bottles **12** in the conveying plate **94** enter an interior bottle sterilization apparatus **116**. A sterilant, such as hydrogen peroxide, oxonia, or any other suitable aseptic sterilant is applied as a heated vapor fog into the interior **118** of each bottle **12**. Preferably, hydrogen peroxide is used as the sterilant in the present invention. The application of sterilant is accomplished with the use of a plurality of sterilant measuring devices **120** and applicator spray nozzles **122**. A separate measuring device **120** and applicator spray nozzle **122** are used for each of the twelve bottle **12** locations in the conveying plate **94**. Each bottle **12** is supplied with the same measured quantity of sterilant, preferably in the form of a hot vapor fog. The measured quantity of sterilant may be drawn from a reservoir **124** of sterilant, heated, vaporized, etc., in a manner similar to that described above with regard to the sterilant application apparatus **36**.

The control system **550** monitors and controls a spray apparatus **126** that includes the applicator spray nozzles **122**. Each applicator spray nozzle **122** sprays the sterilant into the interior **118** of a corresponding bottle **12** as a hot vapor fog. The applicator spray nozzles **122** are designed to extend through the bottle openings **16**. The applicator spray nozzles **122** descends into the interior **118** and toward the bottom of the bottles **12**. This ensures the complete application of sterilant to the entire interior **118** and interior surface **119** of each bottle **12**. Alternately, the applicator spray nozzles **122** may be positioned immediately above the bottle openings **16** prior to the application of sterilant.

FIG. **9** illustrates a perspective view of a partition **130** that provides control of sterile air flow within the sterile tunnel **90** of the filler apparatus **50**. The partition **130** includes a top baffle plate **132**, a middle baffle plate **134**, and a bottom baffle plate **136**. The top baffle plate **132** and the middle baffle plate **134** are provided with cut-outs **133** which correspond to the outer shape of each bottle **12** and to the outer shape of the conveyor plate **94**. The cut-outs **133** allow each bottle **12** and each conveyor plate **94** to pass through the partition **130**. A space **138** between the middle baffle plate **134** and the bottom baffle plate **136** allows each empty conveyor plate **94** to pass through the partition **130** as it travels on its return trip from the pulley **108** toward the pulley **110**.

As illustrated in FIG. **3**, partitions **130**A, **130**B, and **130**C, are located within the sterile tunnel **90**. FIG. **10** illustrates a cross-sectional view of partition **130**A including baffle plates **132**A, **134**A, and **136**A. The partition **130**A is located between stations **8** and **9**. FIG. **11** illustrates a cross-sectional view of partition **130**B including baffle plates **132**B, **134**B, and **136**B. The partition **130**B is located between stations **22** and **23**. FIG. **12** illustrates a cross-sectional view of partition **130**C including baffles **132**C, **134**C, and **136**C. The partition **130**C is located between stations **35** and **36**. As illustrated in

FIG. **3**, sterile air is introduced through sterile air conduits **140**, **142**, and **144** into the sterile tunnel **90**. The sterile air conduit **140** is located at station **23** (FIG. **11**), the sterile air conduit **142** is located at station **27** (FIG. **3**), and the sterile air conduit **144** is located at station **35** (FIG. **12**).

The partition **130**A separates an activation and drying apparatus **152** from the interior bottle sterilization apparatus **116**. The partition **130**B separates the activation and drying apparatus **152** from a main product filler apparatus **160** and a lid sterilization and heat sealing apparatus **162**. Thus, a first sterilization zone **164** is created that includes the activation and drying apparatus **152**. Partition **130**C separates the main product filler apparatus **160** and the lid sterilization and heat sealing apparatus **162** from a bottle discharge apparatus **280**. Thus, partitions **130**B and **130**C create a second sterilization zone **166** that includes the main product filler apparatus **160** and the lid sterilization and heat sealing apparatus **162**. A third sterilization zone **172** includes the bottle discharge apparatus **280**. A fourth sterilization zone **165** includes the interior bottle sterilization apparatus **116**. The second sterilization zone **166** provides a highly sterile area where the bottles **12** are filled with a product and sealed. The second sterilization zone **166** is at a higher pressure than the first sterilization zone **164** and the third sterilization zone **172**. Therefore, any gas flow leakage is in the direction from the second sterilization zone **166** out to the first sterilization zone **164** and the third sterilization zone **172**. The first sterilization zone **164** is at a higher pressure than the fourth sterilization zone **165**. Therefore, gas flow is in the direction from the first sterilization zone **164** to the fourth sterilization zone **165**.

The partitions **130**A, **130**B, and **130**C create sterilization zones **164**, **165**, **166**, and **172** with different concentration levels of gas laden sterilant (e.g., hydrogen peroxide in air). The highest concentration level of sterilant is in the fourth sterilization zone **165**. An intermediate concentration level of sterilant is in the first sterilization zone **164**. The lowest concentration level of sterilant is in the second sterilization zone **166**. Advantageously, this helps to maintain the main product filler apparatus **160** and the lid sterilization and heat sealing apparatus **162** at a low sterilant concentration level. This prevents unwanted high levels of sterilant to enter the food product during the filling and lidding process.

Stations **10** through **21** include twelve stations for directing hot sterile air into each bottle **12** for the activation and removal of the sterilant from the interior of the bottle **12**. The sterile air supply system **146** supplies hot sterile air to a plurality of nozzles **150** in the activation and drying apparatus **152**. Hot sterile air is supplied to the sterile air supply system **146** through conduit **148**. The air is first passed through a filtration system to sterilize the air. The air is then heated in a heating system to about 230° F. The air temperature is regulated by the control system **550**. Also, the control system **550** monitors the air pressure and flow rate to ensure that an adequate flow of hot sterile air is maintained in the sterile tunnel **90** of the application and drying apparatus **152**.

As shown in FIG. **8**, each bottle **12** generally has a small opening **16** compared to its height "H." A ratio of a diameter "D" of the bottle **12** to the height "H" of the bottle **12** is generally less than 1.0. The small bottle opening **16** combined with a larger height "H" restricts the flow of hot gas into the interior **118** of the bottle **12**. Also, PET and HDPE bottle materials have low heat resistance temperatures. These temperatures commonly are about 55° C. for PET and about 121° C. for HDPE. Typically, in the aseptic packaging industry, a low volume of air at a high temperature is applied to the packaging materials. This often results in deformation and softening of packaging materials formed of PET and HDPE. In order to prevent softening and deformation of the bottles **12**, when formed from these types of materials, the present invention applies high volumes of air at relatively low temperatures over an extended period of time in the activation and drying apparatus **152**. The plurality of nozzles **150** of the activation and drying apparatus **152** direct hot sterile air into the interior **118** of each bottle **12** (FIG. **11**). A long exposure time is predicated by the geometry of the bottle **12** and the softening temperature of the material used to form the bottle **12**. In the present invention, about 24 seconds are allowed for directing hot sterile air from the plurality of nozzles **150** into each bottle for the activation and removal of sterilant from the interior surface **119** of the bottle **12**. To achieve aseptic sterilization, a minimum bottle temperature of about 131° F. should be held for at least 5 seconds. To achieve this bottle temperature and time requirements, including the time required to heat the bottle, the sterilant is applied for about 1 second and the hot sterile air is introduced for about 24 seconds. The hot sterile air leaves the nozzles **150** at about 230° F. and cools to about 131° F. when it enters the bottle **12**. The hot sterile air is delivered at a high volume so that the bottle **12** is maintained at about 131° F. for at least 5 seconds. The about 24 seconds provides adequate time for the bottle **12** to heat up to about 131° F. and to maintain this temperature for at least 5 seconds. After bottle **12** has dried, the residual hydrogen peroxide remaining on the bottle **12** surface is less than 0.5 PPM.

A foodstuff product is first sterilized to eliminate bacteria in the product. An "Ultra High Temperature" (UHT) pasteurization process is required to meet the aseptic FDA standard. The time and temperature required to meet the aseptic FDA standard depends on the type of foodstuff. For example, milk must be heated to 282° F. for not less than 2 seconds in order to meet the aseptic standards.

After UHT pasteurization, the product is delivered to a main product filler apparatus **160**. The main product filler apparatus is illustrated in FIGS. **3** and **13**. The main product filler **160** can be sterilized and cleaned in place to maintain aseptic FDA and 3A standards. A pressurized reservoir apparatus **180** that can be steam sterilized is included in the main product filler apparatus **160**. As illustrated in FIG. **13**, the pressurized reservoir apparatus **180** includes an enclosed product tank **182** with a large capacity (e.g., 15 gallons). The product tank **182** is able to withstand elevated pressures of about 60 psig or more. The pressurized reservoir apparatus **180** also includes a level sensor **184**, a pressure sensor **186**, a volumetric measuring device **188**, and a filling nozzle **190**. The product tank **182** includes a single inlet with a valve cluster including a sterile barrier to separate the product process system from aseptic surge tanks and the main product filler apparatus **160**. The product tank **182** has an outlet with twelve connections. At each connections is a volumetric measuring device **188** such as a mass or volumetric flow meter. A plurality of filling nozzles **190**A, **190**B are provided at stations **23**, **25**, respectively. In addition, there are a plurality of volumetric measuring devices **188**A and **188**B to measure the volume of product entering each bottle **12** at stations **23** and **25**, respectively. The control system **550** calculates the desired volume of product to be inserted into each bottle **12**, and controls the product volume by opening or closing a plurality of valves **194**A and **194**B. The activation mechanisms for valves **194**A and **194**B have a sterile barrier to prevent contamination of the product. The plurality of valves **194**A control the volume of product

flowing through a corresponding plurality of nozzles **196**A into the bottles **12** at station **23**. The plurality of valves **194**B control the volume of product flowing through a corresponding plurality of nozzles **196**B into the bottles **12** at station **25**. The control system **550** uses the previously stored information provided by the bottle detection apparatus **112** to only allow filling to occur at the locations where bottles **12** are actually present and correctly aligned.

The initial sterilization process for the pressurized reservoir apparatus **180** includes the step of exposing all of the surfaces of the pressurized reservoir apparatus **180** that come in contact with the product to steam at temperatures above about 250° F. for a minimum of about 30 minutes. Elements such as cups **198**A and **198**B are used to block off nozzle outlets **196**A and **196**B respectively, to allow a build-up of steam pressure to about 50 psig inside the pressurized reservoir apparatus **180**. Condensate generated as the steam heats the interior surfaces of the pressurized reservoir apparatus **180** is collected and released from the nozzles **198**A and **198**B. This condensate is released when the cups **198**A and **198**B are removed from the nozzle outlets **196**A and **196**B. Once the interior surfaces of the pressurized reservoir apparatus **180** are sterilized, the steam is shut off, and sterile air is used to replace the steam. The sterile air reduces the interior temperature of the pressurized reservoir apparatus **180** to the temperature of the product before the product is allowed to enter the enclosed product tank **182**. Sterile air is directed through sterile air conduits **142** and **144** into the second sterilization zone **166** at a volume rate of about 800 scfm (FIG. **13**). The sterile air flow entering the second sterilization zone **166** provides sterile air to the main product filler apparatus **160** and to the lid sterilization and heat sealing apparatus **162**.

The main product filler apparatus **160** includes a separate filling position for each bottle. The bottle **12** filling operation is completed for six bottles at station **23** and for six bottles at station **25**.

FIGS. **3** and **13** illustrate the lid sterilization and heat sealing apparatus **162**. A lid **200** is applied to each of the twelve bottles **12** at station **31**. For a fully aseptic bottle filler, complete lid **200** sterilization is necessary, and therefore a sterilant such as hydrogen peroxide is typically used. In the present invention, the lids are formed of a material such as foil or plastic. The lids **200** are joined together by a small interconnecting band that holds them together to form a long connected chain of lids **200**, hereinafter referred to as a "daisy chain" **202**. A daisy chain **202** of lids **200** is placed on each of a plurality of reels **210**. For the twelve bottle configuration of the present invention, six of the reels **210**, each holding a daisy chain **202** of lids **200**, are located on each side of a heat sealing apparatus **214**. Each daisy chain **202** of lids **200** winds off of a corresponding reel **210** and is sterilized, preferably using a hydrogen peroxide bath **204**. A plurality of hot sterile air knives **208**, which are formed by jets of hot sterile air, activate the hydrogen peroxide to sterilize the lids **200** on the daisy chain **202**. The hot sterile air knives **208** also remove the hydrogen peroxide from the lids **200** so that the residual concentration of hydrogen peroxide is less than 0.5 PPM. The hydrogen peroxide bath **204** prevents any contaminants from entering the sterile tunnel **90** via the lidding operation. Once sterilized, the lids **200** enter the sterile tunnel **90** where they are separated from the daisy chain **202** and placed on a bottle **12**. Each lid is slightly larger in diameter then that of the opening **16** of a bottle **12**. During the placement of the lid **200** on the bottle **12**, a slight mechanical crimp of the lid **200** is formed to locate and hold the lid **200** on the bottle **12**. The crimp holds the lid **200** in place on the bottle **12** until the bottle **12** reaches a station **33** for sealing.

At station **33**, the lids **200** are applied to the bottles **12**. The heat sealing apparatus **214** includes a heated platen **216** that applies heat and pressure against each lid **200** for a predetermined length of time, to form a seal between the lid **200** and the bottle **12**. The heated platen **216** is in a two by six configuration to seal twelve of the bottles **12** at a time.

At station **37**, the lid **200** seal and bottle **12** integrity are checked in a known manner by a seal integrity apparatus (not shown) comprising, for example, a bottle squeezing mechanism and a proximity sensor. Each bottle **12** is squeezed by the bottle squeezing mechanism which causes the lid **200** on the bottle **12** to extend upward. The proximity sensor detects if the lid **200** has extended upward, which indicates an acceptable seal, or whether the seal remains flat, which indicates a leaking seal or bottle **12**. The location of the defective bottles **12** are recorded by the control system **550** so that the defective bottles will not be packed.

Bottle discharge from the sterile tunnel **90** of the filler apparatus **50** occurs at stations **38** and **40** as illustrated in FIGS. **3**, **13** and **14**. A bottle discharge apparatus **280** is located at stations **38** and **40**. At this point in the filler apparatus **50**, the filled and sealed bottles **12** are forced in an upward direction such that a top portion **284** of each bottle **12** protrudes through an opening **282** in the sterile tunnel **90** (FIG. **14**). A rotating cam **290** or other suitable means (e.g., an inflatable diaphragm, etc.) may be used to apply a force against the bottom **120** of each bottle **12** to force the bottle **12** in an upward direction.

As illustrated in FIG. **14**, the bottle discharge apparatus **280** comprises a lifting apparatus **286** that includes a gripper **288** that grasps the top portion **284** of each bottle **12** and lifts the bottle **12** out through the opening **282** in the sterile tunnel **90**. In order to ensure that contaminated air cannot enter the sterile tunnel **90**, the sterile air in the sterile tunnel **90** is maintained at a higher pressure than the air outside the sterile tunnel **90**. Thus, sterile air is always flowing out of the sterile tunnel **90** through the opening **282**. In addition, the gripper **288** never enters the sterile tunnel **90**, because the top portion **284** of the bottle **12** is first lifted out of the sterile tunnel **90** by the action of the rotating cam **290** before being grabbed by the gripper **288**.

FIG. **15** illustrates a top view of the filler apparatus **50** including the bottle infeed and sterilization apparatus **60**, the interior bottle sterilization apparatus **116**, and the activation and drying apparatus **152**. FIG. **15** additionally illustrates the main filler apparatus **160**, the lid sterilization and heat sealing apparatus **162**, and the bottle discharge apparatus **280**.

Referring again to FIGS. **1** and **14**, the lifting apparatus **286** lifts the bottles **12** at station **38** and places the bottles **12** in a first lane **292** that transports the bottles **12** to a first capping apparatus **410**. In addition, the lifting apparatus **286** lifts the bottles **12** at station **40** and places the bottles **12** in a second lane **294** that transports the bottles **12** to a second capping apparatus **400**.

The first capping apparatus **410** secures a cap (not shown) on the top of each bottle **12** in the first lane **292**. The second capping apparatus **400** secures a cap on the top of each bottle **12** in the second lane **294**. The caps are secured to the bottles **12** in a manner known in the art. It should be noted that the capping process may be performed outside of the sterile tunnel **90** because each of the bottles **12** have previously been sealed within the sterile tunnel **90** by the lid sterilization and heat sealing apparatus **162** using a sterile lid **200**.

After capping, the bottles **12** are transported via the first and second lanes **292**, **294** to labelers **460** and **470**. The first labeling apparatus **470** applies a label to each bottle **12** in the first lane **292**. The second labeling apparatus **460** applies a label to each bottle **12** in the second lane **294**.

From the first labeling apparatus **470**, the bottles **12** are transported along a first set of multiple lanes (e.g., **4**) to a first case packing apparatus **490**. From the second labeling apparatus **460**, the bottles **12** are transported along a second set of multiple lanes to a second case packing apparatus **480**. Each case packing apparatus **480**, **490** gathers and packs a plurality of the bottles **12** (e.g., twelve) in each case in a suitable (e.g., three by four) matrix.

A first conveyor **296** transports the cases output by the first case packer **490** to a first palletizer **510**. A second conveyor **298** transports the cases output by the second case packer **480** to a second palletizer **500**. A vehicle, such as a fork lift truck, then transports the pallets loaded with the cases of bottles **12** to a storage warehouse.

Referring again to FIG. **3**, the main conveyor **106** and each conveying plate **94** are cleaned and sanitized once during each revolution of the main conveyor **106**. Specifically, after each empty conveying plate **94** passes around the pulley **108**, the conveying plate **94** is passed through a liquid sanitizing apparatus **300** and a drying apparatus **302**. The liquid sanitizing apparatus **300** sprays a mixture of a sterilizing agent (e.g., oxonia, (hydrogen peroxide and peroxyacetic acid)) over the entire surface of each conveying plate **94** and associated components of the main conveyor **106**. In the drying apparatus **302**, heated air is used to dry the main conveyor **106** and conveying plates **94**.

Stations **1** through **40** are enclosed in the sterile tunnel **90**. The sterile tunnel **90** is supplied with air that is pressurized and sterilized. The interior of the sterile tunnel **90** is maintained at a pressure higher than the outside environment in order to eliminate contamination during the bottle processing. In addition, to further ensure a sterile environment within the sterile tunnel **90**, the sterile air supply provides a predetermined number of air changes (e.g., 2.5 changes of air per minute) in the sterile tunnel **90**.

The bottle infeed and sterilization apparatus **60** and the filler apparatus **50** meet the 3A Sanitary Standards of the Sanitary Standards Symbol Administrative Council. The 3A Sanitary Standards ensure that all product contact surfaces can be cleaned and sterilized on a regular basis such as daily. The present invention allows the product contact surfaces to be cleaned-in-place without dismantling the bottle infeed and sterilization apparatus **60** or the filler apparatus **50**. The 3A Sanitary Standards includes requirements such as the material type, the material surface finish, the elastomer selection, the radius of machined parts and the ability of all surfaces to be free draining. For example, the material type is selected from the 300 series of stainless steel and all product contact surfaces have a finish at least as smooth as No. 4 ground finish on stainless steel sheets.

Before bottle production is initiated, the bottle infeed and sterilization apparatus **60** and the filler apparatus **50** are preferably sterilized with an aseptic sterilant. For example, a sterilant such as a hot hydrogen peroxide mist may be applied to all interior surfaces of the bottle infeed and sterilization apparatus **60** and the filler apparatus **50**. Then, hot sterile air is supplied to activate and remove the hydrogen peroxide, and to dry the interior surfaces of the bottle infeed and sterilization apparatus **60** and the filler apparatus **50**.

FIG. **16** is a side view of the aseptic processing apparatus **10** of the present invention indicating the location of the control and monitoring devices that are interfaced with the control system **550**. The control system **550** gathers information and controls process functions in the aseptic processing apparatus **10**. A preferred arrangement of the control and monitoring devices are indicated by encircled letters in FIG. **16**. A functional description of each of the control and monitoring devices is listed below. It should be noted that these control and monitoring devices are only representative of the types of devices that may be used in the aseptic processing apparatus **10** of the present invention. Other types and combinations of control and monitoring devices may be used without departing from the intended scope of the present invention. Further, control system **550** may respond in different ways to the outputs of the control and monitoring devices. For example, the control system **550** may automatically adjust the operational parameters of the various components of the aseptic processing apparatus **10**, may generate and/or log error messages, or may even shut down the entire aseptic processing apparatus **10**. In the preferred embodiment of the present invention, the control and monitoring devices include:

A. A bottle counter to ensure that a predetermined number of the bottles **12** (e.g., six bottles) on each upper horizontal row **24**, **28** enter the loading area of the bottle infeed and sterilization apparatus **60**.

B. A proximity sensor to ensure that the first group of bottles **12** has dropped into the first bottle position in the bottle infeed and sterilization apparatus **60**.

C1. A conductivity sensor to ensure that the measuring cup used by the sterilant application apparatus **36** is full.

C2. A conductivity sensor to ensure that the measuring cup used by the sterilant application apparatus **36** is emptied in a predetermined time.

C3. A pressure sensor to ensure that the pressure of the air used by the sterilant application apparatus **36** is within predetermined atomization requirements.

C4. A temperature sensor to ensure that each heat heating element used by the sterilant application apparatus **36** is heated to the correct temperature.

D. A proximity sensor (e.g., proximity sensor **71**, FIG. **3**) to ensure that a bottle jam has not occurred within the bottle infeed and sterilization apparatus **60**.

E. A temperature sensor to ensure that the temperature of the heated sterile air entering the bottle infeed and sterilization apparatus **60** is correct.

F. A proximity sensor that to ensure that each conveying plate **94** is fully loaded with bottles **12**.

G1. A conductivity sensor to ensure that the measuring cup used by the interior bottle sterilization apparatus **116** is full.

G2. A conductivity sensor to ensure that the measuring cup used by the interior bottle sterilization apparatus **116** is emptied in a predetermined time.

G3. A pressure sensor to ensure that the pressure of the air used by the interior bottle sterilization apparatus **116** is within predetermined atomization requirements.

G4. A temperature sensor to ensure that each heat heating element used by the interior bottle sterilization apparatus **116** is heated to the correct temperature.

H. A temperature sensor to ensure that the air drying temperature within the activation and drying apparatus **152** is correct.

I. A plurality of flow sensors to ensure that the airflow rate of the sterile air entering the sterile tunnel **90** is correct.

J. A pressure sensor to ensure that the pressure of the sterile air entering the activation and drying apparatus **152** is correct.

K. A measuring device (e.g., volumetric measuring device **188**, FIG. **3**) to ensure that each bottle **12** is filled to a predetermined level.

L. A pressure sensor to ensure that the pressure in the product tank **182** is above a predetermined level.

M. A level sensor to ensure that the level of product in the product tank **182** is maintained at a predetermined level.

N. Proximity sensors to ensure that the daisy chains **202** of lids **200** are present in the lid sterilization and heat sealing apparatus **162**

O. A level sensor to ensure that the hydrogen peroxide level in the hydrogen peroxide bath **204** in the lid sterilization and heat sealing apparatus **162** is above a predetermined level.

P. A temperature sensor to ensure that the temperature of the hot sterile air knives **208** of the lid sterilization and heat sealing apparatus **162** is correct.

Q. A temperature sensor to ensure that the heat sealing apparatus **214** is operating at the correct temperature.

R. Proximity sensors to ensure that the bottles **12** are discharged from the filler.

S. A speed sensor to measure the speed of the conveying apparatus **100**.

T. A concentration sensor to ensure that the concentration of oxonia is maintained at a predetermined level in the sanitizing apparatus **300**.

U. A pressure sensor to ensure that the pressure of the oxonia is maintained above a predetermined level in the sanitizing apparatus **300**.

V. A temperature sensor to ensure that the drying temperature of the drying apparatus **302** is correct.

The foregoing description of the present invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed, and many modifications and variations are possible in light of the above teaching. Such modifications and variations that may be apparent to a person skilled in the art are intended to be included within the scope of this invention defined by the accompanying claims.

I claim:

1. A method for automatically aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the bottles at a rate greater than 100 bottles per minute wherein the disinfecting is with hot atomized hydrogen peroxide, wherein said plurality of bottles are in an upright position during disinfecting; and

aseptically filling the bottles with aseptically sterilized foodstuffs.

2. The method according to claim **1**, wherein the aseptically disinfecting the bottles includes an application of the hot hydrogen peroxide spray for about 1 second into an interior of the bottle and an activation and removal of the hot hydrogen peroxide using hot aseptically sterilized air for about 24 seconds.

3. The method according to claim **1**, wherein the aseptically disinfecting the bottles includes an application of the hot hydrogen peroxide spray for about 1 second onto an outside surface of the bottle and an activation and removal of the hot hydrogen peroxide using hot aseptically sterilized air for about 24 seconds.

4. The method according to claim **1**, wherein the plurality of bottles are made from a glass.

5. The method according to claim **1**, wherein the plurality of bottles are made from a plastic.

6. The method according to claim **5**, wherein the plastic is selected from the group: polyethyelene terepthatlate, and high density polyethylene.

7. The method according to claim **1**, wherein the aseptic filling is at a rate greater than 100 bottles per minute.

8. The method according to claim **1**, further including capping the bottle with a aseptically disinfected lid.

9. The method according to claim **1**, further including a feedback control system for maintaining aseptic bottling conditions.

10. The method according to claim **1**, wherein the step of aseptically filling the bottles further comprises: filling the aseptically disinfected bottling at a rate greater then 360 bottles per minute.

11. The method according to claim **1**, wherein the aseptically sterilized foodstuffs are not a beverage.

12. The method according to claim **1**, wherein the plurality of bottles are made from one of glass and plastic.

13. The method according to claim **1**, wherein the aseptic filling is at a rate greater than 100 bottles per minute.

14. The method according to claim **1**, wherein the disinfecting the bottles is with hot hydrogen peroxide spray.

15. The method according to claim **14**, wherein the aseptically disinfecting the bottles includes an application of the hot hydrogen peroxide spray into an interior of the bottle and an activation and removal of the hot hydrogen peroxide using hot aseptically sterilized air.

16. The method according to claim **1**, wherein the step of aseptically filling the bottles further comprises: filling the aseptically disinfected bottling at a rate greater than 360 bottles per minute.

17. The method according to claim **1**, wherein aseptically denotes meeting the United States FDA level of aseptic.

18. A method for automatically aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the bottles at a rate greater than 100 bottles per minute; and

aseptically filling the bottles with aseptically sterilized foodstuffs, wherein the aseptically sterilized foodstuffs are sterilized to a level producing at least a 12 log reduction in *Clostridium, botulinum.*

19. A method for automatically aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the bottles at a rate greater than 100 bottles per minute, wherein the aseptically disinfected plurality of bottles are sterilized to a level producing at least a 6 log reduction in spore organism; and

aseptically filling the bottles with aseptically sterilized foodstuffs.

20. A method for automatically aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the bottles at a rate greater than 100 bottles per minute, wherein the disinfecting the bottles is with hot hydrogen peroxide spray, wherein a residual level of hydrogen peroxide is less than 0.5 PPM; and

aseptically filling the bottles with aseptically sterilized foodstuffs.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,945,013 B2
DATED : September 20, 2005
INVENTOR(S) : Taggart

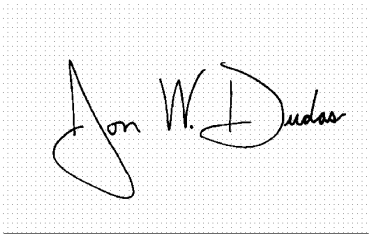
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 4,
Line 40, delete "*subtilis var. globigii*" and insert -- *subtilis var. globigii* --.

Column 16,
Line 41, delete "*Clostridium, botulinum*" and insert -- *Clostridium botulinum* --.
Line 48, delete "organism" and insert -- organisms --.

Signed and Sealed this

Tenth Day of January, 2006



JON W. DUDAS
Director of the United States Patent and Trademark Office

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2020-1083

Short Case Caption: Steuben Foods, Inc. v. Vidal

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The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it meets one of the following:

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July 20, 2022

/s/ W. Cook Alciati
W. COOK ALCIATI