2023-1790

United States Court of Appeals for the Federal Circuit

STEUBEN FOODS, INC.,

Plaintiff-Appellant,

– v. –

SHIBUYA HOPPMANN CORPORATION,
SHIBUYA KOGYO CO., LTD., HP HOOD LLC,

Defendants-Appellees.

On Appeal from the United States District Court for the District of Delaware in No. 1:19-cv-02181-CFC, Honorable Colm F. Connolly, Chief Judge

BRIEF FOR PLAINTIFF-APPELLANT

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JULY 26, 2023

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EXEMPLARY CLAIM FROM U.S. PATENT NO. 6,209,591

26. Apparatus for aseptically filling a series of bottles comprising:

a valve for controlling a flow of low-acid food product into a bottle at a rate of more than 350 bottles per minute in a single production line;

a first sterile region surrounding a region where the product exits the valve;

a second sterile region positioned proximate said first sterile region;

a valve activation mechanism for controlling the opening or closing of the valve by extending a portion of the valve from the second sterile region into the first sterile region, such that the valve does not contact the bottle, and by retracting the portion of the valve from the first sterile region back into the second sterile region.

EXEMPLARY CLAIM FROM U.S. PATENT NO. 6,536,188

19. A device for aseptically bottling aseptically sterilized foodstuffs having at least about a 12 log reduction in *Clostridium botulinum* comprising:

means for providing a plurality of bottles;

means for aseptically disinfecting the plurality of bottles;

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

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

EXEMPLARY CLAIM FROM U.S. PATENT NO. 6,702,985

1. Apparatus for sterilizing a container comprising:

a first supply source of sterile air;

a supply source of sterilant;

an atomizing system producing an atomized sterilant from the mixing of the sterile air from the first supply source of sterile air with the sterilant;

a second supply source providing a non-intermittent supply of hot sterile air to a conduit wherein said conduit is operationally coupled between said atomizing system and a container, and wherein said atomized sterilant is intermittently added to said conduit;

a mechanism for applying the atomized sterilant and the second supply source of hot sterile air on to the container; and

a third supply source of a hot sterile drying air for activating and drying the sterilant in the interior of the container, wherein the container is upright.

3. The apparatus of claim 1, wherein the container is a bottle.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2023-1790

Short Case Caption Steuben Foods, Inc. v. Shibuya Hoppmann Corporation

Filing Party/Entity Steuben Foods, Inc.

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
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I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 05/09/2023

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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).

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5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☐ Yes (file separate notice; see below) ☑ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

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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STATEMENT OF RELATED CASES

There have been no previous appeals in this proceeding. Steuben is unaware of any other case in this or any other tribunal that will directly affect or be directly affected by this Court's decision in the pending case.

INTRODUCTION

Following eleven years of hard-fought litigation, a jury found that Appellees infringed all five asserted claims from three Steuben Foods, Inc. ("Steuben") patents and that the asserted claims were not invalid. Appx5202-5208. For Appellees' infringement, the jury awarded Appellant Steuben the sum of $38,322,283.78. Appx5209. The jury's award represented a royalty of 2 cents for the 1,916,114,189 bottles Steuben's direct competitor, Appellee HP Hood, LLC ("Hood"), sterilized and filled on the bottling equipment sold to it by Appellees Shibuya Hoppmann Corporation and Shibuya Kogyo Co. Ltd. (collectively "Shibuya"). The jury's fact-intensive findings of infringement largely turned on the jury's resolution of conflicting testimony from, and the credibility of, the parties' technical experts.

In a Memorandum Opinion dated March 14, 2023 (the "JMOL Opinion"), the District Court overturned the jury's verdict, found noninfringement as a matter of law as to all five asserted claims from three different patents, found Appellees had waived their invalidity arguments for failure to move during trial, and conditionally granted a new trial.

With respect to U.S. Patent No. 6,209,591 (the "'591 patent"), the District Court found that the reverse doctrine of equivalents ("RDOE") applied (and still exists in the first place) such that no reasonable jury could have found infringement. The District Court erred in finding noninfringement by comparing the accused filling

valve to the specification figures. In so doing, the District Court wholesale rejected Steuben's trial testimony, finding that it was "wrong as a matter of law because it is inconsistent with the patent's specification" and therefore "entitled to no weight by the jury." Appx22. The proper inquiry is not whether the accused filling valve infringed the specification embodiments, but rather whether the accused filling valve infringed the properly construed claim. The jury's finding of the latter is supported by substantial evidence. This Court has never affirmed a judgment of noninfringement under the RDOE, and this case should not be the first—especially post-verdict, where the District Court granted Steuben summary judgment of literal infringement prior to trial.

With respect to U.S. Patent No. 6,536,188 (the "'188 patent"), the District Court disturbed the jury's factually-intensive finding of literal infringement of a "means-plus-function" claim element. In so doing, the District Court erroneously weighed evidence and found conflicts in the evidence in favor of Appellees rather than Steuben as the verdict winner. In short, the District Court substituted its own view of the evidence for the jury's. The District Court erred because Steuben adduced substantial evidence of literal infringement at trial.

With respect to U.S. Patent No. 6,702,985 (the "'985 patent"), the District Court overturned the jury's finding of infringement under the doctrine of equivalents based on a finding of vitiation. The JMOL Opinion finds that in this case the

question of vitiation may be decided with reference to "a binary choice between 'intermittently' and 'continuously." Appx8-9. The District Court erred because this Court has repeatedly and consistently explained that vitiation does not provide a shortcut to a proper equivalents analysis in favor of the type of binary choice presented in the JMOL Opinion.

As to the District Court's conditional grant of a new trial, the JMOL Opinion included a single sentence of explanation: "I believe a new trial would be warranted because, as explained above, the jury's verdicts with respect to infringement of the asserted claims of the #985, #188, and #591 patents are contrary to the evidence." Appx28. The District Court fails to even nominally invoke correct standard, which requires a finding that "the verdict is contrary to the great weight of the evidence, thus making a new trial necessary to prevent a miscarriage of justice." *Roebuck v. Drexel University*, 852 F.2d 715, 736 (3d Cir. 1988). To be sure, the JMOL Opinion fails to provide any reasoning whatsoever for ordering a new trial on the issue of damages and invalidity and makes no effort to explain why a new trial on infringement would be appropriate if this Court were to reverse the JMOL Opinion's finding(s) of noninfringement.

For the reasons that follow, Steuben respectfully requests that the Court reverse the JMOL Opinion, vacate the judgment of noninfringement and grant of a new trial, and direct entry of judgment on the jury verdict.

STATEMENT OF JURISDICTION

Because this is a patent infringement action, the District Court had jurisdiction under 28 U.S.C. § 1338(a). Following the District Court's entry of a Rule 54(b) Judgment, Steuben timely filed a notice of appeal. Appx31-33, Appx6026-6027. This Court has jurisdiction under 28 U.S.C. § 1295(a)(1).

ISSUES ON APPEAL

1. Did the District Court err in granting Appellees judgment of noninfringement of the ’591 patent as a matter of law?

2. Did the District Court err in granting Appellees judgment of noninfringement of the ’188 patent as a matter of law?

3. Did the District Court err in granting Appellees judgment of noninfringement of the ’985 patent as a matter of law?

4. Did the District Court err in conditionally granting a new trial on the issues of infringement, invalidity, and damages?

STATEMENT OF THE CASE

I. The parties compete in the field of aseptic bottling.

Steuben is a family-owned business, which employs approximately 700 individuals at its manufacturing plant in Elma, New York. Appx3021 at 85:3-10; Appx3054 at 218:2-6. At its expansive manufacturing facility, Steuben operates numerous aseptic packaging lines, including one aseptic bottling line manufactured by Steuben's patent licensee, which embodies certain of Steuben's asserted claims. Appx3060 at 244:19-23; Appx3073 at 294:4-14, 295:7-17. Steuben's aseptic bottling business has been quite profitable over the years, netting Steuben between 10-15 cents per bottle run on the line. Appx3060-3061 at 244:24-245:1.

Steuben directly competes with Hood in the aseptic bottling business. Hood purchased three aseptic bottling lines from Shibuya. From the beginning of the damages period through expiration of the '985 patent, Hood produced 1,916,114,189 bottles on the three accused aseptic bottling fillers in violation of Steuben's patents. Appx3141 at 565:17-566:7; Appx5983.

II. Steuben's asserted patents disclose novel aseptic bottling technology.

Aseptic bottling involves the filling of sterile food into a sterile bottle in a sterile environment. Appx3085 at 340:15-22. Such an entirely sterile process allows products that would otherwise need to be refrigerated to be shipped, stored, and sold without refrigeration prior to opening. Appx3055 at 223:3-8. For example, Hood used the infringing Shibuya fillers to produce hundreds of millions of bottles of

Muscle Milk, providing great logistical advantages by eliminating the need for refrigerated shipping and storage. Appx3125 at 500:22-502:18. These are the very benefits provided by Steuben's claimed technology. Appx3055 at 223:1-8.

In or around 1994, Steuben tasked its lead engineer, Thomas Taggart, with finding high throughput aseptic bottling equipment that would meet the FDA's stringent aseptic packaging requirements. Appx3069 at 278:1-11. Following a multi-year investigation, Mr. Taggart was unable to find such equipment on the market, so he decided to design his own aseptic bottling line. *Id*. The results of Mr. Taggart's efforts are disclosed and claimed in the three patents at issue here, which are part of a larger family of patents.

On February 2, 1999, Steuben filed a provisional patent application disclosing Mr. Taggart's inventions in the field of aseptic bottling. Appx72. In his patent applications, Mr. Taggart publicly disclosed—for the first time ever—an aseptic bottling machine that would meet the FDA's stringent requirements for aseptic packaging at a commercially viable throughput. Appx87-88 at 2:1-4:55; Appx3085 at 341:1-21. In addition to the challenges of meeting the FDA's regulations, the patents explain that bottles pose a particular sterilization challenge because a bottle "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.)." Appx87 at 2:42-48; Appx3085-3086 at 340:23-343:2. The patents

note that the difficulty in sterilizing a bottle limits the processing speed of the apparatus. Appx87 at 2:50-55. To overcome the shortcomings of the prior art, Mr. Taggart invented "[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." Appx87 at 2:1-7.

The '591 patent issued on April 3, 2001, and is directed to a novel aseptic filling valve. Appx34. The '188 patent issued two years later on March 25, 2003, and is directed to a novel aseptic bottle sterilization and filling line. Appx72. The '985 patent issued the next year on March 9, 2004, and is directed to a novel device for sterilizing bottles. Appx101.

Following Steuben's assertion of the three patents, they were subject to numerous patentability challenges at the USPTO. For its part, the '188 patent survived one *ex parte* reexamination and two *inter partes* reviews. Appx97-100. During the reexamination, the examiner confirmed, *inter ali*a, the patentability of original claim 19 as well as new claim 22. *Id*. The jury found Appellees to infringe these two claims. Appx5205.

The '591 patent likewise survived two *inter partes* review proceedings and a reexamination filed by Shibuya. During that reexamination, Steuben amended claim 26, which the jury found Appellees to infringe. Appx69-71; Appx5204.

Shibuya also filed for reexamination of the ’985 patent, which resulted in the examiner confirming the patentability of original claims 3 and 7, which the jury found Appellees to infringe. Appx132-134, Appx5203.

All three Steuben patents were licensed to an aseptic bottling equipment manufacturer called Stork as well as to Abbott Laboratories, a well-known producer of beverages. Appx3059 at 238:7-18; Appx3060 at 244:4-9; Appx6171-6181; Appx6281-6290. Abbott used its license to purchase aseptic bottling equipment from Shibuya. Appx3059 at 239:12-20. Neither license was the result of litigation. The last of the three patents expired on November 27, 2019.

III. Hood’s purchase of three aseptic bottling lines from Shibuya.

In 2001, shortly after allowance of the ’591 patent, Steuben entered into discussions with Shibuya concerning a potential aseptic bottling partnership. Appx3056-3057 at 226:4-232:12; Appx6443-6458. While Mr. Taggart had designed an aseptic bottle filler, and tested certain operations of it, Steuben is a packaging company, not an equipment manufacturer. Appx3070-3071 at 281:12-287:16. Accordingly, Steuben sought a partner with manufacturing expertise to assist in commercialization of Steuben’s inventions. Appx3057 at 229:6-21. Under the proposed partnership, Steuben would contribute its expertise in FDA regulated packaging and its bottling technology, while Shibuya would bring to bear its manufacturing expertise. *Id*. As part of those discussions, Steuben informed

Shibuya of the existence of Steuben's patent filings, including the allowance of the '591 patent. *Id*. at 230:3-21. Despite Steuben's efforts, those conversations did not result in a partnership. Appx3058 at 236:4-24.

In 2006, Steuben found out that after Steuben's efforts with Shibuya had failed, Shibuya went ahead and sold an aseptic bottling line to Hood. *Id*. Shibuya's sale of the first of three aseptic bottling line provided Hood with a first-mover advantage, which Hood used to obtain a dominant position in the aseptic bottling market on the back of—and without a license to—Steuben's patented aseptic bottling technology. Appx3061 at 245:2-8. It was not until several years later that Steuben was able to find a manufacturing partner in its licensee Stork. Appx3059 at 237:2-13.

During trial, Steuben presented testimony from Hood's Chief Financial Officer, Mr. Marcinelli, who explained that Hood made the decision to purchase the first aseptic bottling line to service its "very important business partner," Nestlé. Appx3124 at 497:19-498:4. Nestlé is also a Steuben aseptic bottling customer. Appx3073 at 294:4-295:6. According to Mr. Marcinelli, Nestlé sought the benefit of non-refrigerated storage and transportation, which aseptic bottling provided. Appx3125 at 499:4-23. Mr. Marcinelli also testified that Hood expected to run a full production line of volume for Nestlé "forever." Appx3125 at 500:2-4. Mr. Marcinelli further explained that Hood typically expects to make a profit of between

7-9 cents per bottle. Appx3126 at 503:4-10. After Steuben filed suit against Shibuya in 2010, Hood installed two more Shibuya aseptic bottling lines to meet growing customer demand, again in direct competition with Steuben. Appx3123 at 493:2-13.

IV. Relevant procedural history.

On September 1, 2020, the District Court issued its claim construction order in which it construed various claim terms relevant to this appeal. Appx5069-5075. On October 4, 2021, the District Court denied Appellees' motion for summary judgment of noninfringement of the '188 patent. Appx5151-5152. The Court found that Steuben had raised a controverted question of material fact concerning infringement of the claimed "means for filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute." *Id*. Thereafter, the Court denied Appellees' motions for summary judgment of noninfringement of the '591 and '985 patents as well as Appellees' motion for summary judgment of invalidity of the '188 and '591 patents. Appx5153-5154.

On October 13, 2021, the District Court denied Steuben's motion for summary judgment of infringement of the '591 patent. Appx5155-5163. In that order, the District Court found that Hood's accused bottling line "literally infringes claim 26" of the '591 patent, but nonetheless found that Appellees' expert had raised a disputed factual question under the RDOE. Appx5159-5163.

Trial began on November 15, 2021. Steuben's case-in-chief relied on testimony from: (a) Steuben's corporate designee Brian Manka (Appx3053-3068); (b) Mr. Taggart (Appx3069-3072); (c) a former Steuben employee, Tom Krol who was involved in the negotiation of Steuben's two patent licenses (Appx3072-3075); (d) Hood's Rule 30(b)(6) witness Thomas Stucki (Appx3121-3124); (e) Hood's chief financial officer, James Marcinelli (Appx3124-3127); (f) Dr. Andre Sharon, Steuben's technical expert (Appx3083-3121); and (g) Dr. David Blackburn, Steuben's damages expert (Appx3127-3154).

Dr. Sharon is a highly accomplished mechanical engineer with a Ph.D. in mechanical engineering from MIT. Appx3084 at 337:3-338:25. Dr. Sharon is currently a professor at Boston University, where he runs the Fraunhofer Institute for Manufacturing and Innovation. Appx3085 at 339:1-9. Dr. Sharon has expertise in the design of FDA regulated processing machines and has been involved in the design of modules for aseptic machines. *Id*. at 339:10-340:9.

Dr. Blackburn is a highly accomplished economist. Dr. Blackburn has an undergraduate degree in applied mathematics and economics from Brown University and a masters and Ph.D. in economics from Harvard University. Appx3127 at 509:5-17. Following his formal education, Dr. Blackburn began his employment at NERA Economic Consulting, where he is presently a Director. *Id.*

at 510:2-14. Dr. Blackburn has substantial experience working on the economic issues associated with patent infringement disputes. *Id*. at 510:9-23.

The case was submitted to the jury on Friday, November 19, 2021. Appx3357. at 1425:11-18. The jury was unable to reach its decision by the afternoon of November 19 and returned to deliberate on Monday November 22, 2021. *Id*. at 1427:22-24. Thereafter, the jury returned a verdict in Steuben's favor on every single issue with a damages award of $38,322,283.78. Appx5209. Following that verdict, Appellees filed post-trial motions, which the District Court granted on March 14, 2023. Appx29-30. The District Court entered a Rule 54(b) judgment on April 5, 2023, and Steuben filed the present appeal. Appx31-33; Appx6026-6027.

SUMMARY OF ARGUMENT

The District Court erred in overturning the jury's verdict of infringement of the '591 patent by: (1) basing its decision on a comparison of the accused device to the patent figures and embodiments rather than claim 26 as properly construed; (2) finding that Appellees had carried their burden of production on their RDOE defense based on a legally erroneous assessment of claim 26's supposed "principle of operation"; (3) disregarding Steuben's expert evidence as purportedly inconsistent with the patent's specification; and (4) disturbing the jury's implicit credibility findings. In addition, Steuben respectfully submits that this Court should take this opportunity to clarify that the RDOE is not a viable defense to infringement under the 1952 Patent Act.

The District Court erred in overturning the jury's verdict of infringement of the '188 patent by: (1) overlooking substantial evidence of literal infringement adduced by Steuben at trial; (2) weighing the evidence and resolving conflicts in that evidence in favor of Appellees rather than Steuben as the verdict winner; and (3) failing to consider the context of the claimed function in weighing the infringement evidence adduced at trial.

The District Court erred in overturning the jury's verdict of infringement of the '985 patent by presenting the vitiation question as a binary choice between "intermittent" and "continuous." Rather than taking a "binary choice" shortcut, the

District Court should have assessed the record to determine that Steuben had adduced substantial evidence of infringement.

The District Court erred in conditionally granting a new trial by: (1) not even nominally finding the standard for a new trial to have been met; (2) failing to articulate its reasoning for granting a new trial; and (3) failing to extend Appellees' waiver of their post-trial invalidity arguments to their request for a new trial on invalidity.

STANDARD OF REVIEW

This Court's review of a district court's grant of JMOL and a new trial is governed by regional circuit law. *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1301, 1309 (Fed. Cir. 2011). The Third Circuit reviews the grant of JMOL for a fact question de novo, affirming "only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Lightning Lube, Inc. v. Witco Corp*., 4 F.3d 1153, 1166-67 (3d Cir. 1993). The Third Circuit reviews the conditional grant of a new trial for an abuse of discretion. *Id.* at 1167.

"Infringement is a question of fact." *Apple Inc. v. Samsung Elecs. Co*., 839 F.3d 1034, 1040 (Fed. Cir. 2016) (en banc). This Court's "review on appeal is limited to whether there was substantial evidence in the record to support the jury's verdict." *Id*. Such review "presume[s] the jury resolved all underlying factual disputes in favor of the verdict." *Id*.

ARGUMENT

I. The District Court erred in relying on the reverse doctrine of equivalents to overturn the jury's '591 patent infringement verdict.

The District Court invoked an "anachronistic exception, long mentioned but rarely applied" in the RDOE to overturn the jury's factual finding that Appellees infringed claim 26 of the '591 patent. *See Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*, 279 F.3d 1357, 1368 (Fed. Cir. 2002). Despite conflicting expert testimony on the factual question of the principle of operation of the patented invention, the District Court found that Steuben's expert testimony was "wrong as a matter of law because it is inconsistent with the patent's specification" and therefore "entitled to no weight by the jury." Appx22. Accordingly, the District Court found Appellees' RDOE case unrebutted and granted judgment as a matter of law in their favor. As explained below, the District Court erred in several independent ways, any one of which supports reversal.

A. The JMOL Opinion erred in finding noninfringement by comparing the accused filling valve to the '591 patent specification embodiments.

As with all aspects of patent law, when considering infringement "the name of the game is the claim." *In re Hiniker Co.*, 150 F.3d 1362, 1367 (Fed. Cir. 1998). This Court's precedent confirms that this remains true when considering an RDOE defense. For the RDOE to apply, "the accused device must be sufficiently different from that which is ***patented*** that despite the apparent literal infringement, the claims

are interpreted to negate infringement."[1] *Texas Instruments, Inc. v. U.S. Int'l. Trade Commission*, 846 F.2d 1369, 1372 (Fed. Cir. 1988). "That fact question is simple and direct: Is the accused product so far changed in principle that it performs the function of the ***claimed invention*** in a substantially different way?" *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1124 (Fed. Cir. 1985) (en banc). As this Court recognized in *SRI*, the RDOE is seldom (and in fact in this Court never has been) successful as a defense to literal infringement "[b]ecause products on which patent claims are readable word for word often are in fact the same, perform the same function in the same way, and achieve the same result, as the ***claimed invention.***" *Id*. at 1124, n. 19.

For that reason, in connection with the RDOE, "it is error to conduct infringement analyses in a vacuum, without reference to the ***claims*** at issue." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1351 (Fed. Cir. 2003). Similarly, this Court has found that under the RDOE it is improper to "ignore the structural claims, and to substitute a 'gist' drawn from the operation of a disclosed embodiment." *SRI*, 775 F.2d at 1124. Indeed, "claims are infringed, not specifications." *Id*. at 1121. And for that reason, "[i]nfringement, literal or by equivalence, is determined by comparing an accused product ***not*** with a preferred

[1] Emphasis herein is added unless otherwise indicated.

embodiment described in the specification, or with a commercialized embodiment of the patentee, but with the properly and previously construed ***claims*** in suit." *Id*.

Consistent with this settled law, the Court instructed the jury:

> The claims, why are they important? You've heard this a bunch. Right? They define what the patent covers. All right? And only the claims of the patents can be infringed, so the text that precedes it, some folks call it the written description or the specification. You don't look at that, whether that's infringed, and the same with the figures. The question is, have the claims been infringed? Only the claims define the extent of the patent's coverage.

Appx3350 at 1397:1-9; *see also* Appx3021 at 86:24-87:1 (preliminary jury instructions explaining that "it's really the claims that you are going to focus on").

Notwithstanding this clear instruction, the District Court allowed Appellees to present a noninfringement defense that relied entirely on a comparison of the specification embodiments to the accused device. Indeed, neither Appellees during trial, nor the District Court in its JMOL Opinion, addressed the principle of the actual claim language recited in claim 26.

Turning to the claim language, the relevant portion of claim 26 of the '591 patent recites the following:

> a first sterile region surrounding a region where the product exits the valve;
>
> a second sterile region positioned proximate said first sterile region;
>
> a valve activation mechanism for controlling the opening or closing of the valve by extending a portion of the valve from the second sterile

> region into the first sterile region, such that the valve does not contact the bottle, and by retracting the portion of the valve from the first sterile region back into the second sterile region.

Appx70-71.

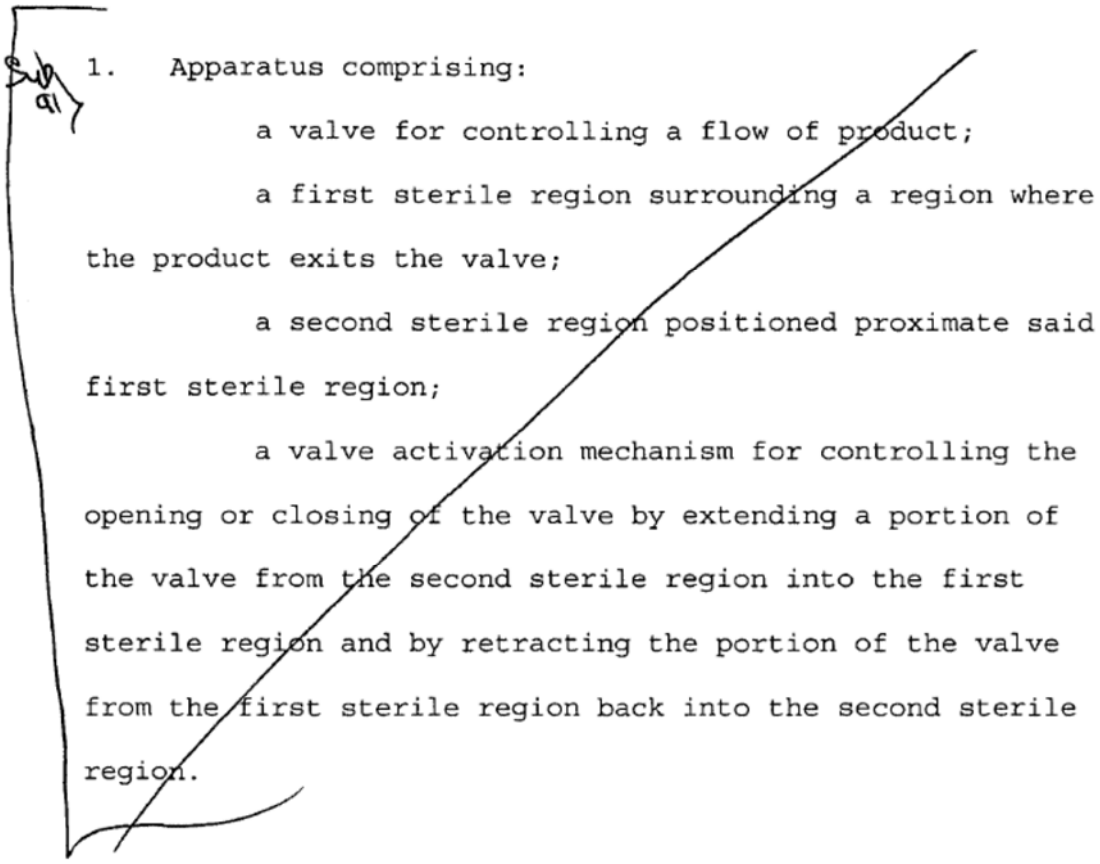
In its *Markman* Order, the District Court ruled that the "second sterile region" needed no construction, rejecting Appellees' argument that the claimed "second sterile region" should be limited to a region that is continuously sterilized in view of a specification embodiment. Appx5074-5075. The District Court explained: "Additionally, claim 26 is not limited to that embodiment. While certain claims of the '591 patent recite the 'continuously sterilized second sterile region,' embodiment that defendants describe, claim 26 did not." Appx6123-6125. Claim 1 recites "***a continuously sterilized second sterile region*** positioned proximate said first sterile region whereby said ***second sterile region is continuously sterilized during operation,***" while claim 16 likewise recites "providing ***a continuously sterilized second sterile region*** positioned proximate said first sterile region whereby said ***second sterile region is continuously sterilized during operation***." Appx70.

Consistent with the District Court's *Markman* ruling, the jury was instructed that the claimed "second sterile region" needed no construction. Appx5172-5173; Appx3350 at 1398:11-17. Yet, Appellees argued, and the JMOL Opinion erroneously finds, that claim 26's principle of operation is limited to the same specification embodiment the District Court expressly declined to read into claim 26

during *Markman*. For example, the JMOL Opinion finds that the "whole purpose of the second sterile region in the patented invention is to ***sterilize*** the portion of the valve stem that is exposed to a non-sterile region" and that the "principle of operation in 'the second sterile region 270A removes any contaminants from the valve stem 256A before any portion of the valve stems 256A enters the first sterile region.'" Appx22-23.

Thus, the District Court limited the principle of operation to the very same embodiment, which it expressly found did not limit claim 26. Doing so was erroneous in and of itself. The District Court then compounded its error by comparing the specification embodiment to the accused filling valves to find that Steuben had not established infringement. That finding was in error because "infringement is to be determined by comparing the asserted claim to the accused device, not by comparing the accused device to the figures of the asserted patent." *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1286 (Fed. Cir. 2002); *Zenith Labs, Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994) ("the only proper comparison is with the claims of the patent.").

The '591 patent's prosecution history further highlights the District Court's error in limiting claim 26 to a "continuously sterilized" principle of operation. During prosecution, Steuben presented the following as original claim 1:



1. Apparatus comprising:

a valve for controlling a flow of product;

a first sterile region surrounding a region where the product exits the valve;

a second sterile region positioned proximate said first sterile region;

a valve activation mechanism for controlling the opening or closing of the valve by extending a portion of the valve from the second sterile region into the first sterile region and by retracting the portion of the valve from the first sterile region back into the second sterile region.

Appx5143. The patent examiner then cited prior art, which led Steuben to amend claim 1. Appx5145. Specifically, Steuben amended claim 1 to recite a "continuously sterilized second sterile region" (underlining indicates amendments):

In the Claims

Please amend the claims as follows:

1. (Amended) Apparatus comprising:

a valve for controlling a flow of product;

a first sterile region surrounding a region where the product exits the valve;

a continuously sterilized second sterile region positioned proximate said first sterile region whereby said second sterile region is continuously sterilized during operation;

a valve activation mechanism for controlling the opening or closing of the valve by extending a portion of the valve from the continuously sterilized second sterile region into the first sterile region and by retracting the portion of the valve from the first sterile region back into the continuously sterilized second sterile region.

Appx5146-5147.

At the same time, Steuben presented new claim 26:

> 26. (New) Apparatus comprising:
>
> a valve for controlling a flow of product into a bottle;
>
> a first sterile region surrounding a region where the product exits the valve;
>
> a second sterile region positioned proximate said first sterile region;
>
> a valve activation mechanism for controlling the opening or closing of the valve by extending a portion of the valve from the second sterile region into the first sterile region, such that the valve does not contact the bottle, and by retracting the portion of the valve from the first sterile region back into the second sterile region.

Appx5148.

Steuben then explained the purpose of both its amended and new claim. With respect to claim 1, Steuben explained that the cited prior art "fails to teach or suggest having a second sterile region that is continuously sterilized." Appx5149. As to claim 26, Steuben explained the cited prior art "requires contact of the nozzle with the bottle," which "contact may result in contamination from one bottle to the next." *Id.* Steuben then explained that "[t]he invention claimed in claims 26-28 do not require contact between the valve and the bottle and in fact are [sic] not desired so as to reduce the possibility of contamination." Appx5149-5150.

Unlike the "continuously sterilized" claims, and as Dr. Sharon explained during trial, claim 26's principle of operation is to constrain the valve to two sterile regions and ensure that the valve does not contact the bottle. This principle of operation is directed to a different contamination problem that may occur when the valve makes contact with a bottle that may carry contaminants (e.g., from incomplete sterilization). In other words, claim 26's principle of operation is not limited to the continuously sterilized embodiment, which the Court compared to the accused filling valves to find noninfringement.

The District Court allowed Appellees to lose in their claim construction attempt to limit claim 26 to a preferred embodiment (an issue that frequently arises in patent litigation) only to turn around and erroneously argue to the jury that the accused filling valves do not infringe a preferred embodiment set forth in the patent figures. If this Court were to affirm this ruling, it would open the floodgates to a deluge of accused infringer attempts to escape infringement by arguing to a jury that—despite a claim construction that is broader than the preferred embodiment—an accused device does not infringe the preferred embodiment of a patent. Such a procedure is fundamentally inconsistent with the basics of patent law and usurps the Court's clear claim construction role as set forth in the Supreme Court's decision in *Markman v. Westview Instruments, Inc.* 517 U.S. 370, 372 (1996) ("We hold that

the construction of a patent, including terms of art within its claim, is exclusively within the province of the court.").

Because the procedure adopted by the District Court here is so fundamentally inconsistent with patent law, district courts around the country—including the District of Delaware—have rejected attempts to limit a claim's principle of operation to a preferred embodiment under the guise of the RDOE. For example, in *Ciena Corp. v. Corvis Corp.*, 334 F. Supp. 2d 598, 605 (D. Del. 2004), the court rejected the defendant's "formulation of the principle of the claimed invention [as] an impermissible attempt to limit the claimed invention to the preferred embodiments disclosed in the patents" noting that it "rejected similar arguments made by [the defendant] during the claim construction phase of this litigation." *Id*.; s*ee also Philips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1353-54 (D. Del. 1987) ("[Defendants] have not attempted to demonstrate that their polypropylene products are different in principle from the claim of the '851 patent. Instead, they have focused on the specification contained in Phillips' 1953 application and have looked to that particular embodiment of Phillips' invention as the basis for the infringement determination."); *Ocean Innovations, Inc. v. Archer*, No. 5:98-cv-1515, 2004 WL 5042296, at *8 (N.D. Ohio Jun. 16, 2004), *rev'd on other grounds*, 145 F. App'x 366 (rejecting RDOE argument where the "majority of [defendant's] reverse doctrine of equivalents argument is based on its claim construction . . . [with which] the court

disagreed."); *Seiko Epson Corp. v. Print-Rite Holdings, Ltd.*, No. 01-cv-500, 2005 WL 503195, at *9 (D. Or. Mar. 3, 2005) (rejecting RDOE argument which "depend[ed] on additional features not described in Epson's Claims."); *DePuy Mitek, Inc. v. Arthrex, Inc.*, No. 04-cv-12457, 2007 WL 2259109, at *4 (D. Mass. Jul. 31, 2007) ("As a preliminary matter, the specification discusses the role of the first and second set of yarns in a preferred embodiment. […]. The claim itself does not require that the two sets of yarns have the properties described by Dr. Mukherjee.").

This Court should reverse the District Court's JMOL grant and direct entry of judgment on the verdict.

B. The JMOL Opinion erred in finding that Appellees had set forth a *prima facie* showing under the RDOE.

With Steuben having established "literal infringement" at summary judgment, it was Appellees' burden "to establish the fact of non-infringement under the reverse doctrine of equivalents." *SRI*, 775 F.2d at 1124. "If the accused infringer makes a *prima facie* case, the patentee, who retains the burden of persuasion on infringement, must rebut that *prima facie* case." *Id*. To grant JMOL in favor of a party that bears the burden, the Court "must be able to say not only that there is sufficient evidence to support the [movant's proposed] finding, even though other evidence could support as well a contrary finding, but additionally that there is insufficient evidence for permitting any different finding." *Fireman's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1177 (3d Cir. 1976). The District Court erred in finding that

Appellees carried their burden because Appellees' presentation of the evidence focused entirely on specification embodiments. Indeed, "[o]ne who takes a claimed structure and merely uses it in a way that differs from that in which a specification-described embodiment uses it, does not thereby escape infringement" under the RDOE. *SRI*, 775 F.2d at 1123.

The JMOL Opinion asserts that Dr. Glancey testified "consistent with the patent's specification, that the principle operation of the second sterile region in the ***claimed invention*** is to 'appl[y] a sterilant to [the potentially contaminated] portion of the valve stem, thus cleaning that part of the valve stem." Appx20-21. But Dr. Glancey did not testify about the "claimed invention." Instead, he testified about the operation of the specification embodiments, which as explained above was legally incorrect.

In fact, Dr. Glancey clearly stated that his analysis focused on the principle of operation of the figures:

> Q. Okay. Now, did you compare the princip[le] operation of Shibuya's valve to the ***princip[le] operation of what the patent called the invention in Figures 25 and 26***?
>
> A. I have.

Appx3227 at 907:8-11.

Dr. Glancey further testified to the jury that claim 26 was limited in scope to the preferred embodiment:

Q. Is it your opinion that claim 26 of the '591 patent is limited in its coverage to only those examples we see in the figures of the patent?

A. Yes.

Appx3248 at 988:15-19

Dr. Glancey then testified that there were substantial differences between how Figures 25 and 26 sterilize the valve stem and how the accused filling valve operates—again without ever addressing the principle of operation recited in the ***claim itself***. Appx3224-3228. However, during cross-examination, Dr. Glancey was forced to admit that it is claims that are infringed, not embodiments, thereby impugning his own credibility. Appx3248 at 988:21-989:2.

Dr. Glancey even went so far as to make legally erroneous claim construction arguments from the stand:

Q. All right. I just want to focus on that sentence in column 14. Do you remember when Dr. Sharon was testifying, he described the figures from the patent, 25 and 26, as examples or embodiments of the invention?

A. I think those are the words that he used, yes.

Q. Do you agree with that characterization?

A. No.

Q. Why not?

A. Read that highlighted sentence. In fact, it doesn't say anything about embodiments or anything like that. ***It says, the present invention***, not some embod[iment], but the invention itself has introduced a second sterile region.

Appx3226 at 900:11-22.

However, it is the Court that decides the question of whether a claimed invention should be limited by a specification embodiment. Here, the Court rejected Appellees' attempt to so limit claim 26, and the jury was correctly instructed that claim 26 was not limited to a second sterile region that sterilizes the valve stem. The jury was correct to reject Dr. Glancey's testimony, the inconsistency of which with the Court's jury instructions left the jury free to find Dr. Glancey's testimony not credible. *Intellectual Ventures I LLC v. Motorola Mobility LLC*, 870 F.3d 1320, 1327 (Fed. Cir. 2017) ("the jury was free to disbelieve [Motorola's] expert and credit [IV's] expert.")

Contrary to the JMOL Opinion, it was not Dr. Sharon's testimony that was incorrect as a matter of law and therefore entitled to no weight; it was Dr. Glancey's. Because Appellees did not carry their burden of production on the RDOE defense, Steuben had no case to rebut, and the District Court erred in overturning the jury's verdict of infringement.

C. Steuben adduced substantial evidence to support the jury's '591 patent infringement verdict.

Even if Appellees had carried their initial burden of production on their RDOE defense—which they did not do—Steuben adduced substantial evidence to carry its burden of persuasion on infringement. During direct examination, Dr. Sharon

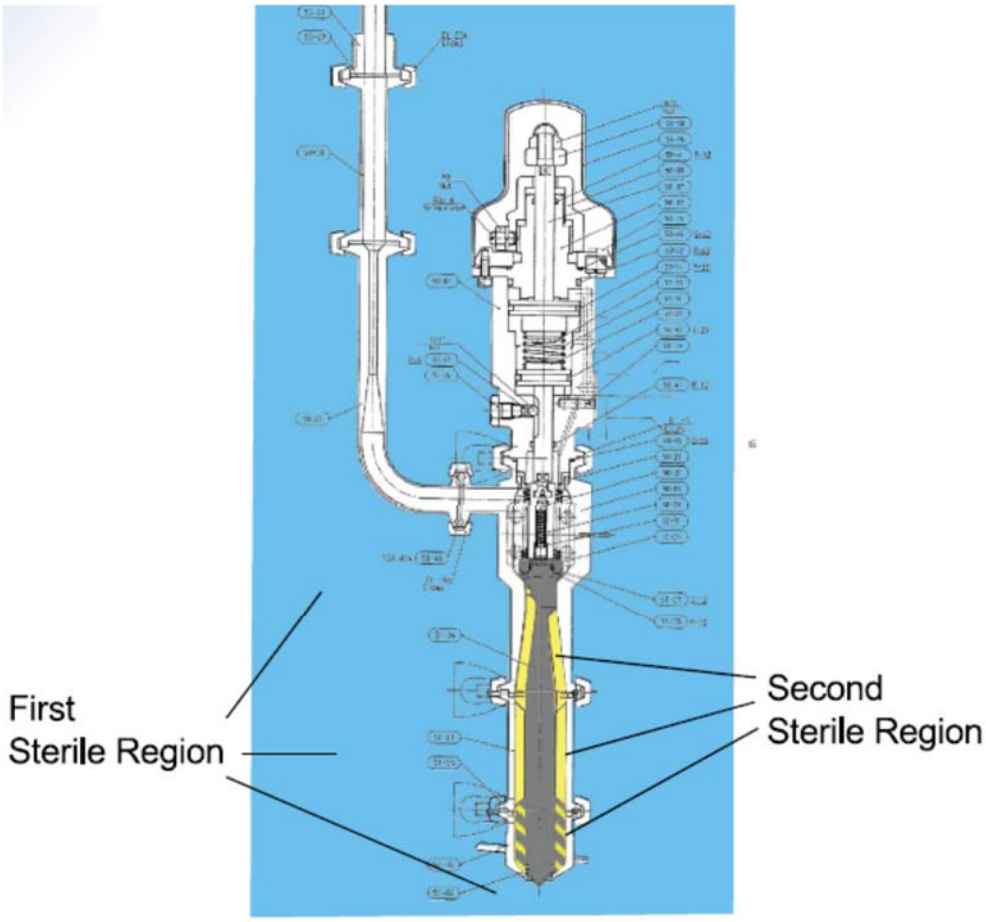
showed the jury claim 26 of the '591 patent and then explained that the principle of operation of claim 26 is "basically filling more than 350 bottles per minute aseptically." Appx3089 at 355:5-13.

Dr. Sharon explained that aseptic (i.e., commercially sterile) filling is achieved in claim 26 "by having these two sterile regions that the valve is sort of constrained to so that as it opens and closes, it only stays within those two regions and it does not go into any non-sterile region and therefore risk the possibility of bringing in contaminants, pathogens, into the food." *Id.* Dr. Sharon further explained that the claimed "second sterile region" "provides a sterile region for the valve tip to go into when it's being opened so that it doesn't, you know, go into a non-sterile area and then bring contaminants into food." Appx3090 at 360:20-361:3.

The JMOL Opinion finds that "Dr. Sharon identified at trial nothing in claim 26 or the #591 patent's specification that requires, discloses, or suggests in any way that a principle of operation of the claimed invention is (in Dr. Sharon's words) to 'constrain[]' the valve 'so that as it opens and closes, it only stays within [the first and second sterile] regions and it does not go into any nonsterile region and therefore [reduces the] risk [of] the possibility of bringing in contaminants, pathogens, into the food.'" Appx23-24. That finding was in error because Dr. Sharon relied on claim 26's express language which plainly recites, "extending a portion of the valve from

the second sterile region into the first sterile region . . . and [] retracting the portion of the valve from the sterile region back into the second sterile region."

Dr. Sharon then explained how claim 26's "second sterile region" principle of operation was present in the accused filling valve with reference to the below demonstrative.



Appx5997; Appx6316.

Dr. Sharon testified:

> So the valve basically just moves up and down a little bit, opening the bottom hole or the seat, what's called the seat of the valve, to let the flow come out. So in the closed position, the tip of the valve was in the

> first sterile region and then to open the valve to let food come down, it goes into the second sterile region, and then to close the food flow again, it goes back into the first sterile region. ***So it toggles between those two sterile regions***.

Appx3089 at 356:1-9; Appx3090 at 359:2-360:19.

According to the JMOL Opinion, "[i]t makes no sense, then, to look to the accused device that literally infringes to determine how the patented inventions performs." Appx25. But that is not what Dr. Sharon did. Instead, Dr. Sharon first established the principle of operation of the ***claimed invention*** with reference to the properly construed claim language. Dr. Sharon also compared that principle to the accused device and explained that the accused filling valve worked according to claim 26's principle of operation. Appx3090 at 359:24-360:19.[2] In other words, in the language of *Graver Tank* the "patented article" (i.e., the valve claimed in claim 26) does perform the aseptic filling function in a substantially similar way; indeed it is the same way. Both claim 26's principle of operation and the accused filling valve accomplish aseptic filling by constraining the filling valve's movement to two sterile regions.

Moreover, while Dr. Glancey disagreed as to what the invention was (an improper usurpation of the Court's claim construction role) and what the principle

[2] Dr. Sharon did testify that an example of claim 26's "second sterile region" principle of operation is found in the Accused Device. Appx3090 at 361:4-19. That testimony was correct because the District Court found the accused filling valve to be a literal embodiment of claim 26.

of that invention is, a determination of the principle of operation for purposes of an RDOE analysis is itself a question of fact. *SRI*, 775 F.2d at 1122-23. And on that factual question, the conflicts in the evidence must be resolved in Steuben's favor as the verdict winner. *Williamson v. Consolidated Rail Corp.*, 926 F.2d 1344 1348 (3d Cir. 1991); *see also Edwards Lifesciences AG v. CoreValve, Inc.*, 699 F.3d 1305, 1313 (Fed. Cir. 2012) (noting that when "testimony at trial [is] in direct conflict, . . . the court may not weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury's version"). Thus, even if Appellees' presentation of the principle of the invention was proper—which it was not—the District Court still erred in failing to draw all inferences in Steuben's favor as the verdict winner. *Williamson*, 926 F.2d at 1348.

D. Appellees' presentation of obviousness at trial undermined their own RDOE argument.

When it came time to argue invalidity, Dr. Glancey no longer argued that the equitable scope of claim 26 excluded the accused filling valve. Instead, Dr. Glancey relied on the testimony of Shibuya's corporate designee to argue that the accused filling valve was disclosed in a prior art reference, which a POSITA would have combined with two other references to render claim 26 obvious. Appx3228-3230 at 909:16-916:6; Appx3189-3190 at 753:17-756:21.

In so doing, Dr. Glancey relied on the exact same mapping Dr. Sharon used to demonstrate infringement:

Q. How about limitation D? Is that present?

A. Yes. The second sterile region, which is the foods passing, is also in this valve.

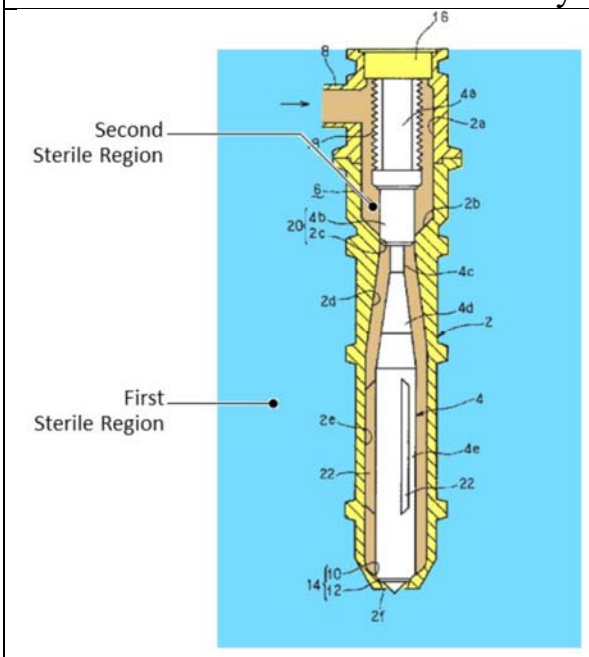
Q. All right. So this is essentially the same first and second [regions] that Dr. Sharon is pointing to in the Shibuya valve?

A. Very much so.

Appx3230 at 916:21-917:2.

Dr. Glancey illustrated his obviousness claim mapping in the below demonstrative presented to the jury. Immediately below Dr. Glancey's demonstrative is the demonstrative Dr. Sharon used to demonstrate infringement. As can be seen, Dr. Glancey pointed to the exact same sterile regions as Dr. Sharon.

Glancey Demonstrative



A. 26. Apparatus for aseptically filling a series of bottles comprising:

B. a valve for controlling a flow of low-acid food product into a bottle at a rate of more than 350 bottles per minute in a single production line;

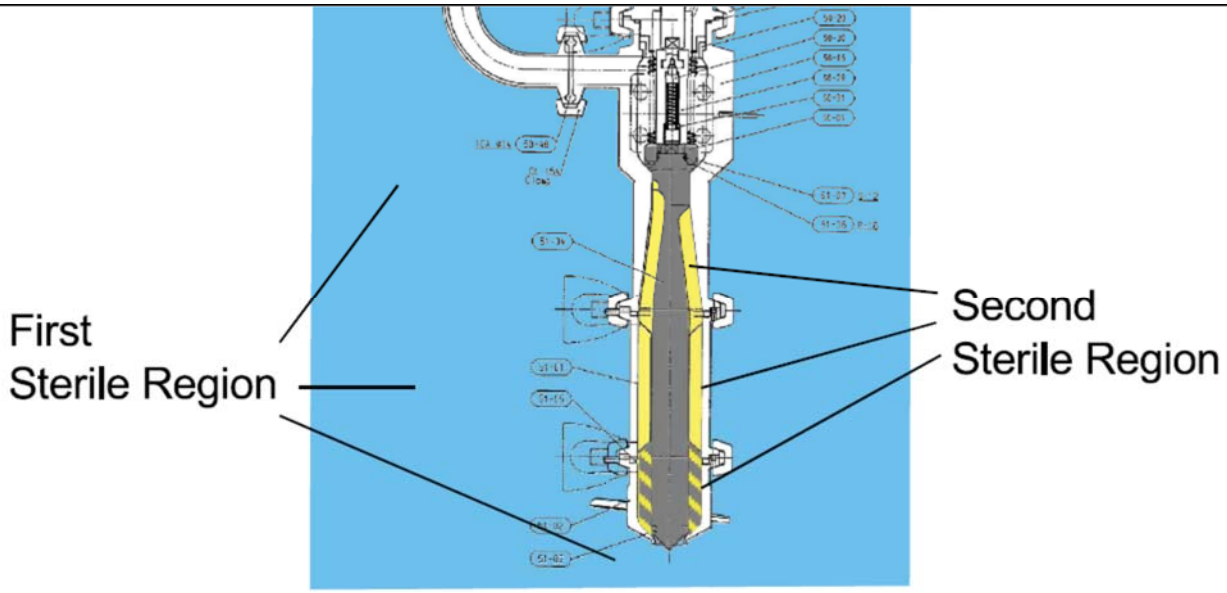
C. a first sterile region surrounding a region where the product exits the valve;

D. a second sterile region positioned proximate said first sterile region;

E. a valve activation mechanism for controlling the opening or closing of the valve by extending a portion of the valve from the second sterile region into the first sterile region, such that the valve does not contact the bottle, and by retracting the portion of the valve from the first sterile region back into the second sterile region.

Appx5384; Appx6161.

Sharon Demonstrative



Appx5997; Appx6316.

While a party may attempt to take alternative positions before a jury, Dr. Glancey never caveated his testimony as an alternative argument.[3] And it was within the exclusive province of the jury to see through Dr. Glancey's attempt to have his noninfringement cake and eat his invalidity cake, too. Indeed, in the context of JMOL, this Court should draw the inference that the jury found Dr. Glancey's conflicting positions to be not credible. *Apple*, 839 F.3d at 1045 n.10 ("A reasonable jury could have concluded that such inconsistencies negatively impacted the persuasiveness of Dr. Jeffay's opinions.").

E. The Court should take this opportunity to clarify that the RDOE is not a viable defense to patent infringement.

If the Court were to affirm the District Court's judgment of noninfringement of the '591 patent, it would represent the first time in history that this Court affirmed a finding of noninfringement under the RDOE. Indeed, in *Tate*, the Court referred to the RDOE as an "anachronistic exception, long mentioned but rarely applied" and then explained:

> Not once has this court affirmed a decision finding noninfringement based on the reverse doctrine of equivalents. And with good reason: when Congress enacted 35 U.S.C. § 112, after the decision in *Graver Tank*, it imposed requirements for the written description, enablement, definiteness, and means-plus-function claims that are coextensive with the broadest possible reach of the reverse doctrine of equivalents.

[3] During their closing, Appellees attempted to set up their noninfringement and invalidity arguments as alternative positions. But Dr. Glancey never offered such testimony, and counsel's statements during closing are not evidence. *See* Appx3343 at 1371:9-25.

Tate, 279 F.3d at 1368.

Steuben respectfully submits that this case provides the Court with the opportunity to clarify that the RDOE does not operate as a defense to infringement under the Patent Act of 1952 for two separate independent reasons as explained below.

1. Negating a finding of "literal infringement" by the RDOE conflicts with the plain language of 35 U.S.C. § 271(a).

In support of its RDOE finding, the JMOL Opinion cites *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 399-400 (Ct. Cl. 1967) for the proposition that "since the law is to benefit the inventor's genius and not the scrivener's talents, claims must not only read literally on the accused structures, but also the structures must 'do the same work, in substantially the same way, and accomplish substantially the same result.'" Appx20. But a determination of infringement does not require the additional step of ensuring that the accused structure performs the same function in substantially the same way to achieve the same result. *See Vertical Doors Inc v. Howitt*, No. 06-cv984, 2009 WL 10701551, at *5 (C.D. Cal. Sept. 14, 2009) ("THG cites *Autogiro Co. of America v. United States*, 384 F.2d 391, 399-00 (Ct. Cl. 1967) [] for the proposition that "claims must not only read literally on the accused structures, but also the structures must 'do the same work, in substantially the same way, and accomplish substantially the same result.' " []. This misrepresents the current law on patent infringement.").

Instead, if there is infringement, then there is infringement; period. This is set forth in the text of 35 U.S.C. § 271(a) itself, which provides:

> ***Except as otherwise provided in this title***, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, ***infringes*** the patent.

Under the plain language of the statute, exceptions to infringement must be found elsewhere in Title 35.

Literal ***infringement*** is ***infringement***, and the judicially created RDOE exception to "literal infringement" contradicts the plain language of § 271(a) because it is not found in Title 35 of the United States Code. Indeed, when Congress passed the 1952 Patent Act, it, for the first time, expressly identified what constitutes patent infringement in a statute. *See* The Patent Act of 1952 – Legislative History – The Federico Commentary, Chapter 28 ("The prior statute had no section defining or dealing with what constitutes infringement of a patent. Paragraph (a) of section 271 for completeness and other reasons, declares that 'Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.'").

In the pre-Patent Act of 1952 context, a judicially created exception to infringement may have been legally appropriate. But when Congress promulgated

35 U.S.C. § 271(a), it made clear that exceptions to infringement must be found in Chapter 35 of the United States Code—and the RDOE is not found there.

2. The RDOE was subsumed in 35 U.S.C. § 112 when Congress promulgated the Patent Act of 1952.

The 1952 Patent Act, for the first time, enacted 35 U.S.C. § 112. As this Court explained in *Tate*, when Congress did so, "it imposed requirements for the written description, enablement, definiteness, and means-plus-function claims that are coextensive with the broadest possible reach of the reverse doctrine of equivalents." *Id*. at 1369.

Here, when Steuben drafted claim 26 of the '591 patent, the USPTO found that it complied with the conditions for patentability set forth in § 112. In this litigation, claim 26 survived challenges to its written description, enablement, and definiteness. Claim 26 also survived an obviousness challenge at trial and before that survived two *inter partes* reviews, and a reexamination proceeding (filed by Shibuya).

Steuben then proved literal infringement at summary judgment and prevailed over Appellees' presentation of a legally improper RDOE defense with the jury finding infringement by Steuben's direct competitor. Yet, despite all of this, the District Court threw out the well-supported jury verdict supposedly because the specification did not support the scope of claim 26. Such a result contravenes the

1952 Patent Act and numerous principles reiterated by this Court and the Supreme Court in the decades since.

If a device falls within the literal scope of the claim, it infringes. If an accused infringer believes that the claim is too broad as written, its recourse is to challenge compliance with §112 or on prior art grounds—both of which happened at trial and in numerous other proceedings.[4] But innovation is hampered when a patentee complies with §112, demonstrates literal infringement and ***still*** has a jury verdict taken away under an antiquated doctrine created before the enactment of the very statute codifying those same requirements.

This Court could right the balance by finding that the RDOE was subsumed into the requirements of §112 and therefore is not a viable defense to infringement. Doing so would serve the important policy goal of providing predictability and consistency in the application of the patent laws. Indeed, if this Court were to affirm the judgment of noninfringement under the RDOE, the defense would proliferate, creating unpredictability while posing a fundamental threat to innovation and the balance of incentives that promote it as provided by statute. Steuben's proposed approach is particularly sensible given that this Court has never affirmed a finding

[4] Despite arguing that the patent describes only a "second sterile region" that is sterilized during operation, Appellees did not challenge written description compliance of the "second sterile region" at trial. Nor would such a challenge have been successful because the specification includes *in haec verba* support for claim 26. *See* Appx57-58 at 2:61-3:5.

of noninfringement under the RDOE—not once—in the seventy-three years since *Graver Tank* first articulated the notion.

II. The District Court erred in overturning the jury's verdict of infringement of the '188 patent.

Claim 19 of the '188 patent recites "means for filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute."[5] The District Court construed the function according to the plain language of the claim as "filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute." Appx5073. For corresponding structure, the District Court identified the following: "filling valves (Items 194A, 194B) and filling nozzles (Items 190A, 190B); a control system (Item 550); ***a conveyor plate (Item 94); conveyor (Item 106)***; and equivalents." Appx5074.

At trial, Appellees disputed only whether the Accused Machines included the equivalent of the conveyor plate and conveyor. That dispute unfolded through a classic battle of the experts, which the jury decided in Steuben's favor. *Lansford-Coaldale Joint Water Authority v. Tonolli Corp.*, 4 F.3d 1209, 1216 (3d Cir. 1993) ("in a battle of the experts, the factfinder 'decides the victor'"). Yet, the District Court overturned the jury's verdict based on its incorrect finding that Steuben adduced only evidence concerning the claimed function performed by the equivalent

[5] Claim 22, which depends from claim 19, includes the same recitation. Appx99.

structures and not the way the equivalent structures perform that claimed function. For the reasons that follow, this Court should vacate the judgment of noninfringement and direct entry of judgment on the verdict.

A. The District Court erred in failing to recognize substantial evidence concerning the equivalent way in which the accused structures perform the claimed function.

Starting with the ’188 patent structure, Dr. Sharon explained that the ’188 patent conveyor plate relates to the claimed function because the conveyor plate carries the bottles through the filling station so that they can be filled at the recited filling rate. Appx3101 at 404:1-19. The conveyor plate does so when the conveyor to which it is attached rotates around pulleys, which cause the conveyor to move through the aseptic bottling line. Appx3102 at 408:7-25.

Dr. Sharon explained that the ’188 patent conveyor would be understood to be a common chain conveyor and explained the way the conveyor moves through the filling stations is by rotating around pulleys, “which is going to make the conveyor go around in this oval shape, just like a tractor track, snowmobile track. As it does that, it’s going to move the conveying plate with the bottle, along through the machine.” *Id.* at 408:7-25. Dr. Sharon explained this to the jury with reference to the below annotated Fig. 3 from the ’188 patent.

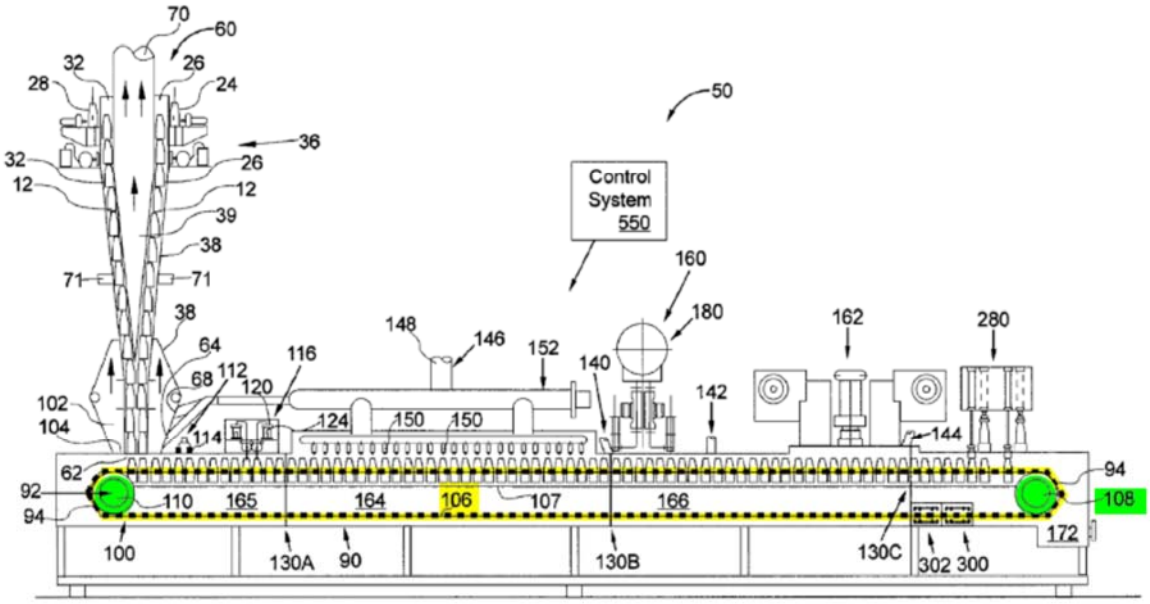


FIG. 3

Appx75.

With reference to Fig. 8 below, Dr. Sharon further expanded on the way the '188 patent structure performs the claimed function by explaining that the conveyor plate holds the bottles at the bottom as they move through the filling station, either in a single file line or in rows of two. Appx3101 at 403:8-406:25.

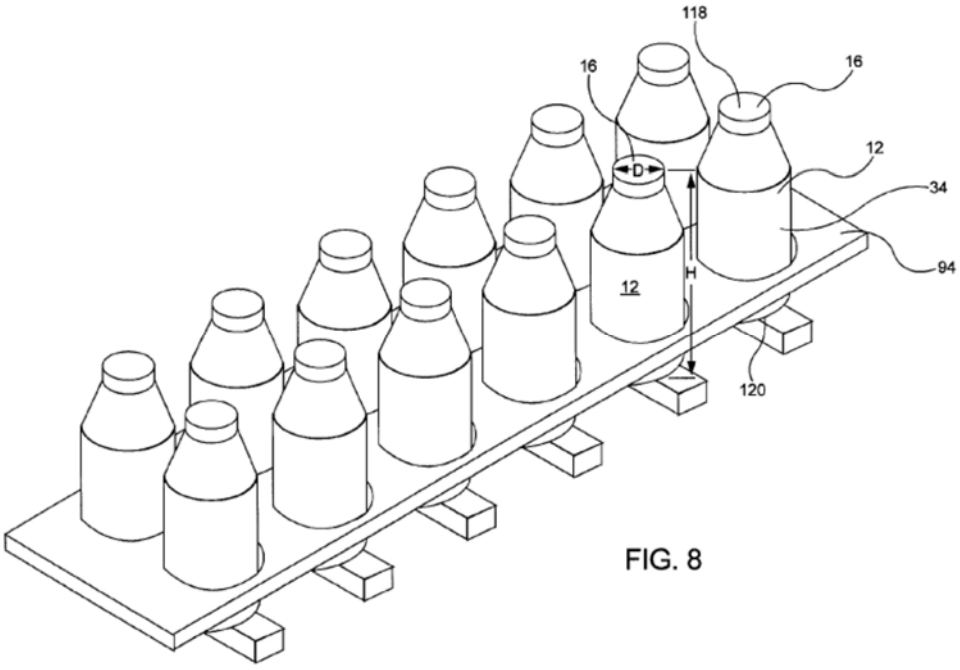


FIG. 8

Appx78.

As equivalent structures to the ’188 patent conveyor plate and conveyor, Dr. Sharon identified the grippers and the rotary wheels of the Accused Machines.[6] Appx3101-3103 at 403:11-412:9. Like the ’188 patent conveyor and conveyor plate, the rotary wheel of the Accused Machine rotates through the filling station with grippers attached to it, which hold the bottles. Dr. Sharon explained, with reference to the physical gripper, that the way the gripper performs the claimed filling function is to “hold the bottles from the neck.” Appx3101 at 405:11-406:25; PDTX-0002; PDTX-0004. Dr. Sharon then compared the way the conveyor plate and gripper perform the claimed function:

[6] Dr. Sharon identified “rotary dials” and “transfer wheels.” Appx3102 at 409:23-410:20. As used herein, the term “rotary wheel” encompasses both.

> So these hold it by the neck like that or the conveying plate in the patents hold it from the bottom. Whether you hold it this way or that way, it's not going to limit whether you can achieve a hundred bottles per minute of filling, so that's why it's insubstantial, whether you hold from the neck or you hold from the side of the bottle.

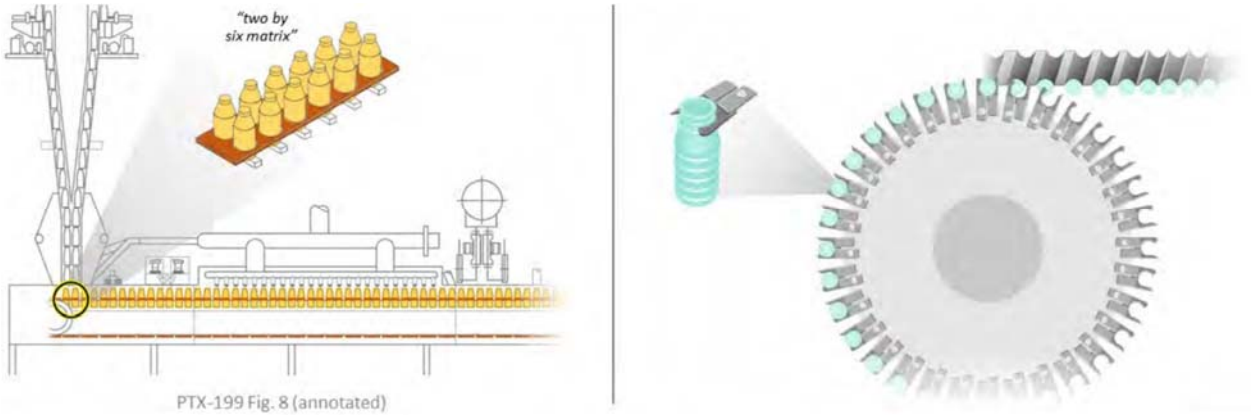
Appx3101 at 406:19-25. The District Court notably failed to acknowledge this testimony despite Steuben's citation of it in its JMOL Opposition.[7] Appx5965.

Dr. Sharon explained that the way the rotary wheels performed the claimed function is by "rotat[ing] with bottles along the circumference" with reference to a video showing the rotary wheels rotating in a circle with grippers attached, which would hold the bottles as they are filled at the recited rate. Appx3102 at 409:9-410:11; Appx6375. Dr. Sharon then testified that the differences between the conveyor rotating around a pulley with bottles held by conveyor plates and the rotary wheels rotating in a circle with bottles held by grippers are insubstantial. Appx3102-3103 at 409:23-411:15.

The below excerpt from Appellees' demonstrative—which Appellees presented to the jury—actually highlights the insubstantial differences between the two structures with reference to the claimed function. On the left is the '188 patent and on the right is the Accused Machine. Both structures hold groups of bottles that

[7] When Steuben submitted its Opposition, the Court had not yet released the final trial transcript and directed the parties to use the rough transcripts. The cited portion appeared in the rough transcript at 406:3-9, which is what Steuben cited.

move through the filling station to be filled at the claimed rate as the structures rotate through the filling station.



Appx5377.

As further support for his opinion, Dr. Sharon testified that the Accused Machines include both rotary wheels and linear conveyors, noting that the Accused Machines "have a linear conveyor on the output that takes the bottles out of the machine." Appx3103 at 411:16-21. The JMOL Opinion incorrectly finds that fact "irrelevant to the question of infringement." Appx13. But the fact that Appellees use both linear and rotary conveyors to move bottles through the bottling line supports the argument that the difference between the two types of conveyors is insubstantial. Indeed, the District Court improperly precluded Steuben from mentioning the linear conveyor during closing despite there being evidence of it in the record—a prejudicial error Steuben was able to overcome with the jury *still* finding in its favor. Appx3312 at 1246:1-15.

As shown above, the JMOL Opinion erred in finding that Dr. Sharon's testimony only addressed the "function" and not the "way." *Odetics, Inc. v. Storage Technology Corp.*, 185 F.3d 1259, 1268 (Fed. Cir. 1999) is particularly instructive here. In *Odetics*, this Court reversed a JMOL grant of noninfringement of a § 112, ¶ 6 limitation, rejecting the appellee's argument that the patentee's expert had addressed "only [] the functional identity of the two structures" and not the way the structures performed the claimed function. *Id.* at 1270. The Court explained that patentee's expert had in fact specifically addressed the "way" the structures performed the claimed function and reversed the JMOL grant. *Id.* at 1268. Here, the same result is warranted because, as explained above, Dr. Sharon plainly addressed the equivalent way in which the corresponding and accused structures perform the claimed function.

B. The District Court erred in substituting its choice for that of the jury between conflicting elements in the evidence.

"Whether an accused device infringes a § 112, ¶ 6 claim as an equivalent is a question of fact." *Id.*. The JMOL Opinion points to various differences between the '188 patent structure and the Accused Machines and concludes that "[t]hese differences are undisputed and so substantial that no reasonable juror could conclude that the accused machines had the structural equivalents of a conveyor and conveyor plate." Appx12. In so doing, the District Court improperly "substitute[d] its choice

for that of the jury between conflicting elements in the evidence." *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984).

This case involves straightforward conflicts in the evidence, specifically the testimony of two expert witnesses, which the District Court should not have disturbed. *Tennant v. Peoria & P. U. Ry. Co.*, 321 U.S. 29, 35 (1944) ("Courts are not free to reweigh the evidence and set aside the jury verdict merely because the jury could have drawn different inferences or conclusions or because judges feel that other results are more reasonable."). Those conflicts were resolved by the jury in Steuben's favor based on its overall assessment of the evidence and the credibility of the witnesses. *MobileMedia Ideas LLC v. Apple Inc.*, 780 F.3d 1159, 1168 (Fed. Cir. 2015) ("[T]he jury is permitted to make credibility determinations and believe the witness it considers more trustworthy").

Indeed, the credibility of the dueling experts was a central factor during trial. Appx3323-3324 at 1291:14-1292:7; Appx3321-3322 at 1281:13-1284:5 (closing arguments asking the jury to assess credibility). Dr. Sharon acknowledged and owned the differences between the corresponding and accused structures, testifying that such differences were insubstantial. Appx3101 at 405:20-406:4; Appx3102-3103 at 410:21-411:15. Dr. Glancey, on the other hand, denied basic facts and contradicted the testimony of Hood's engineer, Mr. Larrick. For example, Dr. Glancey argued that multiple grippers affixed to the same spinning wheel do not

move in groups, directly contradicting Mr. Larrick, who conceded that six adjacent grippers move "together." Appx3176 at 702:15-703:14; Appx3233-3234 at 930:12-932:3. The District Court erred in disturbing the jury's factual finding of infringement.

C. The District Court further erred in failing to consider the infringement question in the context of the claimed function.

The JMOL Opinion's weighing of the evidence on the substantiality of differences—even if proper, which it was not—erroneously failed to account for the specific context of the claimed function. "[T]he context of the invention should be considered when performing a § 112, ¶ 6 equivalence analysis just as it is in a doctrine of equivalents determination." *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1436 (Fed. Cir. 2000); *see also Utah Medical Prods., Inc. v. Graphic Controls Corp.*, 350 F.3d 1376, 1383-84 (Fed. Cir. 2003). Accordingly, "[i]n some cases, an analysis of insubstantial differences in the context of the invention results in a finding of equivalence under § 112, ¶ 6 even though two structures arguably would not be considered equivalent structures in other contexts, e.g., if performing functions other than the claimed function." Indeed, "when in a claimed 'means' limitation the disclosed physical structure is of little or no importance to the claimed invention, there may be a broader range of equivalent structures . . . ." *IMS*, 206 F.3d at 1436.; *see also Hearing Components Inc. v. Shure Inc.*, 600 F.3d 1357, 1371 (Fed. Cir. 2010) (reversing the district court's grant of JMOL following infringement

verdict of means plus function claim and noting that "an infringement analysis is fact-specific.").

Here, the claimed function is filling sterilized bottles at a rate greater than 100 bottles per minute. Unlike the JMOL Opinion, and Appellees' presentation of their evidence, Dr. Sharon's testimony properly framed the insubstantiality of the differences with reference to the claimed function. For example, with respect to the gripper of the Accused Machine Dr. Sharon testified:

> Well, because, again, the claim is -- the function of the claim is filling bottles at a rate greater than a hundred bottles per minute. How you hold the bottles is not important. If this was, if the claim was directed towards novel and new ways of holding bottles, then, yes, those differences may be substantial[.]

Appx3101 at 406:6-13.

As another example, Dr. Sharon testified:

> Q. In the context of filling at a hundred bottles or more per minute, does it matter whether the bottles are moving in a straight line or in a circular fashion?
>
> A. No. I mean, you know, again, if the claim was directed towards novel new ways of transporting bottles, then maybe those differences would be substantial, but in terms of filling at a rate of 100 bottles per minute, you can do it with a linear conveyor, rotary dial. It's not – it's not a substantial difference.

Appx3102 at 410:12-20; *see also* Appx3103 at 411:3-15 ("you can use either strategy and still achieve 100 bottles per minute").

The District Court further erred by "improperly import[ing] unclaimed functions when analyzing the way in which the disclosed embodiment performed the claimed function." *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1335 (Fed. Cir. 2006). For example, the District Court found that the grippers can hold bottles of different sizes whereas conveyor plates "can accommodate only bottles with bases barely smaller than the size of the plates' holes." Appx12. "That two structures may perform unrelated—and, more to the point, unclaimed—functions differently or not at all is simply not pertinent to the measure of § 112, ¶ 6 equivalents." *Odetics*, 185 F.3d at 1271. Here, the District Court did not construe the claimed function to require filling bottles of different sizes or otherwise limit the claimed filling function. The District Court erred by failing to properly consider the equivalence context in view of the claimed function.

III. The District Court erred in overturning the jury's '985 patent infringement verdict.

A. The District Court erred in finding vitiation with reference to a "binary choice" between "continuous" and "intermittent."

The jury found that the asserted claims of the '985 patent were infringed under the doctrine of equivalents and not invalid. In overturning the jury's infringement finding, the JMOL Opinion found that Steuben's equivalents infringement theory "vitiates the 'intermittently added' limitation of the asserted claims, and therefore cannot be sustained as a matter of law." Appx6. The JMOL Opinion premised its

ruling on its finding that "in this case there is a ***binary choice*** between 'intermittently' and 'continuously.'" Appx9.[8]

The District Court's finding that vitiation could be decided with reference to a "binary choice" was in error because this Court has explained that "[c]ourts should be cautious not to shortcut this inquiry by identifying a ***'binary' choice*** in which an element is either present or 'not present.'" *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1356–57 (Fed. Cir. 2012). Indeed, this Court has repeatedly found error in a district court's decision to shortcut a proper equivalence analysis by presenting a binary choice between the equivalent and the claim limitation—even when at first blush the equivalent appears to be the opposite of the claim limitation.

For example, *Bio-Rad Labs., Inc. v. 10X Genomics, Inc.*, 967 F.3d 1353, 1368 (Fed. Cir. 2020), the Court affirmed the district court's denial of JMOL following a jury finding of infringement where the claim element recited "non-fluorinated channels" and "reject[ed] 10X's attempt to limit the inquiry to a binary choice between 'fluorinated' and 'non-fluorinated' microchannels," explaining instead that "[t]he appropriate inquiry is whether a reasonable juror could have found that a negligibly-fluorinated microchannel performs the same function, in the same way, and achieves the same result, as a non-fluorinated microchannel." *Id*. at 1368.

[8] Dr. Sharon expressly explained that his theory of equivalence did not rely on a binary choice between continuous and intermittent. Appx3107 at 428:19-429:19.

Similarly, in *Deere*, this Court vacated a district court's vitiation finding where "the district court construed 'contact' to require 'direct contact,' and thus found that allowing 'no direct contact' would vitiate the court's construction." *Deere*, 703 F.3d at 1357. Rather than a "binary choice" between "direct contact" and "no direct contact," the question the district court should have considered was whether "a reasonable jury could find that a small spacer connecting the upper and lower deck walls represents an *insubstantial difference* from direct contact." *Id*. (original emphasis).

As another example, in *Edgewell Personal Care Brands, LLC v. Munchkin, Inc.*, 998 F.3d 917, 924 (Fed. Cir. 2021), the district court had construed the disputed claim term as requiring a single component structure, while the alleged equivalent included a multi-component structure. This Court "conclude[d] that the district court erred in evaluating this element as a binary choice between a single-component structure and a multi-component structure, rather than evaluating the evidence to determine whether a reasonable juror could find that the accused products perform substantially the same function, in substantially the same way, achieving substantially the same result as the claims." *Id.*

As a final example—and one that is particularly on point here—in *Epos Techs. Ltd. v. Pegasus Techs. Ltd.*, 766 F.3d 1338, 1347 (Fed. Cir. 2014), the claims at issue required "an ultrasonic receiver or transmitter device for receiving or transmitting

an '***intermittent***' ultrasound signal." The district court found that allowing ***continuous*** ultrasound signals to be equivalent "would eliminate the intermittent limitation entirely," and that "the doctrine of equivalents cannot extend that far." *Id.* at 1348. This Court vacated the district court's grant of summary judgment of noninfringement as erroneous in "'shortcut[ting]' the inquiry by identifying a binary choice (continuous or intermittent)." *Id.*

Here, the District Court erred in taking the same shortcut.[9] Rather than analyzing the factually-intensive function-way-result test Steuben presented to the jury, the District Court found "'[i]ntermittently' and 'continuously' are *antonyms* of each other, not equivalents." Appx6 (original emphasis). For support, the District Court erroneously cites not to record evidence concerning Steuben's equivalence theory, but instead to Merriam-Webster's definition of intermittently. *Cadence Pharms. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1372 (Fed. Cir. 2015) ("Characterizing an element of an accused product as the 'antithesis' of a claimed element is also a conclusion that should not be used to overlook the factual analysis required to establish whether the differences between a claimed limitation and an accused structure or step are substantial *vel non.*)."

[9] The JMOL Opinion attempts to distinguish *Epos* (which is just one of many cases prohibiting a binary choice) by finding that construction of "intermittent" in *Epos* did not necessarily preclude a continuous signal. But that finding is nowhere made in *Epos*, and the district court in *Epos* did find that its construction would necessarily preclude a continuous signal. *See Epos*, 766 F.3d at 1347-48.

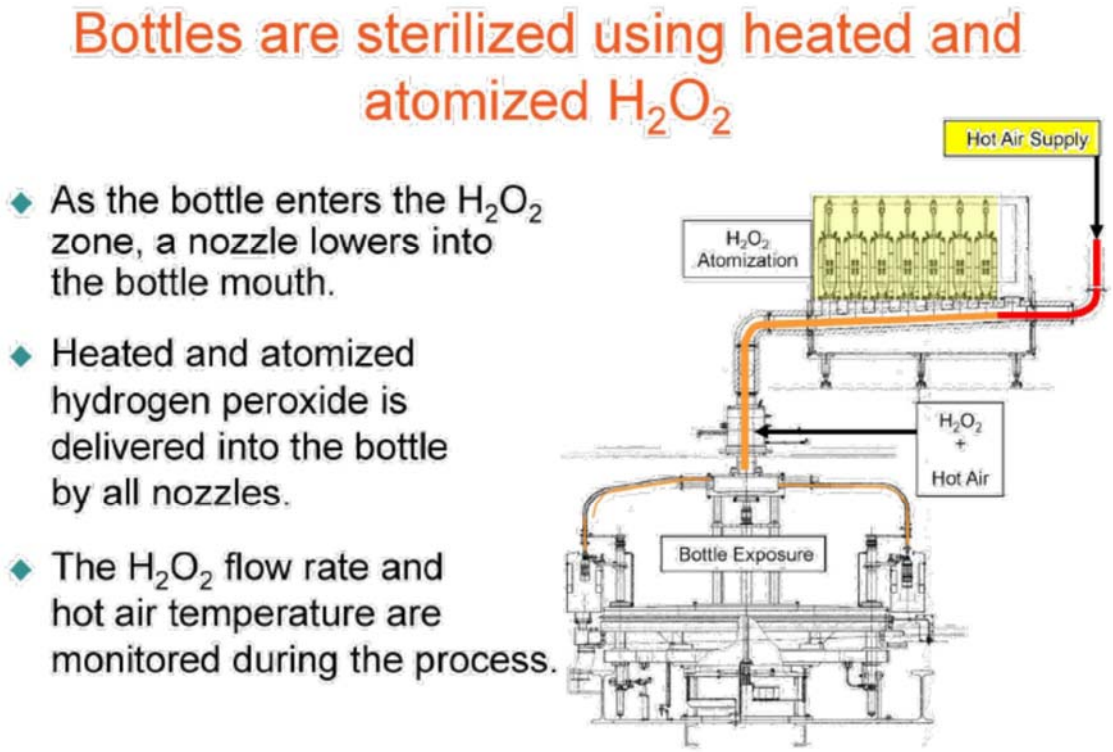
The District Court then found that "doing something in a non-continuous manner cannot be achieved by doing it 'continuously' even if you were doing it 'continuously, but very precisely and with control,'" presenting a binary choice between the non-intermittent limitation being either present or not present. The District Court is correct that doing something continuously is not literally the same as doing something intermittently. But that is always the case when a patentee invokes the doctrine of equivalents. For that reason, this Court has repeatedly found that a proper equivalence analysis cannot boil down to a binary choice between present and not present. "'Vitiation' is not an exception or threshold determination that forecloses resort to the doctrine of equivalents, but is instead a legal conclusion of a lack of equivalence based on the evidence presented and the theory of equivalence asserted."[10] *Cadence*, 780 F.3d at 1372. The District Court erred in taking a shortcut to a binary choice between "continuous" and "intermittent."

B. Substantial evidence supports the jury's finding of infringement of the '985 patent.

The parties' presentation of the evidence featured a classic battle of the experts on Steuben's equivalence theory. There was no dispute that most every element of the asserted claims was literally present in the Accused Machines. The only dispute

[10] The jury was even instructed—at Appellees' urging and over Steuben's objection—on the doctrine of vitiation. Appx5174 ("[S]pecifically, the alleged equivalent cannot eliminate or ignore an element or requirement of the claim."); Appx3351 at 1401:2-8.

presented to the jury centered around the limitation reciting: "a second supply source providing a non-intermittent supply of hot sterile air to a conduit wherein said conduit is operationally coupled between said atomizing system and a container, and wherein said atomized sterilant is intermittently added to said conduit." Appx129. It was undisputed that the Accused Machines feature a non-intermittent supply of sterile air through a conduit that is operationally coupled between an atomizing system and a container. This can be seen in the image below.



Appx6245.

The hot air supply flows continuously through the conduits. Atomized hydrogen peroxide, produced by an atomizing system, mixes with the continuous hot air supply in a conduit that is between the atomizing system and the bottle. In

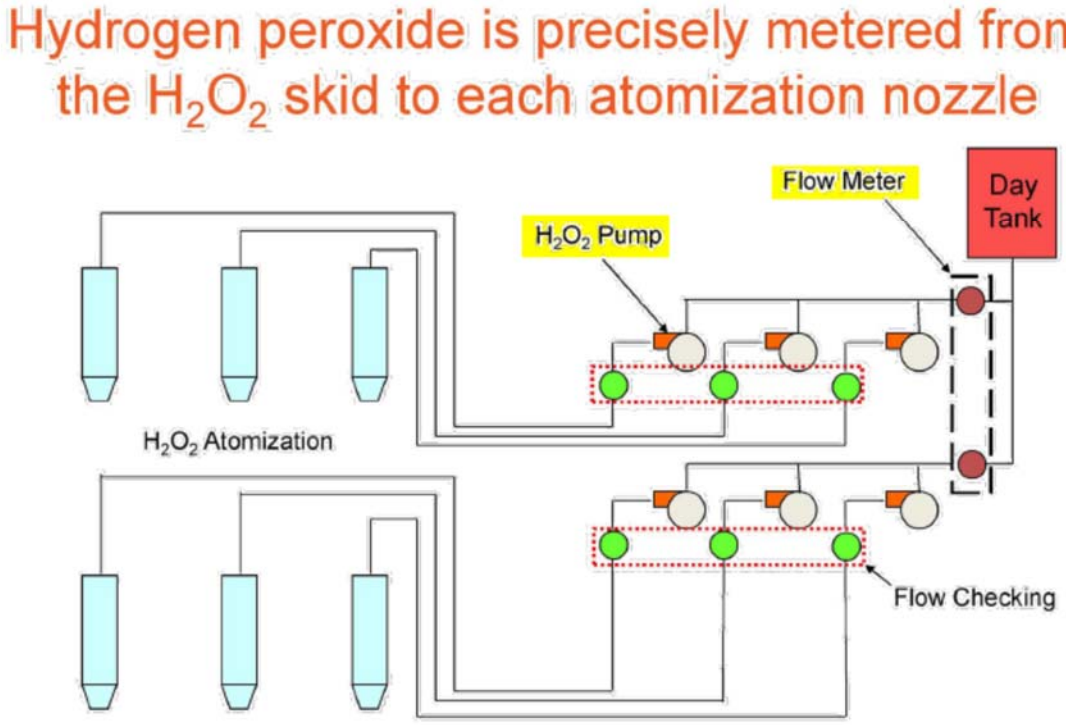
the Accused Machine the atomized sterilant is always flowing into conduit carrying the continuous air flow. Steuben acknowledged this would not literally meet the claim and presented an equivalents theory to the jury through the function-way-result test, focusing on "wherein said atomized sterilant is intermittently added to said conduit." Appx3106 at 426:5-11; Appx3108 at 433:1-434:13.

Dr. Sharon testified that the function of the "intermittently added" limitation was to ensure that the correct amount of sterilant was applied to the bottle with the result being a properly sterilized bottle. Appx3108 at 433:1-434:2. Dr. Sharon identified the equivalent structures, which perform that function as flow meters and metering pumps in the Accused Machines:

> What I'm saying is that the equivalent of this adding sterilant intermittently is continuously using flow sensors and metering pumps to achieve the same function because in the end, the point is to get the right amount of sterilant into the bottle. And so what is equivalent to this atomized sterilant [intermittently] being added in the accused machines, [is to ensure] the right amount of sterilant gets to the bottles by using metering pumps and flow meters that constantly monitor how much sterilant is basically on its way to the bottles.

Appx3107 at 429:9-19 (cleaned up).

The metering pumps and flow meters (depicted below) measure the amount of sterilant that flows to the atomization system and into the conduit carrying the non-intermittent supply of sterile air where the sterilant mixes with the continuous air flow for application to the bottle.

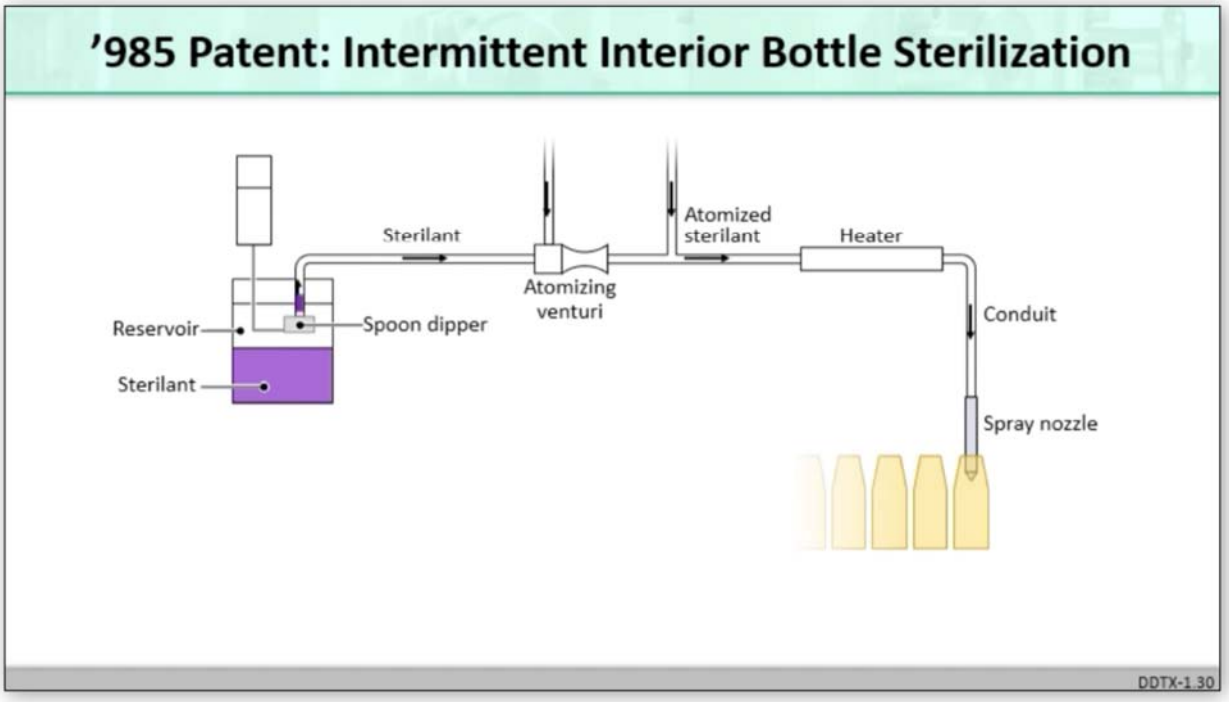


Appx6203.

Dr. Sharon explained that the "metering pumps and the flowing meters [] basically guarantee that you get the right amount of sterilant from the reservoir to the atomizers, which eventually gets to the bottles." Appx3108 at 432:7-15. Dr. Sharon's testimony was consistent with testimony from Hood's engineers establishing that the flow meters "precisely control" sterilant supply and ensure a properly sterilized bottle. Appx3178 at 711:17-24; Appx3122-3123 at 489:16-491:7.

Dr. Sharon then turned to a discussion of the '985 patent embodiment. Like the Accused Machines, the '985 patent discloses an embodiment where sterilant is

measured, then atomized, mixed with a continuous flow of air, and then applied to the bottle. The only difference is that, in the '985 patent embodiment, the measured sterilant is intermittently added to the continuous air flow. Dr. Sharon explained the '985 patent embodiment with reference to the screen shot below from an animation Appellees presented to the jury. Appx3108 at 431:4-7.



Appx6003; Appx3049 at 198:11-19 (Appellees' counsel explaining that "a spoon gets dipped into the sterilant to measure out the correct amount of sterile for a bottle.").

Dr. Sharon explained that the function of the "spoon dipper" is to ensure that "the right amount of sterilant gets to the bottle" and that spoon dipper is the way the sterilant is intermittently added to the conduit in the '985 patent embodiment.

Appx3108 at 431:4-16. And as with the Accused Machines, the result is a properly sterilized bottle. Appx3108 at 432:1-4. While Appellees adduced conflicting evidence from Dr. Glancey, "[e]ven in cases in which a court concludes that a reasonable jury could have found some facts differently, the verdict must be sustained if it is supported by substantial evidence on the record that was before the jury." *Apple*, 839 F.3d at 1062. Here, the District Court erred in overturning the jury's factual determination of infringement under the doctrine of equivalents.

IV. The District Court erred in conditionally granting a new trial.

The JMOL Opinion finds that "were the Federal Circuit to vacate the judgment of noninfringement, I believe a new trial would be warranted because, as explained, above, the jury's verdicts with respect to infringement of the asserted claims of the #985, #188, and #591 patents are contrary to the evidence." Appx28. The JMOL Opinion does not explain why a new trial on infringement would be appropriate if this Court were to find sufficient evidence to support the jury's infringement verdicts. Nor does the JMOL Opinion even mention a new trial on the jury's not invalid and damages verdicts. Nonetheless, the District Court's Rule 54(b) judgment—without explanation—expanded the scope of a new trial to include invalidity and damages.

The District Court erred in granting a new trial as explained below.

A. The District Court erred in granting a new trial despite not finding that the governing standard had been met while failing to provide any reasoning.

The JMOL Opinion orders a new trial because the jury's infringement verdicts were purportedly "contrary to the evidence." Appx28. However, there is no provision under Third Circuit precedent for the grant of a new trial in a civil case simply where the jury's determination is "contrary to the evidence." Instead, the question is whether "the verdict is contrary to the great weight of the evidence, thus making a new trial necessary to prevent a miscarriage of justice." *Roebuck*, 852 F.2d at 736. The District Court did not find that standard met and accordingly erred in ordering a new trial.

The difference between finding the verdict simply "contrary to the evidence" and finding the verdict "contrary to the great weight of the evidence, thus making a new trial necessary to prevent a miscarriage of justice" is not just semantics. *Roebuck*, 852 F.2d at 736. Indeed, the distinction goes to the very heart of Third Circuit's precedent on the grant of a new trial: "[T]he district court ought to grant a new trial on the basis that the verdict was against the weight of the evidence ***only where a miscarriage of justice would result if the verdict were to stand***." *Williamson*, 926 F.2d at 1352. The Third Circuit has explained that this requirement is both necessary and important because when a district court orders a new trial it has "to some extent at least, substituted [its] judgment of the facts and the credibility

of the witnesses for that of the jury. Such an action effects a denigration of the jury system and to the extent that new trials are granted the judge takes over, if he does not usurp, the prime function of the jury as the trier of facts." *Id*. (quoting *Lind v. Schenley Indus. Inc.*, 278 F.2d 79, 90 (3d Cir. 1960) (en banc).

Even assuming the District Court had found the standard to be met, the District Court would still be in error because it provided no reasoning for the new trial grant. *See Portage II v. Bryant Petroleum Corp.*, 899 F.2d 1514, 1524 (6th Cir. 1990) ("We have held that a district court's contingent grant of a motion for a new trial after granting a judgment notwithstanding the verdict constitutes error where: the grounds for the contingent grant of a new trial are not specified; proper instruction of applicable law are given; and the record is bereft of prejudicial error); *Ross v. Chesapeake & O. Ry. Co.*, 421 F.2d 328, 330 (6th Cir. 1970) ("The order here under review, however, does not specify the grounds for the 'contingent' granting of the motion and a review of the record discloses no sound basis therefor.").

In this vein, "an appellate court's review of the grant of a new trial should be more substantial than the review of a denial." *Kingsley Assocs., Inc. v. Moll PlastiCrafters, Inc*., 65 F.3d 498, 506–07 (6th Cir. 1995). Such a review requires a stricter application of the abuse of discretion standard "because when the jury verdict is set aside usual deference to the trial judge conflicts with deference to the jury on

questions of fact." *Rixey v. West Paces Ferry Hospital, Inc.*, 916 F.2d 608 (11th Cir. 1990).

Here, if this Court were to find the jury's infringement verdicts to be amply supported, the Court should reverse the new trial grant. *Uniloc*, 632 F.3d at 1309-10 (reversing grant of new trial following reversal of JMOL where the district court "did not present any analysis apart from its analysis of the JMOL infringement issues."); *Biogen MA Inc. v. EMD Serono, Inc*., 976 F.3d 1326, 1331, 1336–37 (Fed. Cir. 2020) (reversing grant of new trial where the "district court's grant of a new trial was based on the same legal errors supporting its grant of JMOL."). To be sure, the District Court did not articulate why a new trial on the issues of invalidity and damages would be appropriate were this Court to find sufficient evidence of infringement and vacate the judgments of noninfringement. *See Motter v. Everest & Jennings, Inc*., 883 F.2d 1223, 1232 n.12 (3d Cir. 1989). Reversal, rather than vacatur, is appropriate because it would be incredibly prejudicial for Steuben to prevail in this Court on one or more of the infringement issues only to have the case remanded for the District Court to explain why a new trial would nonetheless be appropriate.

B. The Court erred in granting Appellees a new trial on their waived invalidity challenge.

The District Court correctly held that Appellees waived their post-trial JMOL invalidity challenge due to their failure to move during trial at the close of evidence.

Appx26-27. Despite having the opportunity to do so, Appellees did not appeal that waiver finding, making it final.

The District Court erred in failing to extend its waiver finding to Appellees' request for a new trial on invalidity. In the Third Circuit, "failure to move for directed verdict at the close of all evidence . . . wholly waives the right to mount any post-trial attack on the sufficiency of the evidence." *Greenleaf v. Garlock, Inc.*, 174 F.3d 352, 364 (3d Cir. 1999) (quoting *Yohannon v. Keene Corp.,* 924 F.2d 1255, 1262 (3d Cir. 1991)). In *Greenleaf*, the Third Circuit distinguished a "sufficiency of the evidence" argument from a new trial argument asking the District Court to find that despite substantial evidence being present to support the verdict, a new trial was nonetheless appropriate. In the latter situation, JMOL waiver does not extend to a new trial request. But here, Appellees made only the former argument by attacking the sufficiency of the evidence. Consequently, Appellees' JMOL waiver extends to their new trial request, and the District Court erred in ordering otherwise.

While Appellees nominally argued that their motion attacked the "great weight of the evidence," the entirety of that conclusory argument was: "First, the jury's liability findings are against the great weight of the evidence ***for the reasons explained above***." [11] Appx5252. The "reasons explained above" all went to the

[11] Appellees also moved for a new trial alleging improper conduct by Steuben's counsel at trial. The District Court did not address that motion, and it was not the basis of the District Court's conditional new trial grant.

sufficiency evidence. For example, with respect to enablement of the asserted claims of the '591 and '188 patents, Appellees argued that there was "no record evidence that the specifications enable a skilled artisan . . . to achieve a bottling rate faster than 360 BPM." Appx5241. Similarly, with respect to written description, Appellees argued that "there is no indication that the inventors possessed an aseptic filling machine that operated at a rate greater than 360 BPM." Appx5239. And with respect to the alleged obviousness of the '591 and '985 patents, Appellees argued that "Steuben presented no contrary evidence" to rebut Appellees' purported showing of obviousness. Appx5243, Appx5246. The District Court erred in granting Appellees' motion for a new trial because they attacked only the sufficiency of the evidence—an argument they waived under Third Circuit precedent.

C. If the Court were to find substantial evidence of infringement on any one of the three patents, no new trial is needed on damages.

"A single damages award 'can be sustained' if, despite the fact that some of the asserted claims were held invalid or not infringed subsequent to the award, 'undisputed evidence' demonstrated that the sustained patent claim was necessarily infringed by all of the accused activity on which the damages award was based." *Hologic, Inc. v. Minerva Surgical, Inc.*, 957 F.3d 1256, 1271 (Fed. Cir. 2020). The undisputed evidence here shows that Hood necessarily infringed any one of the five infringed claims each time it ran the Accused Machines because it sterilized bottles

('985 and '188 patents), filled bottles ('591 and '188 patents), and used the claimed means for doing so ('188 patent).

Moreover, Steuben's damages model at trial sought a per bottle royalty based on the number of bottles Hood ran during the damages period, which did not depend on how many patents or claims Appellees infringed. Importantly, *neither side* presented a damages theory that depended on infringement of any particular claims or patents. Quite the contrary, Appellees argued that their theory of damages "[d]oes not vary based on the number of claims infringed." Appx3306 at 1221:14-22; Appx3346 at 1380:15-21. Accordingly, in the event this Court were to vacate the District Court's noninfringement judgment as to any one of the three asserted patents, there would be no need for a new trial on damages. *Tivo, Inc. v. EchoStar Commc'ns Corp.,* 516 F.3d 1290, 1312 (Fed. Cir. 2008) ("Because the damages calculation at trial was not predicated on the infringement of particular claims, and because we have upheld the jury's verdict that all of the accused devices infringe the software claims, we affirm the damages award entered by the district court.").

In such a situation, entry of judgment on the jury's finding of a 2 cents per bottle royalty would be appropriate. For example, the record discloses that Hood produced 383,245,933 bottles between issuance of claim 26 in the '591 patent reexamination certificate and expiration of claim 26. Appx3258 at 1031:2-6. Applying the jury's damages award of 2 cents per bottle, the damages for

infringement of the ’591 patent only would be $7,664,918.66. In the event the Court were to reverse judgment of noninfringement of either the ’188 or ’985 patent, the jury’s original award of $38,322,283 would be appropriate based on the number of bottles Hood ran between the start of the damages period and patent expiration.[12]

[12] For simplicity’s sake, Steuben sought damages only through the expiration of the ’985 patent, which expired earlier than the ’188 patent.

CONCLUSION

For the foregoing reasons, Steuben respectfully requests that the Court reverse the JMOL Opinion, vacate the District Court's Rule 54(b) Judgment and direct entry of judgment on the jury's verdict.

Dated: July 26, 2023

Respectfully submitted,

/s/ W. Cook Alciati

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ADDENDUM

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

STEUBEN FOODS, INC., Plaintiff, v. SHIBUYA HOPPMANN CORP., SHIBUYA KOGYO CO., LTD., and HP HOOD LLC, Defendants.	C.A. No. 19-2181-CFC

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MEMORANDUM OPINION

March 14, 2023
Wilmington, Delaware

COLM F. CONNOLLY
CHIEF DISTRICT JUDGE

I held a five-day jury trial in this patent infringement case filed by Plaintiff Steuben Foods, Inc. against Defendants Shibuya Hoppmann Corp., Shibuya Kogyo Co., Ltd., and HP Hood LLC (collectively, Shibuya). The asserted patents are directed to apparatuses and methods for aseptic bottle filling. Steuben asserted five claims at trial: claims 3 and 7 of U.S. Patent No. 6,702,985 (the #985 patent); claims 19 and 22 of U.S. Patent No. 6,536,188 (the #188 patent); and claim 26 of U.S. Patent No. 6,209,591 (the #591 patent). The jury found that Shibuya's bottle filling machines infringed all the asserted claims, that the asserted claims were not invalid, and that Steuben was entitled to approximately $38 million in damages. D.I. 787.

Pending before me is Shibuya's Motion for Judgment as a Matter of Law or, Alternatively, for a New Trial (D.I. 795). Shibuya brings the motion pursuant to Federal Rule of Civil Procedure 50(b). It seeks by the motion a judgment of noninfringement of the asserted patents, invalidity of the #591 and #188 patents for lack of adequate written description and enablement, and invalidity of the #985 and #591 patents for obviousness. It asks in the alternative for a new trial and vacatur of the jury's damages award.

I. MOTION FOR JUDGMENT AS A MATTER OF LAW

A. Legal Standard

"If the court does not grant a motion for judgment as a matter of law made under Rule 50(a), . . . the movant may file a renewed motion for judgment as a matter of law and may include an alternative or joint request for a new trial under Rule 59." FED. R. CIV. P. 50(b). A motion filed under Rule 50(b) "should be granted only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993).

B. Analysis

1. Noninfringement of the #985 Patent

Asserted claims 3 and 7 of the #985 patent depend from claim 1, which requires among other things that a "sterilant [be] intermittently added to [a] conduit." PTX-112 at claim 1 (19:56–57). Before trial, by stipulation of the parties, I construed the term "intermittently added" to mean "[a]dded in a non-continuous manner." D.I. 529-1 at 2; D.I. 531 at 7.

It is undisputed that the accused machines add sterilant to their conduit continuously. Steuben's expert, Dr. Sharon, expressly "agree[d] that in the accused system, the addition of the sterilant, the atomized sterilant[,] to the conduit is continuous." Tr. 446:8–11 (Sharon). Steuben nevertheless maintained at trial

that the accused machines infringe the "intermittently added" limitation under the doctrine of equivalents. Dr. Sharon explained Steuben's equivalents infringement theory to the jury as follows:

> Q. Okay. So, now you have said that, nevertheless, you think that the machine infringes under the doctrine of equivalents; is that right?
>
> A. Correct.
>
> Q. And let me see. And if I understand your point correctly, your point is that the way you read the patent, the point of the intermittent adding is to ensure that the right amount of sterilant is added; right?
>
> A. That is correct.
>
> Q. Okay. And so whatever structures in Shibuya's machine allow the right amount of sterilant to be added will be equivalent to whatever structure intermittently adds in the patent. Is that fair?
>
> A. I'd agree with that.

Tr. 446:12–25 (Sharon).

At the close of Steuben's case, Shibuya moved for judgment of noninfringement of the #985 patent as a matter of law. Tr. 621:14–18; *see also* D.I. 780. At Steuben's urging, I reluctantly reserved ruling and let the issue go to the jury. Tr. 625:12–19; 1068:14–18.

In his closing argument, Steuben's counsel argued:

> You heard a lot and you may hear it on closing that intermittent is not the same as continuous, as if that is the

> question you're being asked to answer, but that's not the precise question.
>
> Dr. Sharon was very specific. It's not just adding sterilant continuously, it's doing that using flow sensors and metering pumps to achieve a very precise amount of sterilant that's going into the system, and so that's the alleged equivalent. *You can do it intermittently or as in the accused machines, you can do something continuously, but very precisely and* [*with*] *control.* That's the equivalent that's being talked about here from Dr. Sharon.

Tr. 1265:20–1266:6 (emphasis added). The jury found that Shibuya infringed claims 3 and 7 of the #985 patent under the doctrine of equivalents. D.I. 787 at 1.

Shibuya argues, and I agree, that as a matter of law the "intermittently added" limitation cannot be met under the doctrine of equivalents by a continuous addition of sterilant. This conclusion is required by *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997), in which a unanimous Supreme Court held:

> Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety.

Id. at 29. Here, Steuben's equivalency theory effectively eliminates the "intermittently added" limitation in its entirety, and therefore a judgment of

noninfringement is warranted as a matter of law. No reasonable juror could conclude that adding sterilant continuously is substantially the same as adding sterilant intermittently.

"Intermittently" and "continuously" are *antonyms* of each other, not equivalents. *See Intermittently*, Merriam-Webster.com Thesaurus, https://www.merriam-webster.com/thesaurus/intermittently (last visited Mar. 6, 2023). As noted above, at the request of both sides, I construed "intermittently added" to mean "[a]dded in a non-continuous manner." D.I. 529-1 at 2; D.I. 531 at 7. As a matter of logic and contrary to counsel's statements in his closing argument, doing something in a non-continuous manner cannot be achieved by doing it "continuously" even if you were doing it "continuously, but very precisely and with control." Steuben's doctrine of equivalents theory defies logic, vitiates the "intermittently added" limitation of the asserted claims, and therefore cannot be sustained as a matter of law. *Warner-Jenkinson*, 520 U.S. at 29; *see also Planet Bingo, LLC v. GameTech Int'l, Inc.*, 472 F.3d 1338, 1345 (Fed. Cir. 2006) (affirming district court's refusal to find infringement by equivalents where "proposed application of the doctrine of equivalents would change 'before' to 'after'" and noting that "[t]his court has refused to apply the doctrine in other cases where the accused device contained the antithesis of the claimed structure"); *Asyst Techs., Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1195 (Fed. Cir. 2005) (holding that

"the district court was correct in ruling that the doctrine of equivalents cannot be extended to reach an 'unmounted' system . . . without vitiating the 'mounted on' limitation altogether"); *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1346 (Fed. Cir. 2001) ("[T]he doctrine of equivalents cannot be employed in a manner that wholly vitiates a claim limitation. Thus, if a patent states that the claimed device must be 'non-metallic,' the patentee cannot assert the patent against a metallic device on the ground that a metallic device is equivalent to a non-metallic device." (internal citations omitted)); *Moore U.S.A., Inc. v. Standard Reg. Co.*, 229 F.3d 1091, 1106 (Fed. Cir. 2000) (holding that patentee's "use of the term 'majority' is not entitled to a scope of equivalents covering a minority" for the independent reason that "it would defy logic to conclude that a minority—the very antithesis of a majority—could be insubstantially different from a claim limitation requiring a majority, and no reasonable juror could find otherwise").

Steuben insists that in *Epos Technologies, Ltd. v. Pegasus Technologies, Ltd.*, 766 F.3d 1338 (Fed. Cir. 2014), "the Federal Circuit rejected [the idea that there is] a 'binary choice' between the very same terms ***continuous*** and ***intermittent***." D.I. 798 at 14 (emphasis in original). But the construction of those terms by the district court in *Epos Technologies* makes that case inapplicable here. The patents at issue in *Epos Technologies* covered digital pens and receiver

devices; a claim limitation of one of the patents—the #371 patent—required a "device for receiving or transmitting an 'intermittent' ultrasound signal." 766 F.3d at 1347. Based on the undisputed fact that the accused devices "generate[d] a continuous ultrasound signal," the district court rejected the plaintiff's infringement theory under the doctrine of equivalents and granted summary judgment of noninfringement. *Id.* at 1348. The district court "reasoned that allowing continuous ultrasound signals to be equivalents 'would eliminate the intermittent limitation entirely,' and that 'the doctrine of equivalents cannot extend that far.'" *Id.* (internal citations omitted). The Federal Circuit reversed that decision and remanded the case for further consideration, finding that "the district court 'shortcut' the [doctrine of equivalents] inquiry by identifying a binary choice (continuous or intermittent) that is not compelled by the [#]371 patent and the record evidence." *Id.*

Epos Technologies is distinguishable from this case because, unlike here, the district court in *Epos Technologies* had not construed the intermittent limitation to necessarily preclude a device that generated a continuous ultrasound signal. Rather, the district court had construed "'intermittent' as 'something that occurs occasionally, in a non-continuous manner, in a random or unpredictable manner, *or* at selected times.'" *Id.* at 1347 (emphasis added). In this case, however, I construed "intermittently added" to mean—and only mean—"[a]dded in a non-

continuous manner." D.I. 529-1 at 2; D.I. 531 at 7. It is, of course, impossible to add something continuously in a non-continuous manner. Thus, unlike in *Epos Technologies*, in this case there is a binary choice between "intermittently" and "continuously."

Accordingly, I will enter judgment of noninfringement of the asserted claims of the #985 patent as a matter of law.

2. Noninfringement of the #188 Patent

Asserted claim 22 of the #188 patent depends from asserted claim 19, which has two claim limitations written in means-plus-function form. The first limitation requires a "means for providing a plurality of bottles," PTX-199 at claim 19 (16:65); the second requires a "means for filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute," PTX-199 at claim 19 (17:5–6).

A claim limitation that recites a function to be performed rather than a definite structure, is subject to the requirements of 35 U.S.C. § 112, ¶ 6 (1994). *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1266 (Fed. Cir. 1999). Such limitations "must be construed 'to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.'" *Id.* at 1266–67 (citing 35 U.S.C. § 112, ¶ 6; *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997)). "Literal infringement of a § 112, ¶ 6 limitation requires that the

relevant structure in the accused device perform the identical function recited in the claim *and* be identical or equivalent to the corresponding structure in the specification." *Id.* (emphasis added). If the relevant structure in the accused device is not identical to the corresponding structure in the patent's written description, then the test for § 112, ¶ 6 equivalence is whether the two structures "perform the identical function, in substantially the same way, with substantially the same result." *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 1364 (Fed. Cir. 2000). Because "[f]unctional identity *and* either structural identity or equivalence *are both necessary*," *Odetics,* 185 F.3d at 1267 (some emphasis added), a court is required "to give *independent meaning to both* the 'function' and 'way' prongs of the equivalency test." *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 312 F. App'x 326, 332 n.3 (Fed. Cir. 2009) (emphasis added).

I construed the corresponding structure for the "means for providing a plurality of bottles" limitation to be "a pushing element, and equivalents." D.I. 531 at 2. I construed the corresponding structure for the "means for filling the aseptically disinfected bottles at a rate greater than 100 bottles per minute" limitation to be, among other things, a conveyor and a conveyor plate and equivalents. D.I. 531 at 5–6.

Steuben alleged at trial that the accused machines have an infeed screw, rotary wheels, and neck grippers that are the structural equivalents respectively of a

pushing element, conveyor, and conveyor plate. Tr. 365:3–12, 405:7–10, 409:1–6 (Sharon). Shibuya argues that no reasonable juror could conclude based on the record evidence that the three alleged equivalents operate in substantially the same way as their corresponding structures, and therefore a judgment of noninfringement of the #188 patent is warranted.

With respect to the infeed screw, Dr. Sharon testified:

> [T]he way the infeed screw works is that as it rotates, you can see that it pushes the bottles forward along the axis of the screw. Okay.
>
> So this thread that is on a screw is actually no different than the thread on a bolt, only that it's bigger, and basically, it, as it's turning, it's kind of wedging the bottle and pushing it along. The thread is like a helix. It kind of does that as I rotate here, you know, it pushes it along.
>
> * * * *
>
> [T]he only way the screw can move the bottles is by pushing on their side, you know, through the wedging action.

Tr. 369:1–370:10 (Sharon). A reasonable juror could conclude from this testimony that the infeed screw operates in substantially the same way as a pushing element—i.e., by pushing. Indeed, a rational juror could conclude from this testimony that an infeed screw *is* a pushing element.

I agree with Shibuya, however, that Steuben did not adduce at trial sufficient evidence for a reasonable juror to conclude that the way the accused machines' rotary wheels and neck grippers operate is substantially the same as the way a

conveyor and conveyor plate operate. Rotary wheels move rotationally, not linearly like a conveyor. Tr. 410:21–411:2, 477:19–22 (Sharon). And rotary wheels operate continuously, not intermittently like a conveyor. Tr. 411:3–8, 477:15–18 (Sharon). The neck grippers of the accused machines each hold one bottle at a time, Tr. 676:6–8 (Larrick), whereas the conveyor plates described in the patent move six or 12 bottles at a time, PTX-199 at Fig. 8; PTX-199 at 7:38–47; Tr. 476:16–477:14 (Sharon). Neck grippers pinch the bottles at the neck, whereas a conveyor plate surrounds the bottom of the bottles. Tr. 406:16–25 (Sharon). Neck grippers can hold different bottle sizes, Tr. 676:25–677:2 (Larrick); Tr. 854:5–10 (Glancey), whereas conveyor plates can accommodate only bottles with bases barely smaller than the size of the plates' holes, Tr. 849:24–850:3 (Glancey). These differences are undisputed and so substantial that no reasonable juror could conclude that the accused machines had the structural equivalents of a conveyor and conveyor plate. *See Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1324 (Fed. Cir. 2004) (affirming grant of summary judgment because "the two systems accomplish [the claimed] function in fundamentally different ways"); *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1309, 1311 (Fed. Cir. 1998) (finding no infringement under either § 112, ¶ 6

or the doctrine of equivalents because the accused device operated in a "substantially different way").[1]

Steuben insists that it adduced at trial sufficient evidence to support the jury's finding of equivalency of the accused machines' components with the patent's corresponding structures. But in the testimony it cites in support of its position, Dr. Sharon merely opined that the neck grippers and rotary wheels were insubstantially different from a conveyor and conveyor plate because they fulfill the claimed function of filling aseptically disinfected bottles at a rate greater than 100 bottles per minute. *See* Tr. 406:4–9 (Sharon testifying that the differences between neck grippers and conveyor plates are "insubstantial . . . because, again, . . . the function of the claim is filling bottles at a rate greater than a hundred bottles per minute. How you hold the bottles is not important."); Tr. 411:9–15 (Sharon testifying that the differences between rotary wheels and a conveyor are

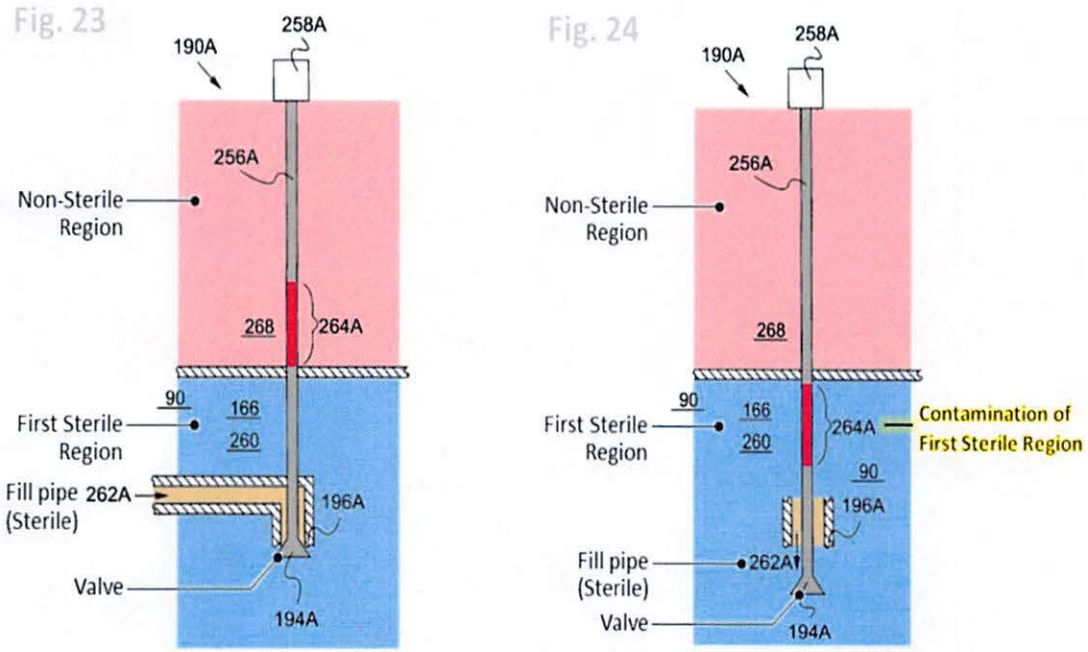
[1] Before trial, I had denied Shibuya's motion for summary judgment of noninfringement of the #188 patent based on Steuben's denial of Shibuya's factual assertion that the accused machines do not use a linear conveyor. *See* D.I. 751 at 1. In support of its denial of that assertion, Steuben cited record evidence of a linear conveyor. *See* D.I. 751 at 1. I learned at trial—from Steuben's own expert—that that linear conveyor moves the bottles *after* they have been sterilized by the accused machines to a labeling and packaging station. *See* Tr. 477:19–478:16 (Sharon testifying that the linear conveyor "is not part of the sterilization" and is "not part of the filling the bottles."). In other words, the linear conveyor plate Steuben referred me to in its summary judgment briefing is irrelevant to the question of infringement.

insubstantial because "you can use either strategy and still achieve 100 bottles per minute. It's not like using one or the other is going to allow you to do that and the other one isn't. So it's an insubstantial difference."); Tr. 410:15–20 (Sharon testifying that "if the claim was directed towards novel new ways of transporting bottles, then maybe those differences [between rotary wheels and a conveyor] would be substantial, but in terms of filling at a rate of 100 bottles per minute, you can do it with a linear conveyor [or] rotary dial. It's not – it's not a substantial difference."). "Function" and "way," however, are independent considerations in determining structural equivalence under § 112, ¶ 6. *Odetics,* 185 F.3d at 1267; *Applied Med. Res.*, 312 F. App'x at 332. And because Steuben adduced no other evidence to show that the accused machines' rotary wheels and neck grippers operate in substantially the same way as a conveyor and conveyor plate, I will grant judgment of noninfringement of the asserted claims of the #188 patent as a matter of law.

3. Noninfringement of the #591 Patent

Steuben accused Shibuya's P7 filling machine of infringing claim 26 of the #591 patent. Claim 26 covers an apparatus that has, among other things, "a first sterile region surrounding a region where the [food] product exits the valve" of a fill pipe into a bottle and "a second sterile region positioned proximate [to] said first sterile region." PTX-212 at reexamined claim 26 (2:59–62).

As the patent explains, the second sterile region solved a contamination problem traceable to the design of existing bottle fillers' valves used to stop and start the flow of sterile food product into the bottles. PTX-212 at 14:1–23. In that design, illustrated in Figures 23 and 24 of the patent and reproduced below, "the valve stem 256A may carry contaminants from the non-sterile region 268 into the first sterile region 260" as it moves up (into the non-sterile region) to stop and down (into the sterile region containing food product) to start the flow of food product into the bottles. PTX-212 at 14:18–21.



DDTX-3.92 (annotated). The patent purports to solve this contamination problem by adding a "second sterile region" into which a sterilant is introduced to clean the portion of the valve stem that is exposed to the non-sterile region during the valve's operation. *See* PTX-212 at 14:21–30.

According to the patent's written description and as illustrated in Figures 25 and 26 of the patent, which are reproduced below: "In the present invention, the first portion 264A of the valve stem 256A has not introduced contaminants into the first sterile region 260 because the first portion 264A of the valve stem 256A was pre-sterilized in the second sterile region 270A before entering the first sterile region 260." PTX-212 at 14:49–53.

Fig. 25

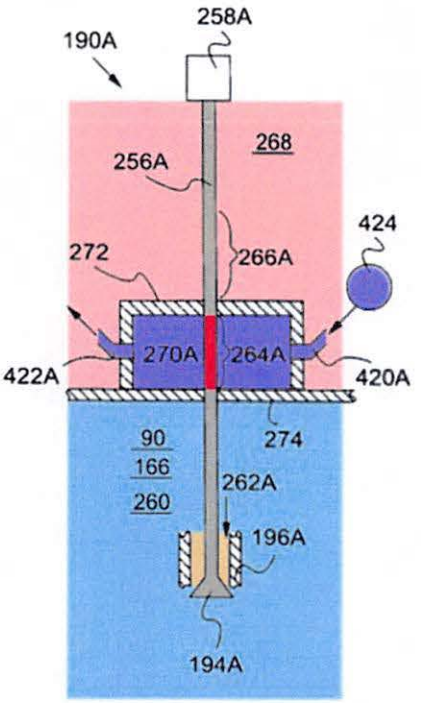
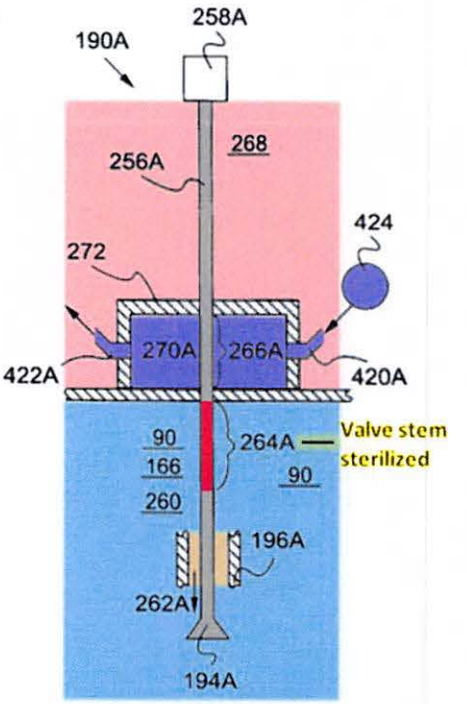


Fig. 26



DDTX-3.96 (annotated). Region 270A (highlighted in purple) is the patent's only depiction of a second sterile region. Tr. 468:12–469:20 (Sharon).

At the *Markman* hearing, I agreed with Steuben that the "second sterile region positioned proximate [to] said first sterile region" limitation (i.e., the "second sterile region" limitation) did not require a construction and should be given its plain and ordinary meaning. D.I. 531 at 6; D.I. 755 at 3 (quoting oral

ruling made at *Markman* hearing). Steuben later moved for summary judgment of infringement of claim 26 by the P7. D.I. 614. Shibuya argued that I should deny the motion because the P7 does not meet the "second sterile region" limitation and because Shibuya's so-called "reverse doctrine of equivalents" defense raised a factual dispute. D.I. 707 at 7–12.[2]

The P7 uses a flexible, impenetrable barrier called a bellows that surrounds the portion of the valve stem that is exposed to a non-sterile region and thereby prevents that portion of the valve stem from entering (and thus from contaminating) the sterile zone (i.e., the first sterile region). Tr. 469:4–17

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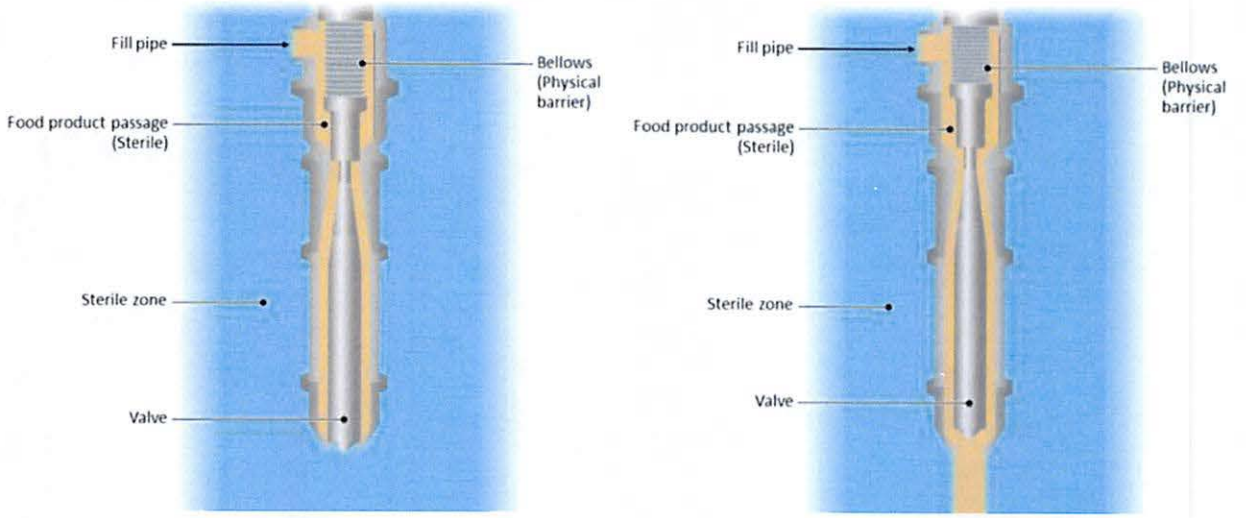
[2] Courts, including the Federal Circuit, have used the phrase "reverse doctrine of equivalents" when a defendant invokes the doctrine of equivalents; and the parties used that phrase here to describe Shibuya's doctrine of equivalents defense. The Supreme Court made clear in *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, that the doctrine of equivalents applies *equally* to plaintiffs and defendants in a patent infringement case:

> The wholesome realism of th[e] doctrine [of equivalents] is not always applied in favor of a patentee but is sometimes used against him. Thus, where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement.

339 U.S. 605, 608–09 (1950). For ease of reference, I will follow the parties' lead and refer to Shibuya's doctrine of equivalents defense as a reverse doctrine of equivalents defense.

(Sharon); Tr. 688:4–689:17 (Larrick); Tr. 905:18–906:14, 908:2–10 (Glancey). The following images depict the P7's fill-pipe valve in its closed (left image) and open (right image) positions:



DDTX-3.99–100.

Because it was undisputed that the inside of the P7's fill pipe (i.e., the "Food product passage" in the above images) is both sterile and proximate to the P7's first sterile region (i.e., the "Sterile zone" in the above images), I found that the P7 meets the "second sterile region" limitation and literally infringes claim 26. D.I. 755 at 5. But I denied Steuben's motion for summary judgment because of Shibuya's invocation of the reverse doctrine of equivalents defense and the fact that Shibuya had adduced on the record an expert's opinion that the P7's fill pipe (which carries food and does not carry a sterilant) does not clean the valve stem.

That opinion evidence, I held, gave rise to a fact question—namely, whether the P7 performed the second sterile region's claimed function in a substantially different way—and thus precluded summary judgment of infringement. *See* D.I. 755 at 7.

At trial, Steuben maintained its position that the P7 met the "second sterile region" limitation solely by virtue of the sterile region inside of the P7's fill pipe. Steuben did not allege that any other area or component of the P7 constitutes a "second sterile region." Steuben also did not dispute that the P7's fill pipe does not clean the valve stem. Thus, not surprisingly, Dr. Sharon conceded during his cross-examination that the P7 "doesn't have a sterile region that cleans the valve stem while the machine is in operation." Tr. 469:18–20 (Sharon); *see also* Tr. 468:22–469:20 (Sharon).

At the close of Steuben's infringement case and again at the conclusion of the presentation of evidence, Shibuya moved for judgment of noninfringement of the #591 patent as a matter of law. Tr. 629:8–17; Tr. 1064:7–12. Shibuya argued that Steuben had "admitted that what has been called the second sterile region in the accused device . . . does not solve the problem . . . the patent purports to solve, and therefore under the reverse doctrine of equivalents, the accused invention is so far changed in principle that it's just not doing what the patented claim is about." Tr. 629:11–17. Although I stated that this was a "really, really good argument[]," I denied the motion and told counsel I would revisit the argument during posttrial

motion practice. Tr. 629:18–22. In retrospect, I should have granted the motion, as no reasonable juror could have concluded that Steuben rebutted Shibuya's *prima facie* showing of noninfringement under the reverse doctrine of equivalents.

"When a patentee establishes literal infringement, the accused infringer may undertake the burden of going forward to establish the fact of non-infringement under the reverse doctrine of equivalents. If the accused infringer makes a *prima facie* case, the patentee, who retains the burden of persuasion on infringement, must rebut that *prima facie* case." *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1123–24 (Fed. Cir. 1985).

To make a *prima facie* showing of noninfringement under the reverse doctrine of equivalents, the defendant must adduce evidence from which a rational juror could conclude that the accused "device is so far changed in principle from [the] patented article that it performs the same or a similar function in a substantially different way." *Graver Tank*, 339 U.S. at 608–09; *see also Autogiro Co. of Am. v. United States*, 384 F.2d 391, 399–400 (Ct. Cl. 1967) ("[S]ince the law is to benefit the inventor's genius and not the scrivener's talents, claims must not only read literally on the accused structures, but also the structures must 'do the same work, in substantially the same way, and accomplish substantially the same result.'" (internal citation omitted)). Shibuya easily met this burden of production at trial. Its expert, Dr. Glancey, testified: (1) consistent with the patent's

specification, that the principle of operation of the second sterile region in the claimed invention is to "appl[y] a sterilant to [the potentially contaminated] portion of the valve stem, thus cleaning that part of the valve stem," Tr. 905:16–17 (Glancey); (2) based on engineering drawings, documents, and a site visit to Shibuya's facility, Tr. 904:2–7 (Glancey), that the P7's principle of operation is the use of a "flexible" bellows that "stretches or contracts" and "provide[s] an impervious barrier to prevent th[e] internal contaminants inside the bellows from migrating out and contacting the food" as the valve stem "moves up or down," Tr. 906:6–12 (Glancey); (3) that there is therefore "no need for sterilant" in the P7's fill pipe (i.e., the alleged second sterile region), Tr. 907:16–18 (Glancey); and (4) that these differences between the principles of operation of the claimed invention and the P7 are substantial and therefore under the reverse doctrine of equivalents, the P7 does not infringe claim 26, Tr. 908:11–19 (Glancey).

Steuben argues that it rebutted Dr. Glancey's testimony with Dr. Sharon's testimony. D.I. 798 at 9. Although Dr. Sharon never expressly stated that the principles of operation of the P7 and of the patented invention are not substantially different, he did testify that the P7 "embod[ies] the principles of operation of claim 26," including "the principles of operation of the first and second sterile regions." Tr. 361:17–22 (Sharon). But, according to Dr. Sharon, "the whole principle of operation" of claim 26 is "basically filling more than 350 bottles per minute

aseptically and doing that with, *by having these two sterile regions that the valve is sort of constrained to so that as it opens and closes, it only stays within those two regions and it does not go into any non-sterile region* and therefore [reduces the] risk [of] the possibility of bringing in contaminants, pathogens, into the food." Tr. 355:6–13 (Sharon) (emphasis added). This characterization of the patented invention, however, is wrong as a matter of law because it is inconsistent with the patent's specification. It therefore was entitled to no weight by the jury. *See Roche Palo Alto LLC v. Apotex, Inc.*, 531 F.3d 1372, 1378–79 (Fed. Cir. 2008) (affirming grant of summary judgment of infringement and district court's ruling that expert's declaration did not establish *prima facie* case of reverse doctrine of equivalents where declaration was contrary to the patent's claims and specification and therefore "d[id] not properly establish the principle of the [asserted] patent"); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996) ("[T]he expert testimony, which was inconsistent with the specification and file history, should have been accorded no weight.").

The valve stem in the patented invention does *not* stay in the two sterile regions. On the contrary, the whole purpose of the second sterile region in the patented invention is to sterilize the portion of the valve stem that is *exposed to a non-sterile region*. As the patent's written description explains and Figures 25 and 26 illustrate, "[t]he first portion 264A of the valve stem 256A is surrounded by the

second sterile region 270A," PTX-212 at 14:40–41, and "[*a*] *second portion 266A of the valve stem lies in the non-sterile region* 268" when the invention's valve is in the closed position, PTX-212 at 14:35–36 (emphasis added). To open the valve, an actuator "displace[s] the valve stem 256A in a downward direction . . . . allowing [food] product 262A to flow into a bottle." PTX-212 at 14:44–47. At this point, "[t]he first portion 264A of the valve stem 256A has entered the first sterile region 260," PTX-212 at 14:47–49, and "[*t*]*he second portion 266A of the valve stem 256A has entered the second sterile region 270A from the non-sterile region 268*," PTX-212 at 14:53–55 (emphasis added). The second portion of the valve stem is then "sterilized in the second sterile region 270A removing any contaminants." PTX-212 at 14:56–57. This principle of operation in "the second sterile region 270A removes any contaminants from the valve stem 256A before any portion of the valve stem 256A enters the first sterile region." PTX-212 at 14:58–60. When the valve is closed, the actuator displaces the valve stem in an upward direction, returning the first portion of the valve stem to the second sterile region and the second portion of the valve stem to the non-sterile region. *See* PTX-212 at 13:63–65; PTX-212 at Fig. 23–26.

Steuben cites in its posttrial briefing and Dr. Sharon identified at trial nothing in claim 26 or the #591 patent's specification that requires, discloses, or suggests in any way that a principle of operation of the claimed invention is (in Dr.

Sharon's words) to "constrain[ ]" the valve "so that as it opens and closes, it only stays within [the first and second sterile] regions and it does not go into any non-sterile region and therefore [reduces the] risk [of] the possibility of bringing in contaminants, pathogens, into the food." Tr. 355:10–13 (Sharon). At trial, Dr. Sharon relied solely on the P7 to establish the principle of operation of the patent. Using a valve taken from a P7, design documents for the P7, and demonstrative exhibits, Dr. Sharon explained to the jury how the P7 worked, Tr. 356:14–361:3 (Sharon), and then offered his opinion that the P7 "embod[ies] the principles of operation of claim 26" and "the principles of operation of the first and second sterile region[s]," Tr. 361:17–22 (Sharon).

Steuben's position at trial was that it did not have to rely on claim 26 or the patent's specification to establish claim 26's or the second sterile region's principles of operation because I had found that the P7 literally infringed claim 26. It made this point unequivocally in the following exchange between Steuben's counsel and Dr. Sharon:

> Q. So just to be clear, what we were talking about was, you know, how the patent claim works and you're using [the P7] as an example?
>
> A. That is correct.
>
> Q. Do you think it's fair to use that valve as an example of the patent claim?
>
> A. I do.

> Q. Why?
>
> A. Because the—because the accused machine was found to literally infringe, so, you know, if we know that it has that element.
>
> Q. Thank you.

Tr. 357:23–358:9 (Sharon).

But this approach turns the reverse doctrine of equivalents on its head. The doctrine *rescues* from infringement devices that literally satisfy the elements of a claim but perform the same function of the invention in a substantially different way. It makes no sense, then, to look to the accused device that literally infringes to determine how the patented invention performs. But that is what Dr. Sharon did here. He based his description of the *patented invention's* principle of operation on *the P7's* principle of operation. This logic nullifies the reverse doctrine of equivalents.

Because Dr. Sharon's testimony about the principles of operation of claim 26 and the second sterile region was contrary to the patent's specification, it was wrong as a matter of law and entitled to no weight at trial. And because Steuben adduced no other evidence to rebut Dr. Glancey's testimony, Shibuya is entitled to a judgment of noninfringement of the #591 patent under the reverse doctrine of equivalents as a matter of law.

4. Invalidity of the #188, #591, and #985 Patents

Shibuya also argues that it is entitled to judgment as a matter of law of invalidity of the #591 and #188 patents for lack of adequate written description and enablement and of the #985 and #591 patents for obviousness. But as Steuben points out, Shibuya did not present these arguments in its Rule 50(a) motion at trial and therefore it has waived them.

"A motion under Rule 50(b) is not allowed unless the movant sought relief on similar grounds under Rule 50(a) before the case was submitted to the jury." *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 486 n.5 (2008); *see also Kars 4 Kids Inc. v. Am. Can!*, 8 F.4th 209, 220 (3d Cir. 2021) ("[P]ost-trial Rule 50 motion can only be made on grounds specifically advanced in a motion for a directed verdict at the end of plaintiff's case." (internal quotation marks and citation omitted)); 9B Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* §2537 (3d ed.) ("[T]he district court only can grant the Rule 50(b) motion on the grounds advanced in the preverdict [Rule 50(a)] motion, because the former is conceived of as only a renewal of the latter.").

Shibuya does not dispute that it failed to raise in a Rule 50(a) motion the invalidity arguments it makes now in its pending motion. Instead, it argues that it raised these arguments in its summary judgment motions and that "[a] party preserves a legal issue by moving for summary judgment" on that issue. D.I. 800

at 12. But as the authorities it cites in support of that assertion make clear, a motion for summary judgment on an issue preserves that issue for an appeal, not for a Rule 50(b) motion. *See ePlus, Inc. v. Lawson Software, Inc.*, 700 F.3d 509, 517–18 (Fed. Cir. 2012) (denial for motion of summary judgment on indefiniteness preserved that issue for appellate review); *Ericsson Inc. v. TCL Commc'n Tech. Holdings Ltd.*, 955 F.3d 1317, 1321 (Fed. Cir. 2020) ("Ericsson argues as a threshold matter that TCL has waived any right to appeal the issue of ineligibility under § 101 by failing to raise it in a motion for judgment as a matter of law."); *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1302 (Fed. Cir. 2019) ("We may review this denial of summary judgment."); 9B Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* §2537 (3d ed.) ("[W]hen a party has been denied summary judgment, the failure to move for judgment as a matter of law will not preclude that party from seeking appellate review of the denial of summary judgment.").

Accordingly, I will deny Shibuya's motion insofar as it seeks judgment of invalidity of the asserted patents as a matter of law.

II. MOTION FOR A NEW TRIAL AND VACATUR OF DAMAGES AWARD

Because I will enter judgment of noninfringement of the asserted patents, I need not and do not address Shibuya's request to vacate the damages award and grant a new trial.

Under Rule 50(c)(1), "[i]f the court grants a renewed motion for judgment as a matter of law, it must also conditionally rule on any motion for a new trial by determining whether a new trial should be granted if the judgment is later vacated or reversed." Fed. R. Civ. P. 50(c)(1). In this case, were the Federal Circuit to vacate the judgment of noninfringement, I believe a new trial would be warranted because, as explained above, the jury's verdicts with respect to infringement of the asserted claims of the #985, #188, and #591 patents are contrary to the evidence.

III. CONCLUSION

For the reasons stated above, I will enter a judgment of noninfringement of the asserted patents as a matter of law. I will also conditionally grant Shibuya's motion for a new trial under Federal Rule of Civil Procedure 50(c)(1).

The Court will issue an Order consistent with this Memorandum Opinion.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

STEUBEN FOODS, INC., Plaintiff, v. SHIBUYA HOPPMANN CORP., SHIBUYA KOGYO CO., LTD., and HP HOOD LLC, Defendants.	C.A. No. 19-2181-CFC

ORDER

At Wilmington on this Fourteenth day of March in 2023:

For the reasons set forth in the Memorandum Opinion issued this day, IT IS HEREBY ORDERED that Defendants' Motion for Judgment as a Matter of Law or, Alternatively, for a New Trial (D.I. 795) is GRANTED IN PART and DENIED IN PART:

1. The motion is GRANTED insofar as it seeks a judgment of noninfringement of the asserted patents;

2. The motion is DENIED insofar as it seeks a judgment of invalidity of the asserted patents;

3. The motion is CONDITIONALLY GRANTED insofar as it seeks a new trial.

It is FURTHER ORDERED that the parties shall file no later than March 21, 2023 a proposed judgment for the Court to enter.

COLM F. CONNOLLY
CHIEF DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

STEUBEN FOODS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 19-2181-CFC-CJB
	)	
SHIBUYA HOPPMANN CORP., SHIBUYA KOGYO CO., LTD., and HP HOOD LLC,	)	
	)	
Defendants.	)	

~~[PROPOSED]~~ PARTIAL JUDGMENT

This action came before the Court for a trial by jury between Plaintiff Steuben Foods, Inc. ("Steuben") and Defendants Shibuya Hoppman Corp., Shibuya Kogyo Co., LTD, and HP Hood LLC ("Shibuya").

The Court held a trial before a jury on the claims and counterclaims between Steuben and Shibuya, and the jury rendered its verdict on November, 22, 2021, accompanied by a verdict form (ECF No. 786, unsealed at ECF No. 787). Pursuant to Federal Rules of Civil Procedure 50 and 59 Shibuya moved for Judgment as a Matter of Law or, Alternatively, for a New Trial (ECF No. 795). On March 14, 2023, the Court issued an Opinion (ECF No. 807) and Order (ECF No. 808) holding the asserted patents not infringed as a matter of law and conditionally granting a new trial.

Now, therefore, for the reasons set forth in that Opinion and Order,

Pursuant to Federal Rule of Civil Procedure 54(b), IT IS HEREBY ORDERED AND ADJUDGED that judgment be and is hereby entered in favor of Defendant Shibuya and against Plaintiff Steuben that:

1. As a matter of law, Shibuya does not infringe claims 3 and 7 of U.S. Patent No. 6,702,985 within the scope of 35 U.S.C. § 271(a), (b), and (c);
2. As a matter of law, Shibuya does not infringe claims 19 and 22 of U.S. Patent No. 6,536,188 within the scope of 35 U.S.C. § 271(a), (b), and (c); and
3. As a matter of law, Shibuya does not infringe claim 26 of U.S. Patent No. 6,209,591 within the scope of 35 U.S.C. § 271(a), (b), and (c).

There is no just reason for delay for entering final judgment as to the infringement liability issues, as doing so minimizes the need for three separate trials on the asserted patents.

IT IS HEREBY ORDERED AND ADJUDGED that, pursuant to Federal Rule of Civil Procedure 50(c), the Court conditionally grants a new trial regarding the issues of infringement and invalidity of U.S. Patent Nos. 6,702,985, 6,536,188, and 6,209,591, along with any possible damages, if this Partial Judgment with respect to noninfringement is later vacated or reversed.

Dated: 4.5.23

The Honorable Colm F. Connolly
United States District Judge

US006209591B1

(12) **United States Patent**
Taggart

(10) **Patent No.: US 6,209,591 B1**
(45) **Date of Patent: Apr. 3, 2001**

(54) **APPARATUS AND METHOD FOR PROVIDING CONTAINER FILLING IN AN ASEPTIC PROCESSING APPARATUS**

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

(73) Assignee: **Steuben Foods, Inc.**, Elma, 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.: **09/376,992**

(22) Filed: **Aug. 18, 1999**

Related U.S. Application Data

(60) Provisional application No. 60/118,404, filed on Feb. 2, 1999.

(51) **Int. Cl.**[7] **B65B 1/04**
(52) **U.S. Cl.** **141/89**; 141/129; 141/48
(58) **Field of Search** 141/89–93, 97, 141/172, 129, 275–278, 48, 63

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0 569 754 B1	5/1998	(EP) .
96-8699	6/1996	(KR) .

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Primary Examiner—Steven O. Douglas
(74) *Attorney, Agent, or Firm*—Schmeiser, Olsen & Watts

(57) **ABSTRACT**

An apparatus and method for providing container product filling in an aseptic processing apparatus. An apparatus including a valve mechanism for controlling the opening or closing of a valve including extending a portion of the valve from a second sterile region into a first sterile region, thereby, preventing contaminants from being carried into the first sterile region.

28 Claims, 22 Drawing Sheets

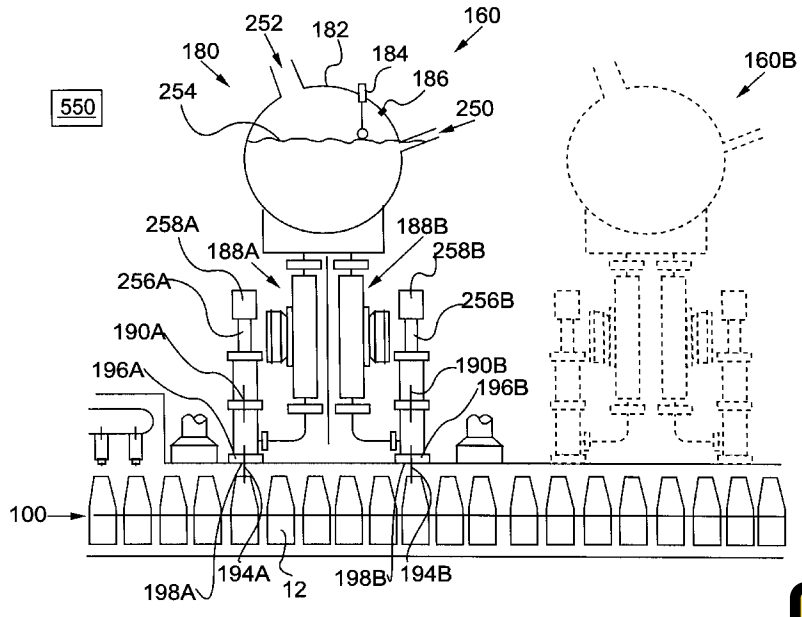

EXHIBIT
PTX212

Exhibit 13

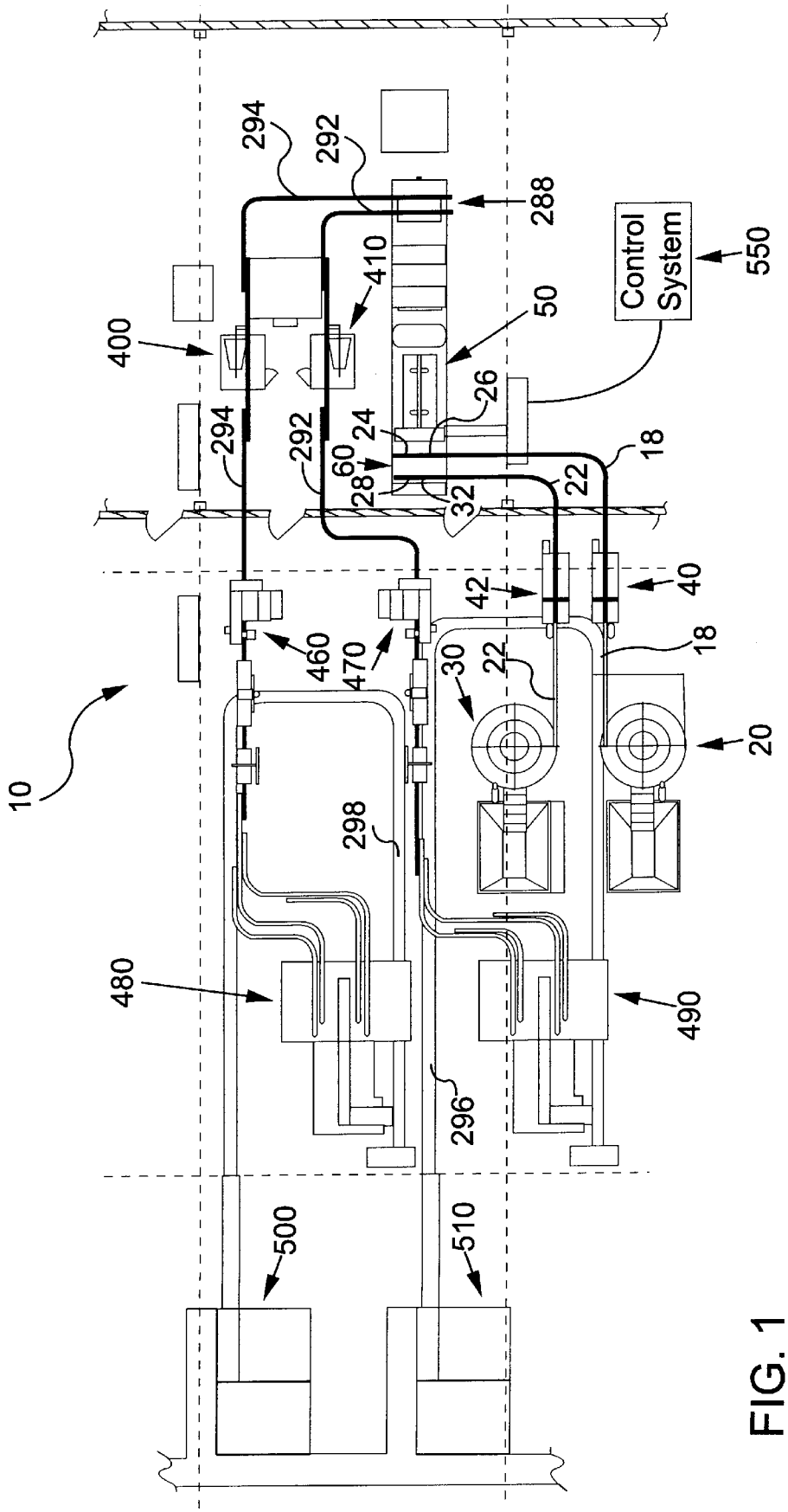
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FIG. 1

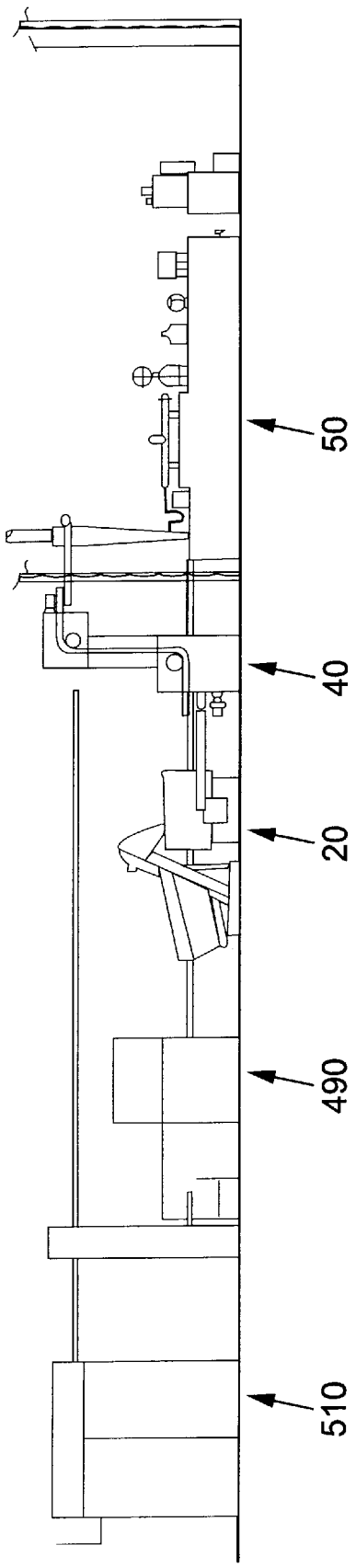
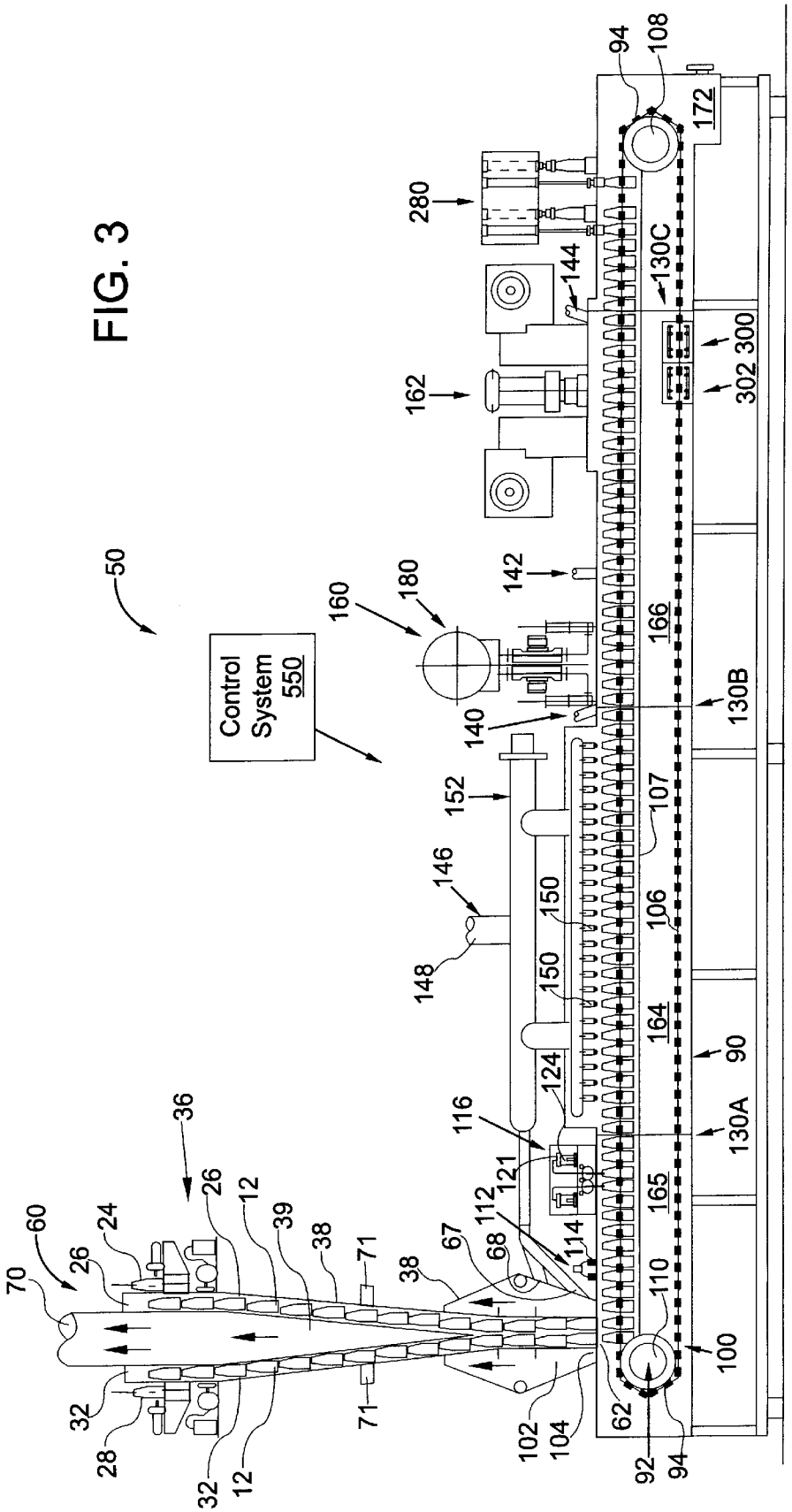


FIG. 2

FIG. 3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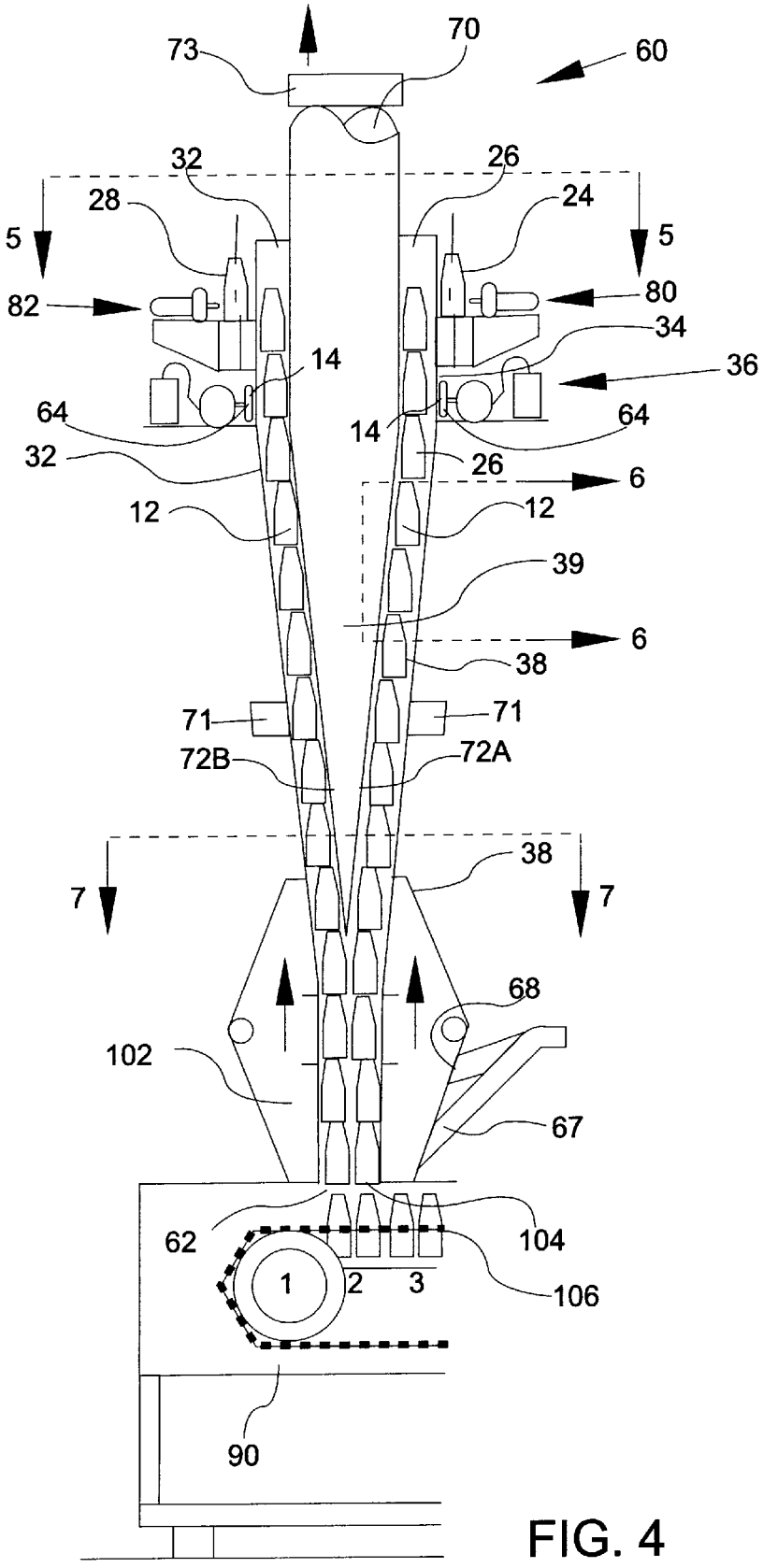
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FIG. 4

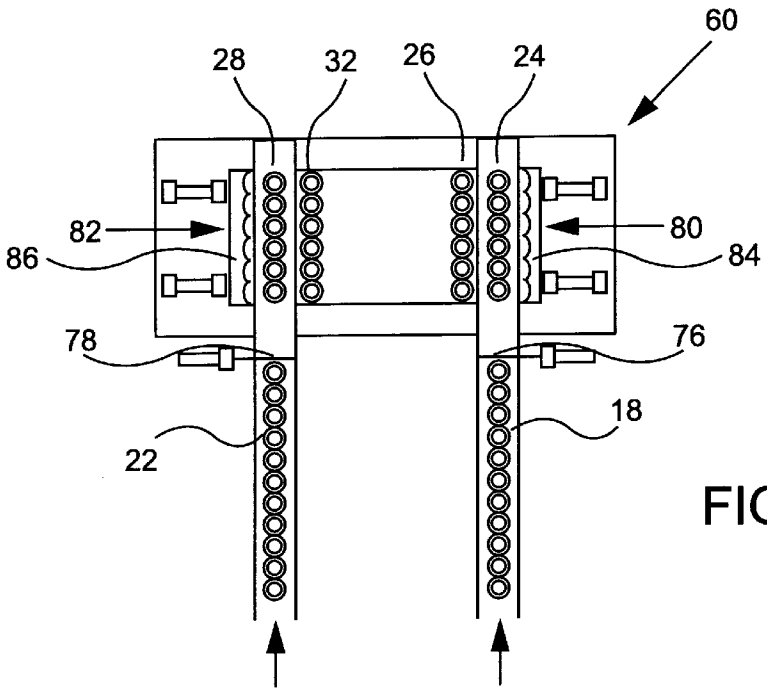

FIG. 5

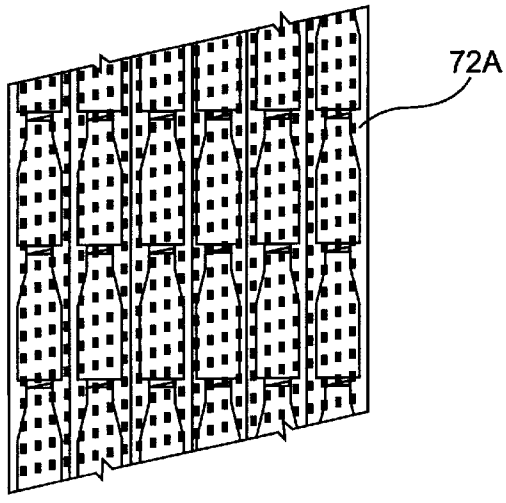

FIG. 6

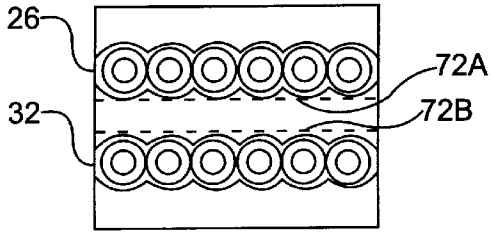

FIG. 7

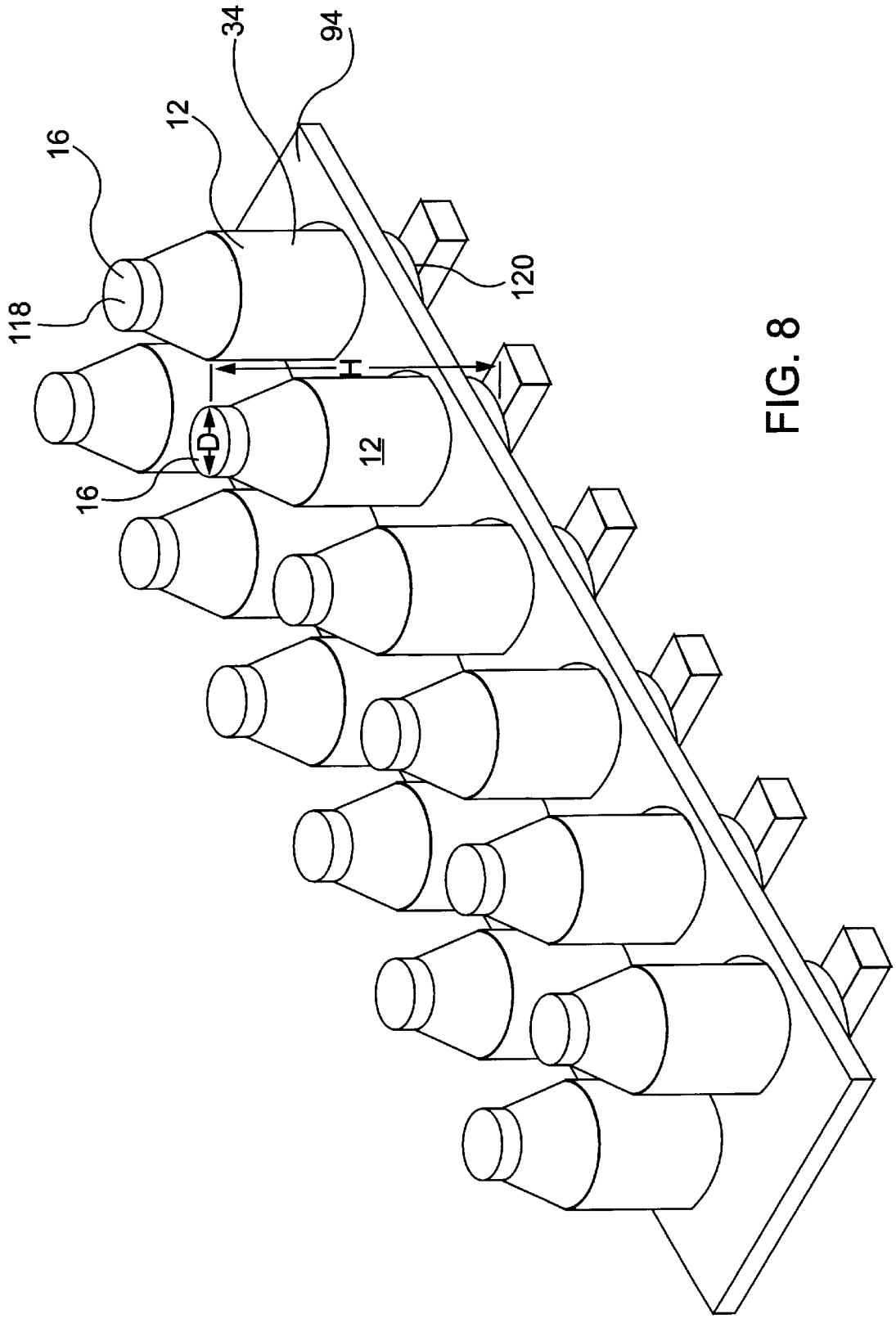

FIG. 8

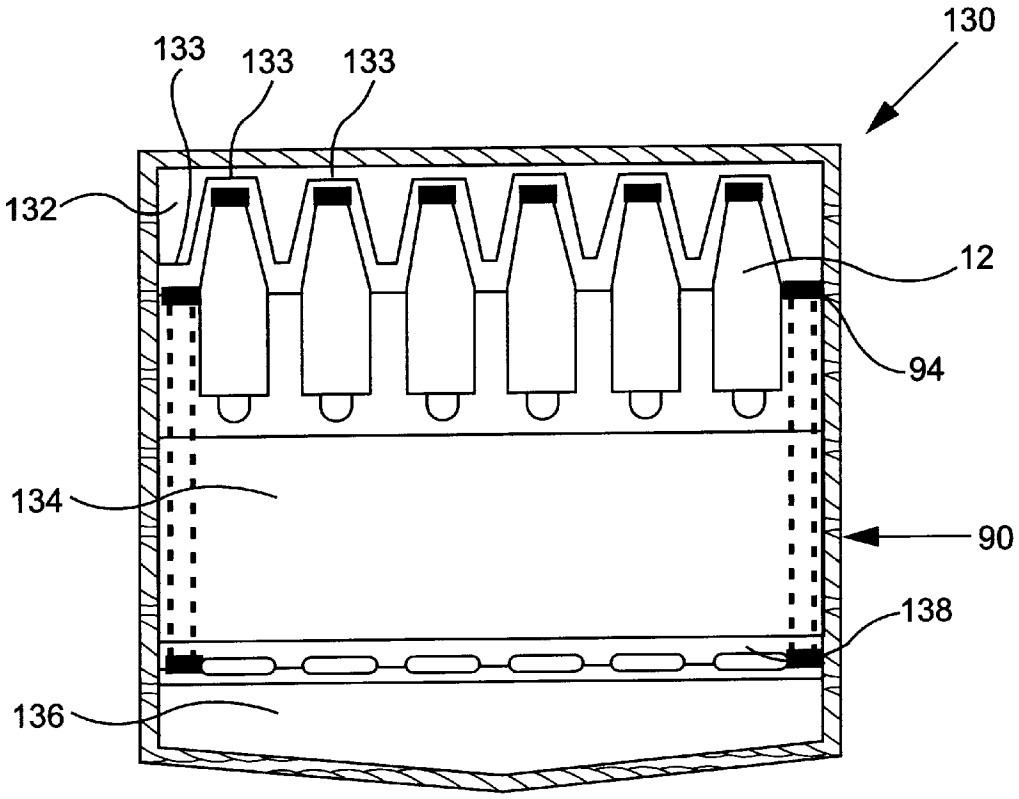

FIG. 9

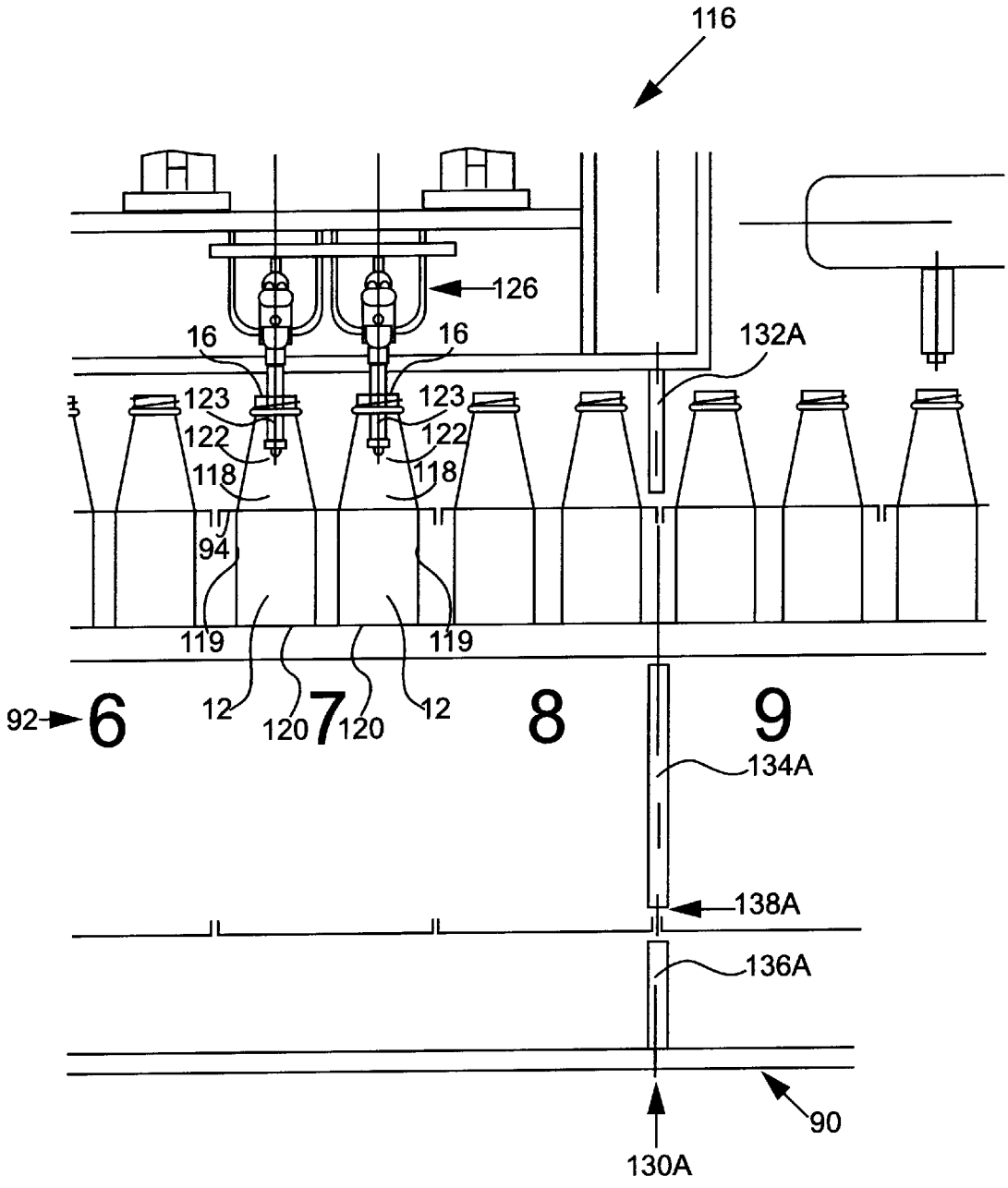
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FIG. 10

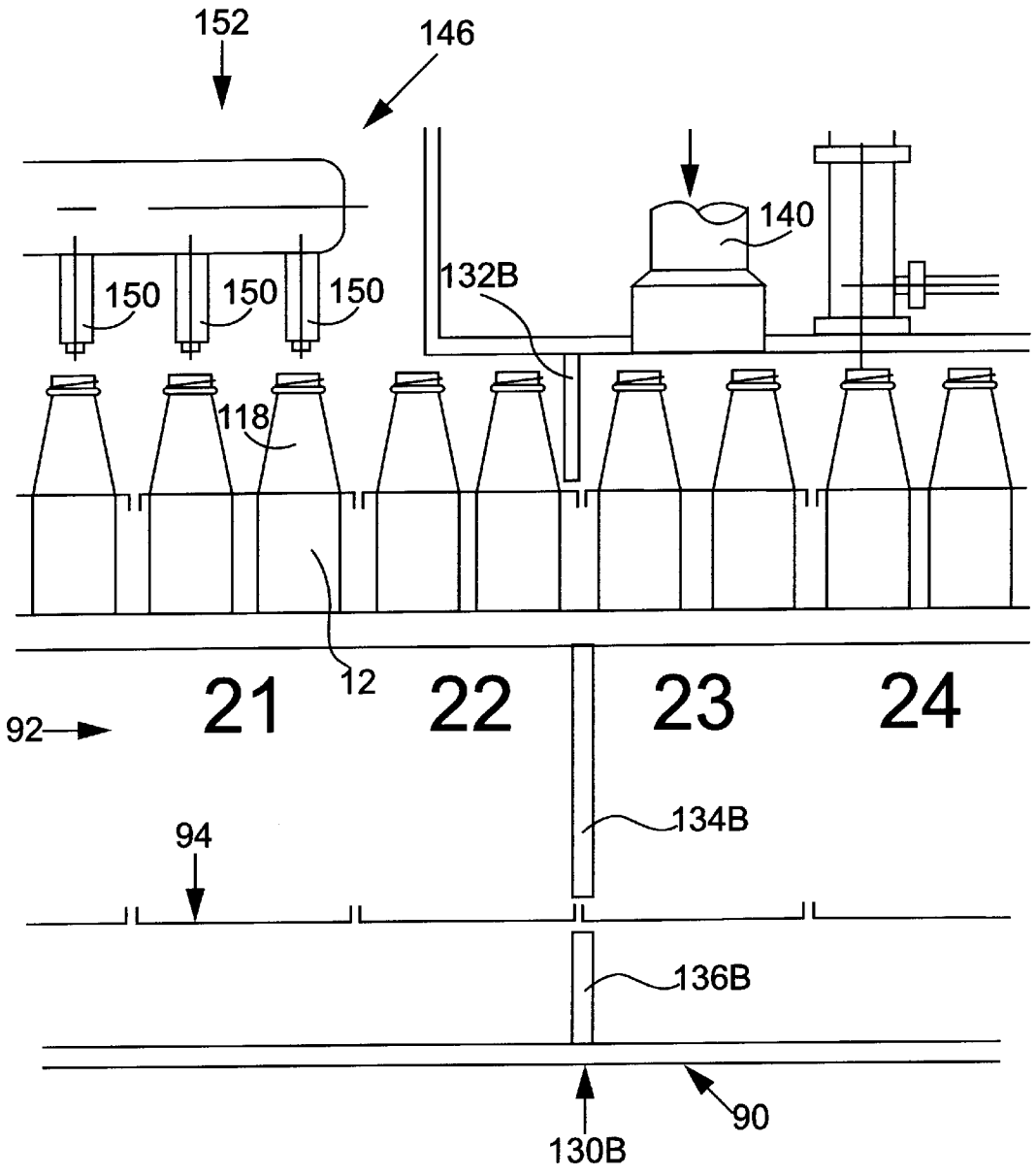
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FIG. 11

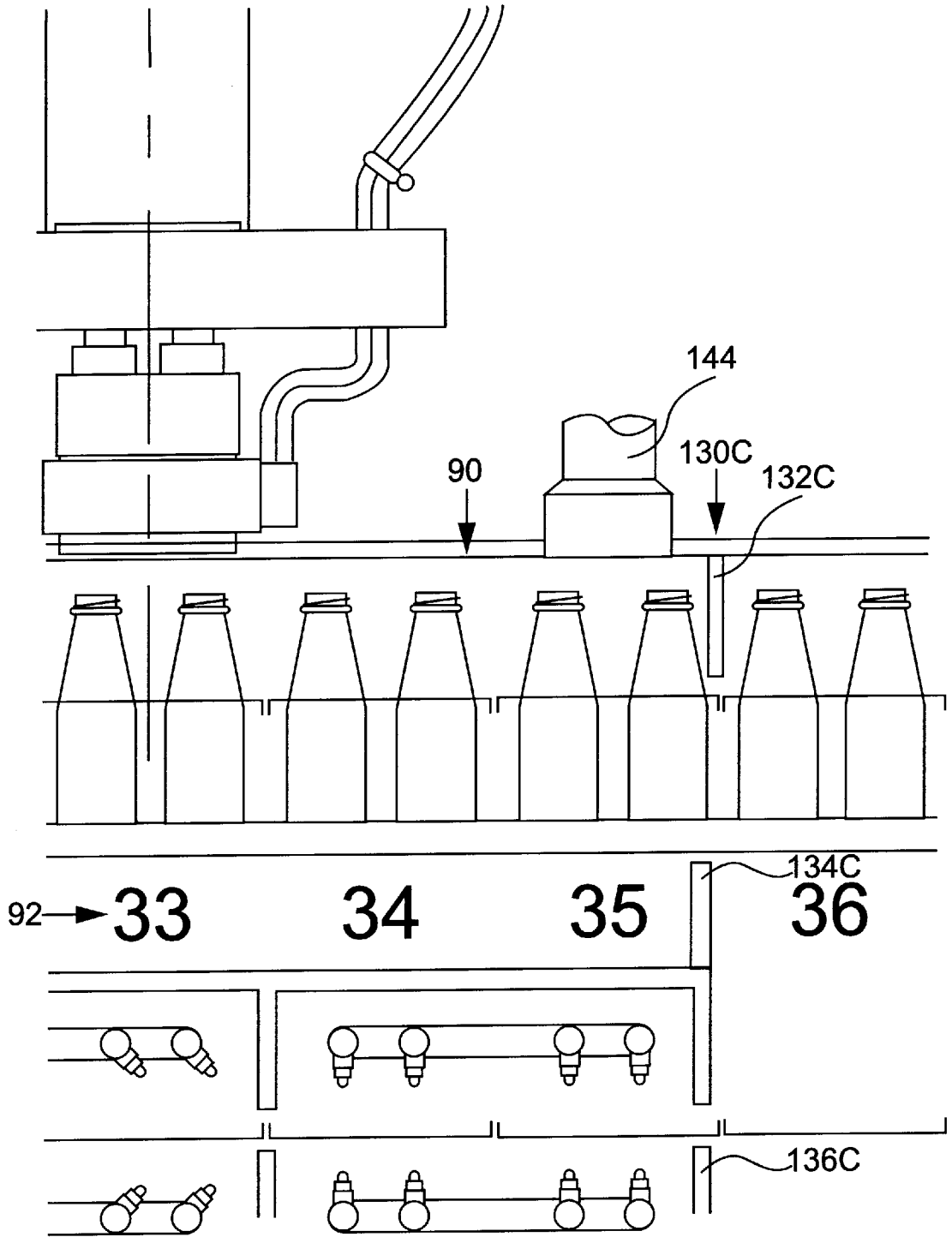

FIG. 12

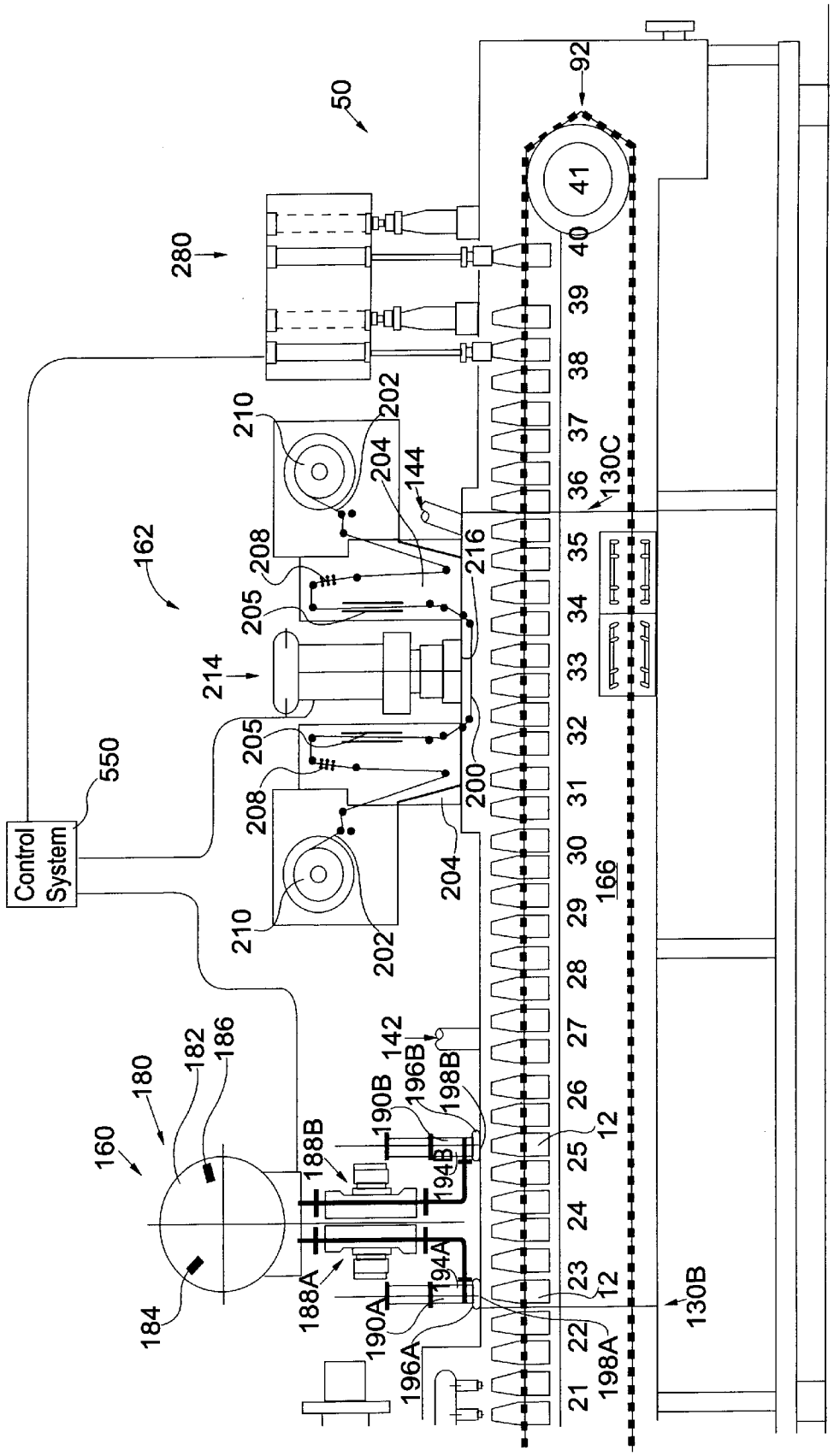
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FIG. 13

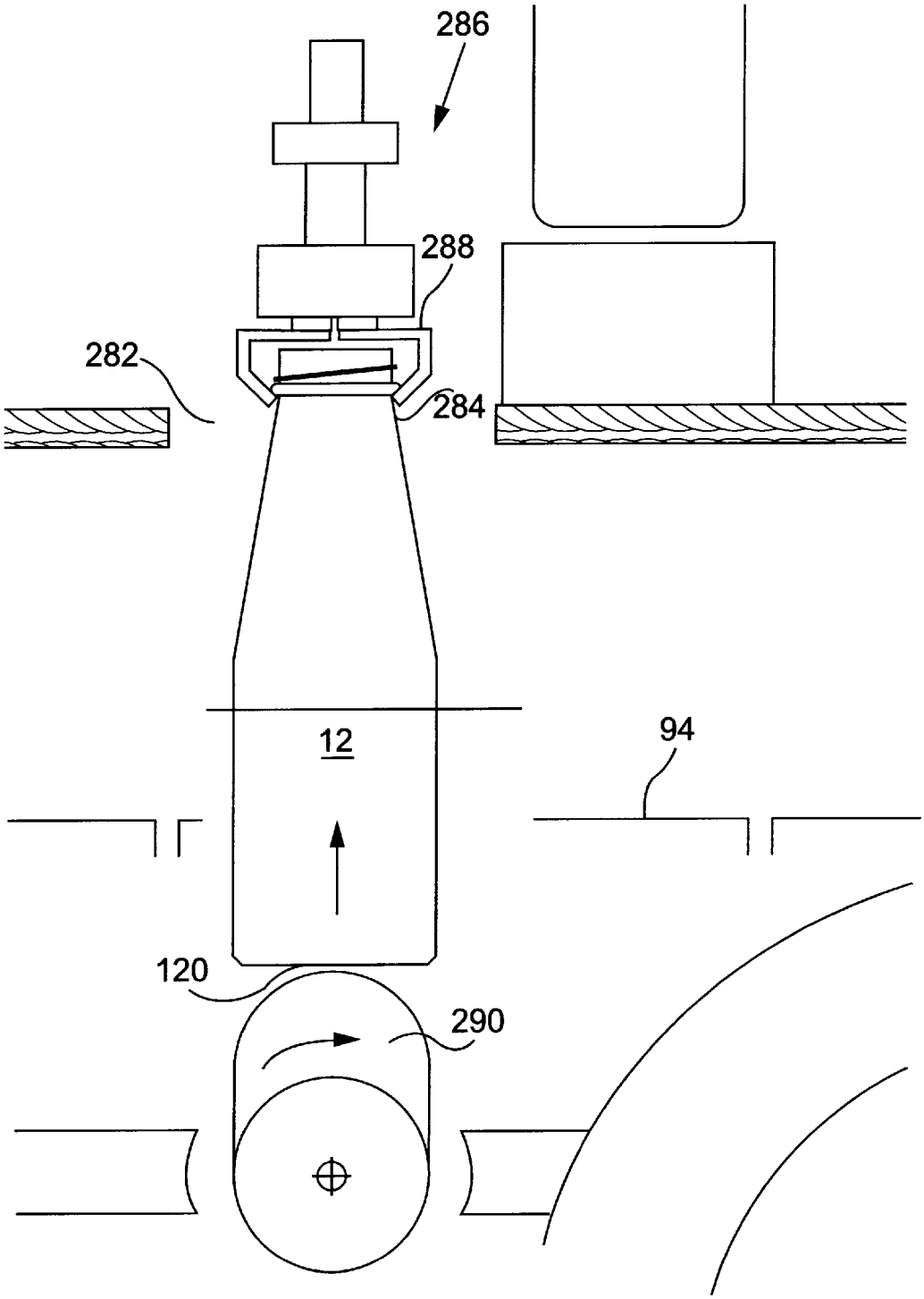

FIG. 14

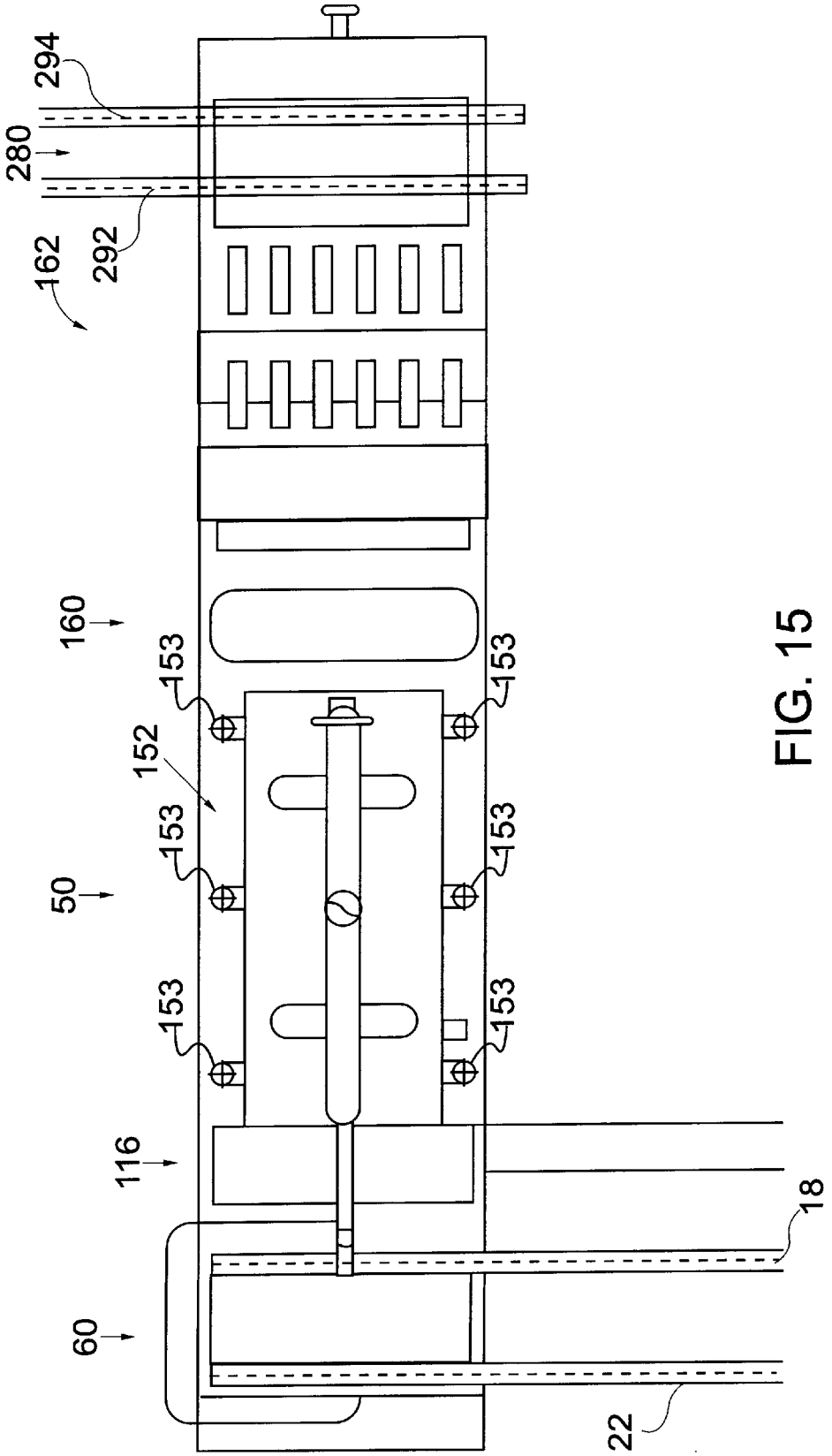

FIG. 15

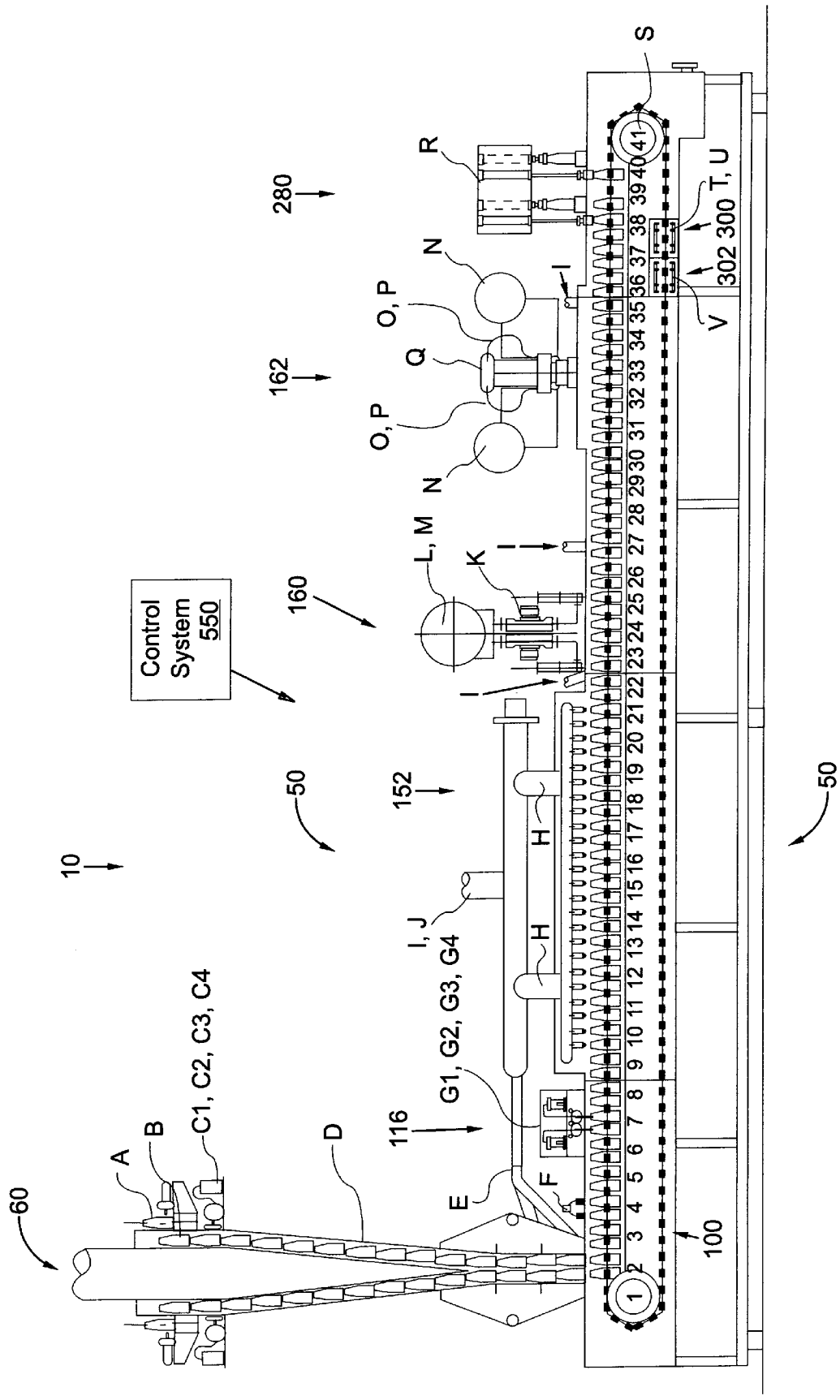
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FIG. 16

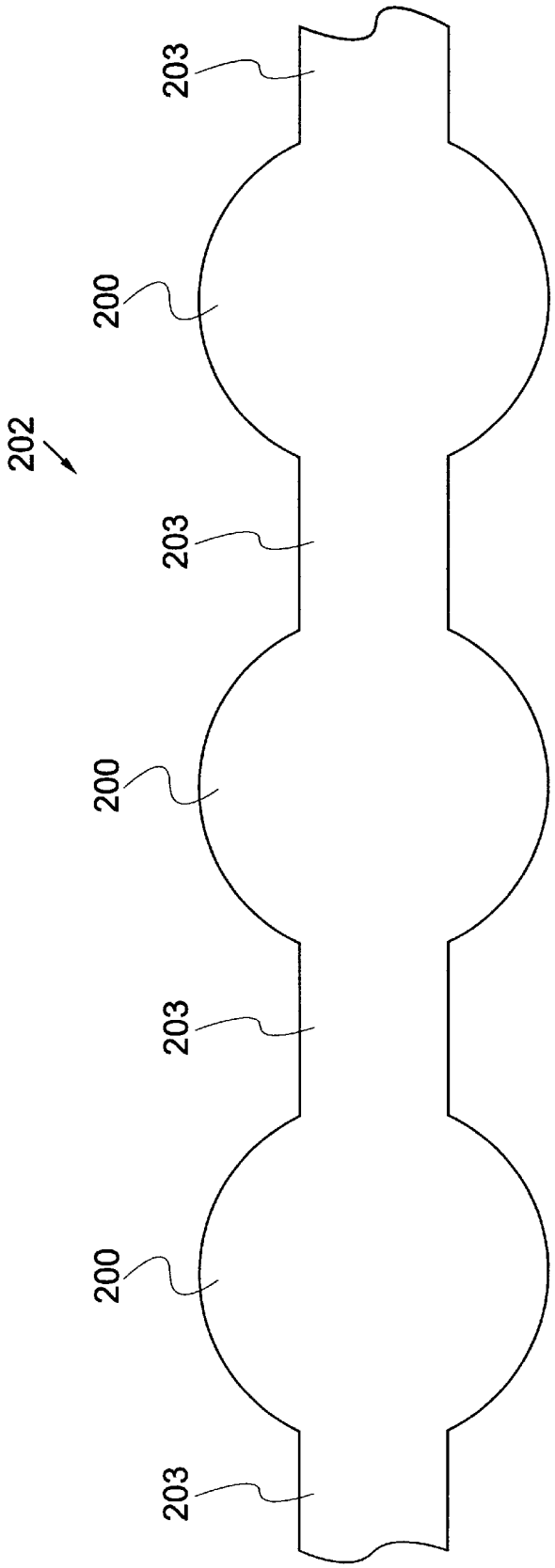


FIG. 17

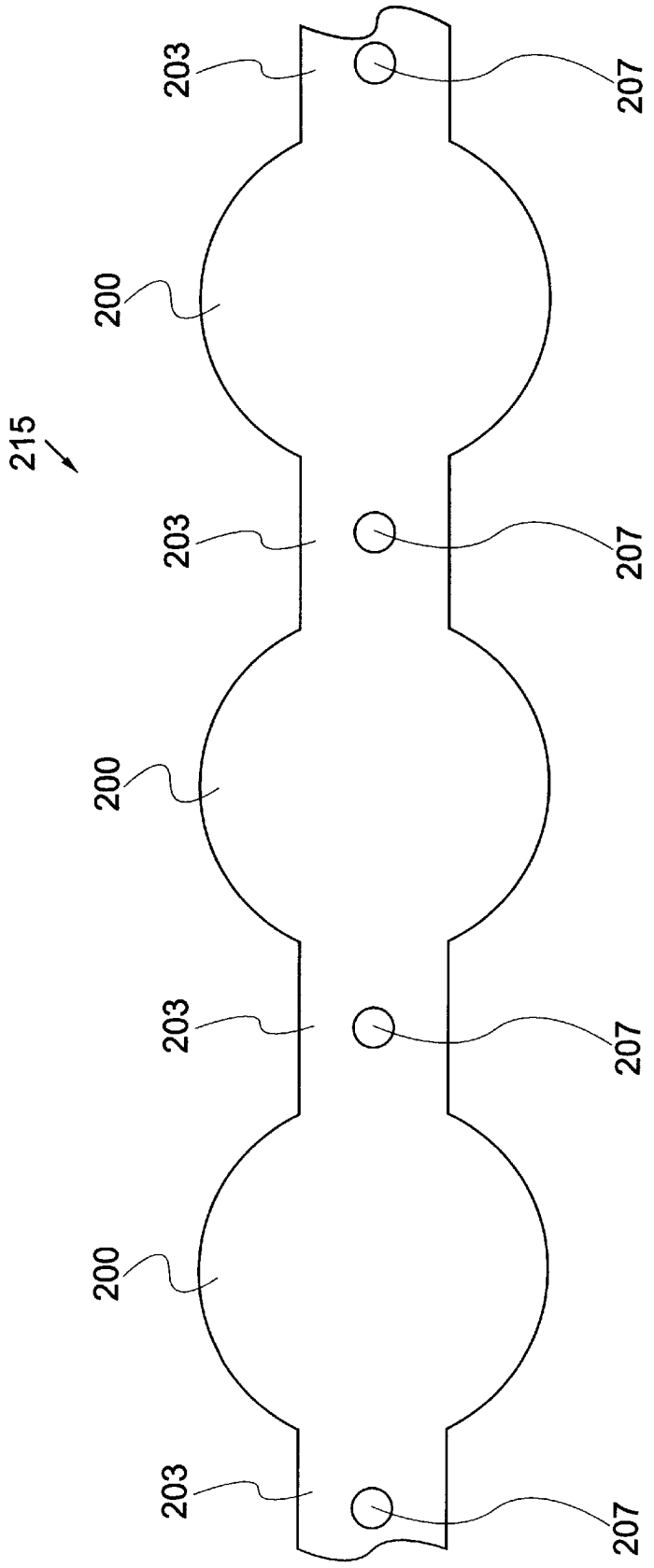
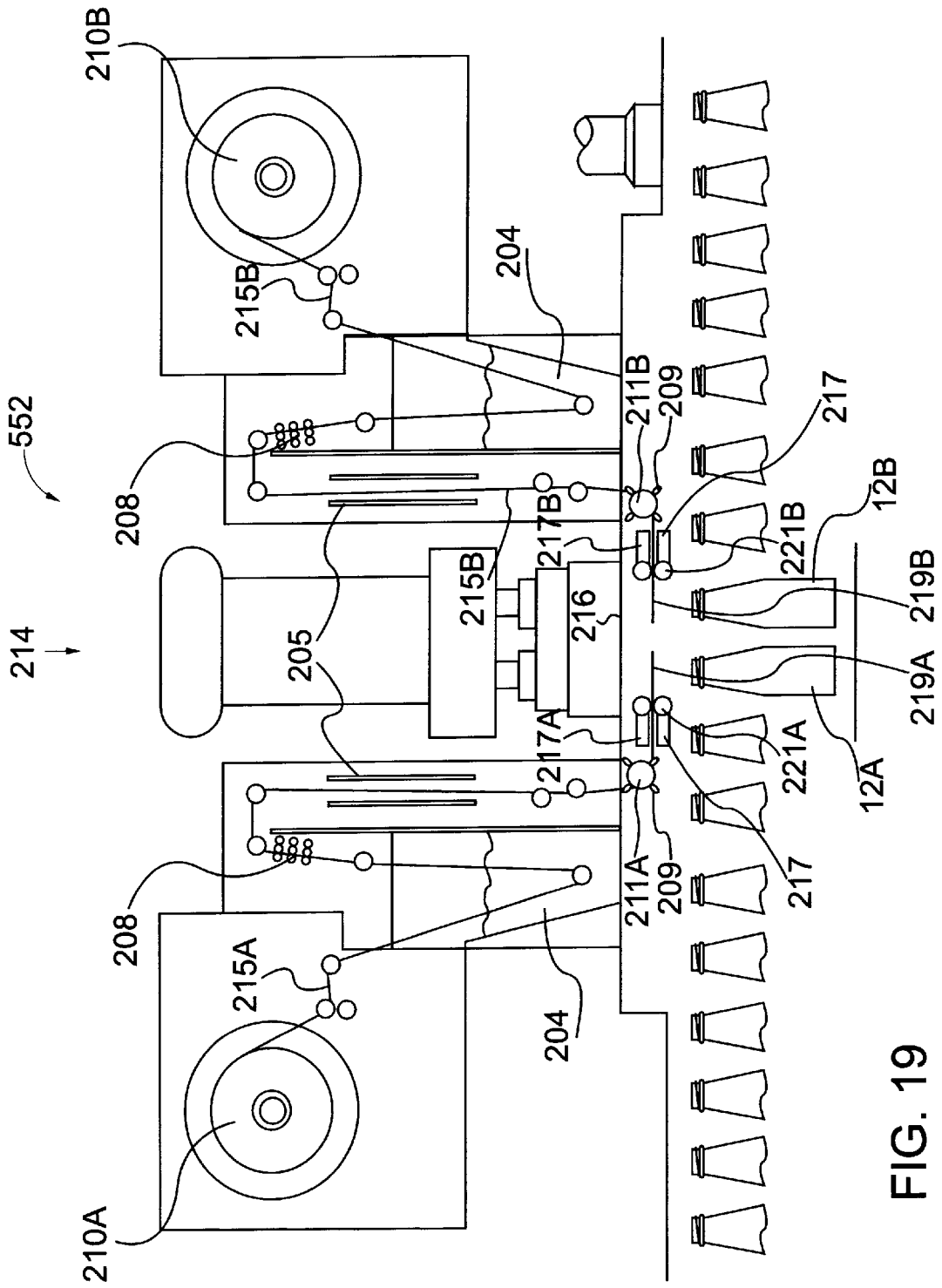


FIG. 18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215B
204
552
211B
209
217
208
217B
221B
12B
214
215B
216
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219B
219A
217A
221A
12A
208
211A
209
217
215A
204
210A

FIG. 19

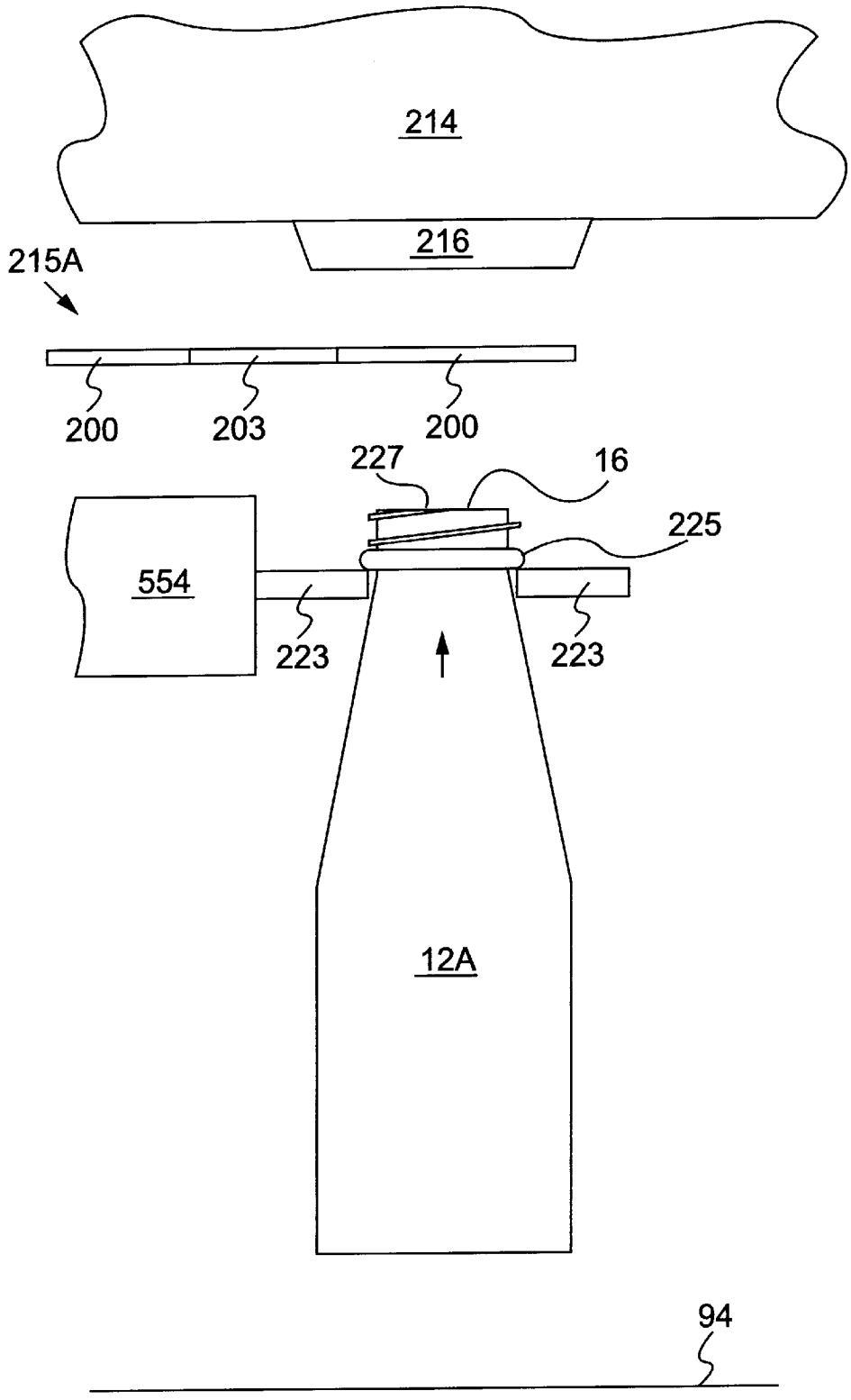


FIG. 20

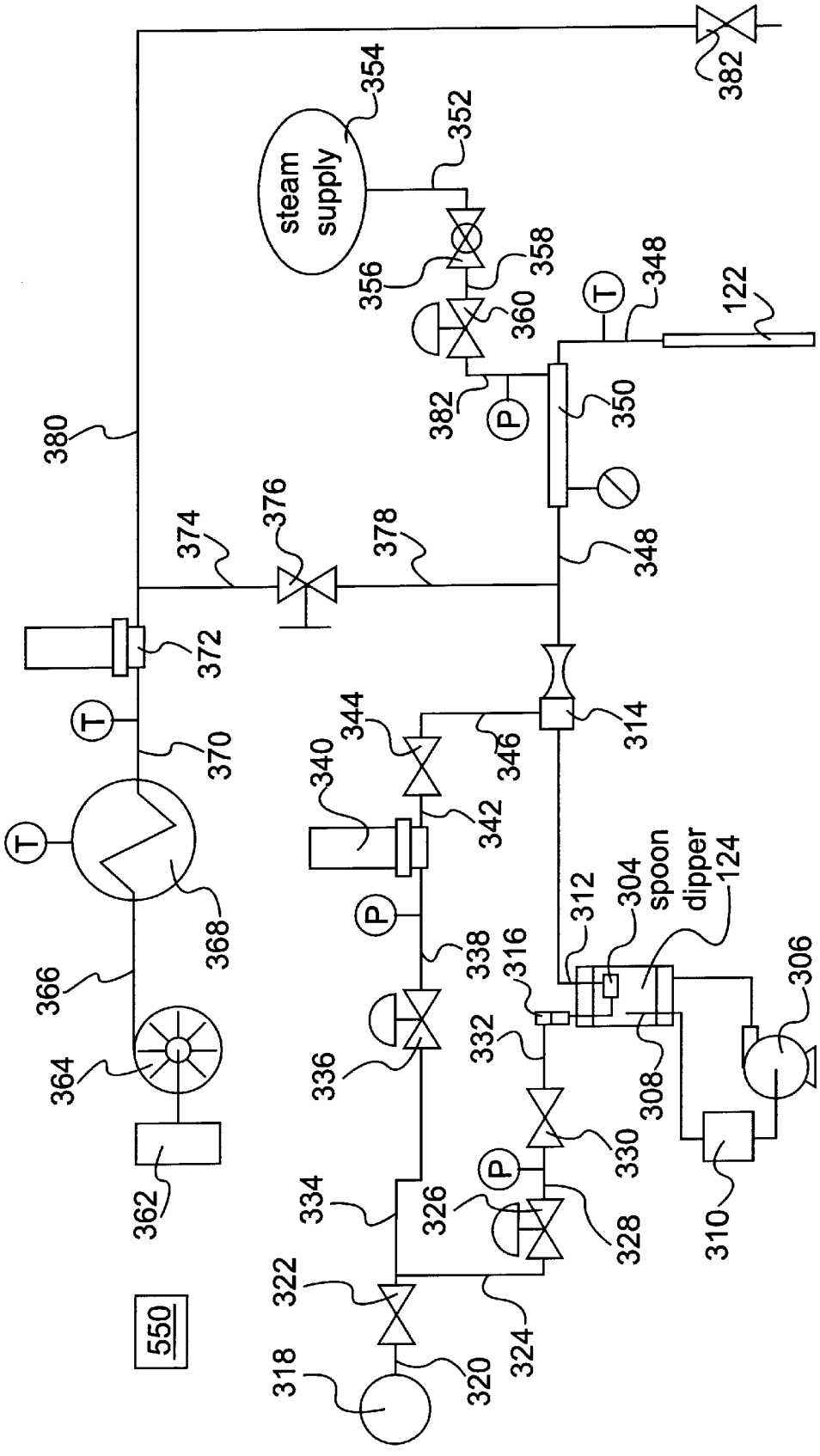
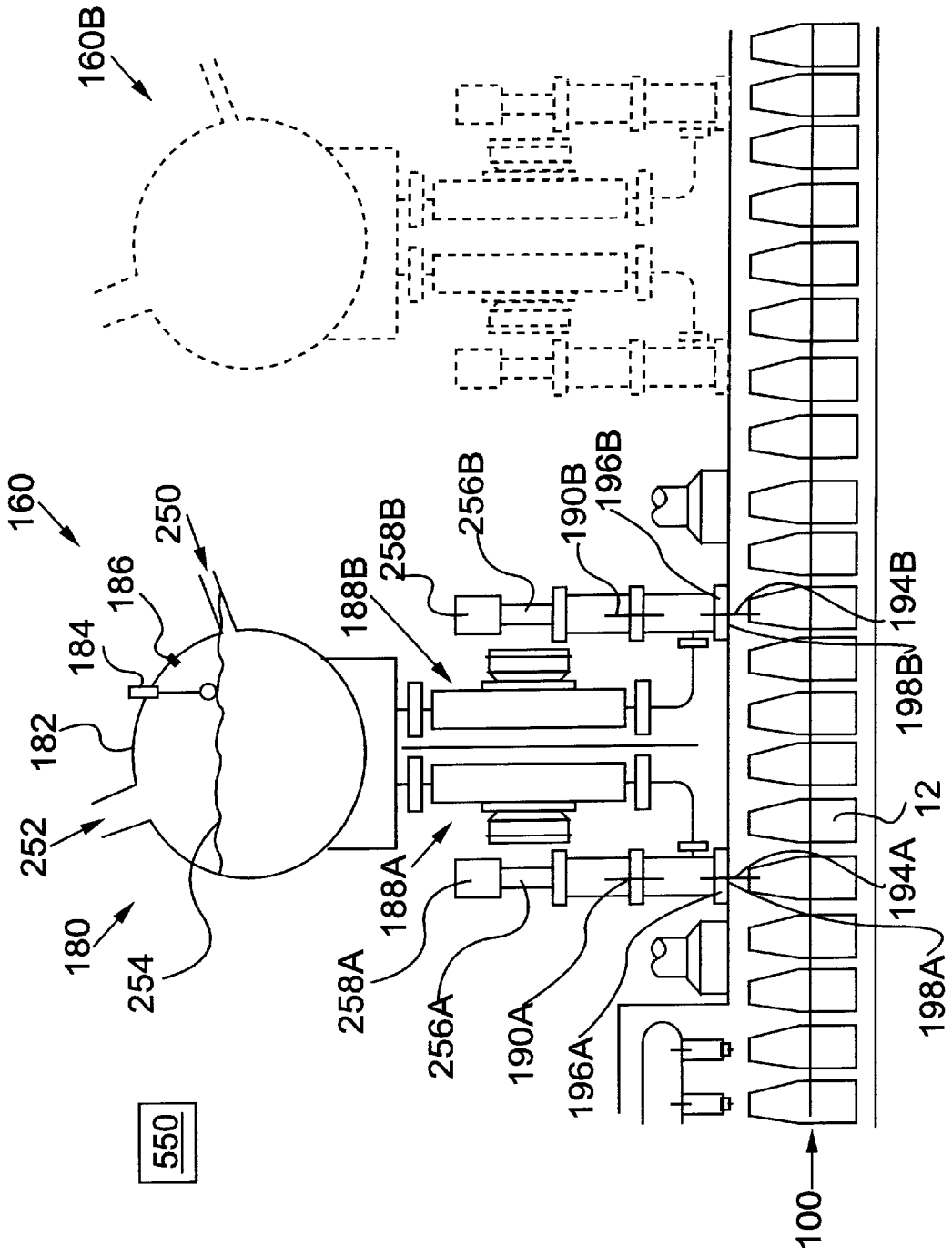

steam supply
354
352
356
358
360
382
348
122
350
380
374
376
378
372
370
344
340
342
346
314
312
304
spoon
dipper
124
316
338
336
332
330
328
326
334
322
324
318
320
306
308
310
366
364
362
368
550
T
P

FIG. 21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160
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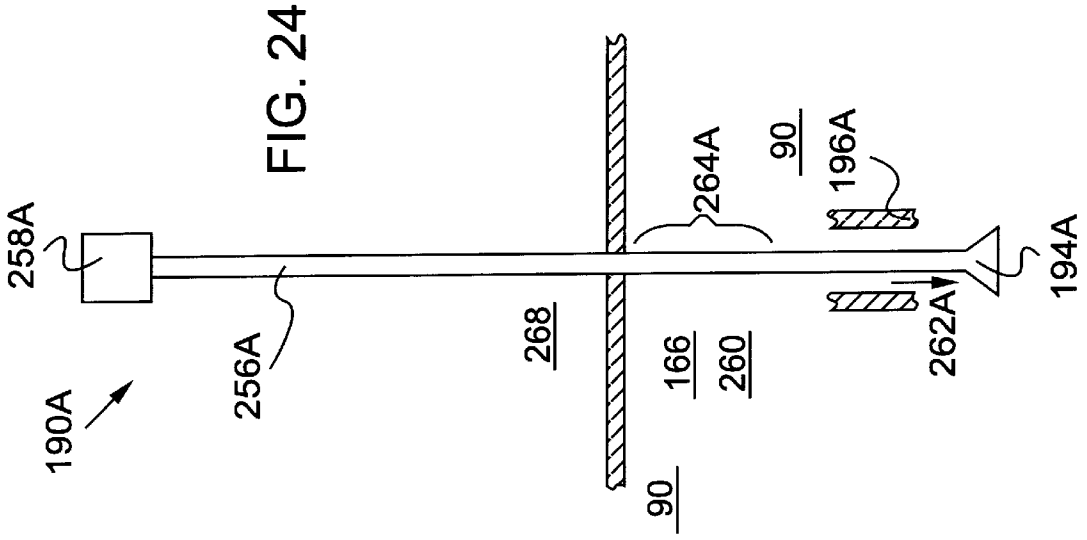
186
184
182
252
180
254
188B
258B
256B
190B
196B
194B
198B
188A
258A
256A
190A
196A
194A
198A
12
100
550

FIG. 22

FIG. 24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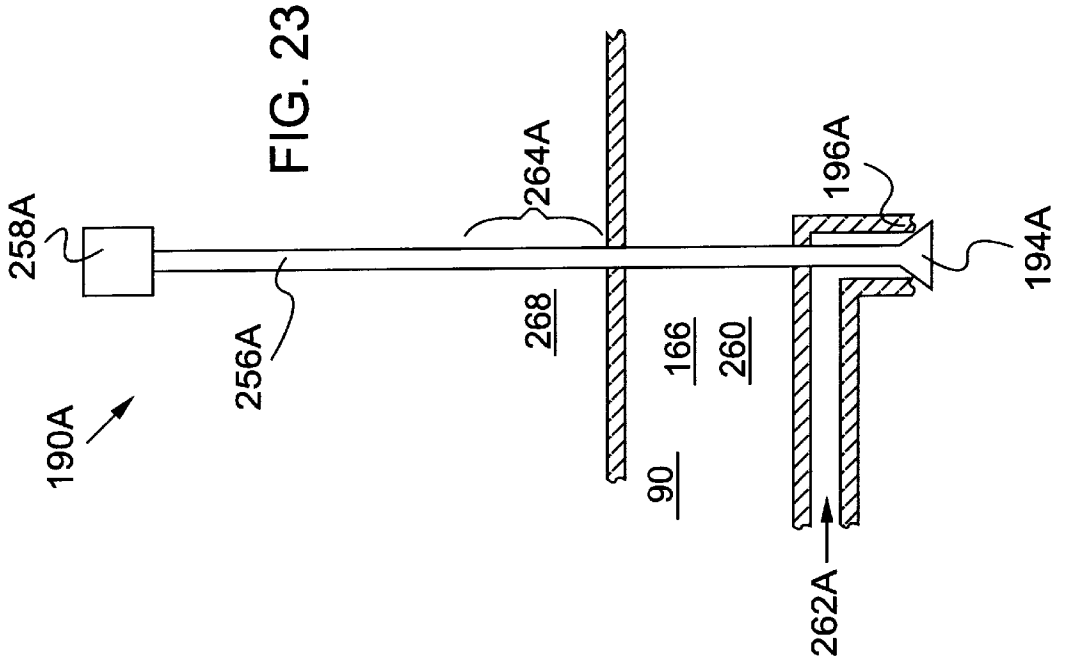
256A
268
90
166
260
264A
90
196A
194A
262A

FIG. 23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190A
256A
268
90
166
260
264A
196A
194A
262A

FIG. 26

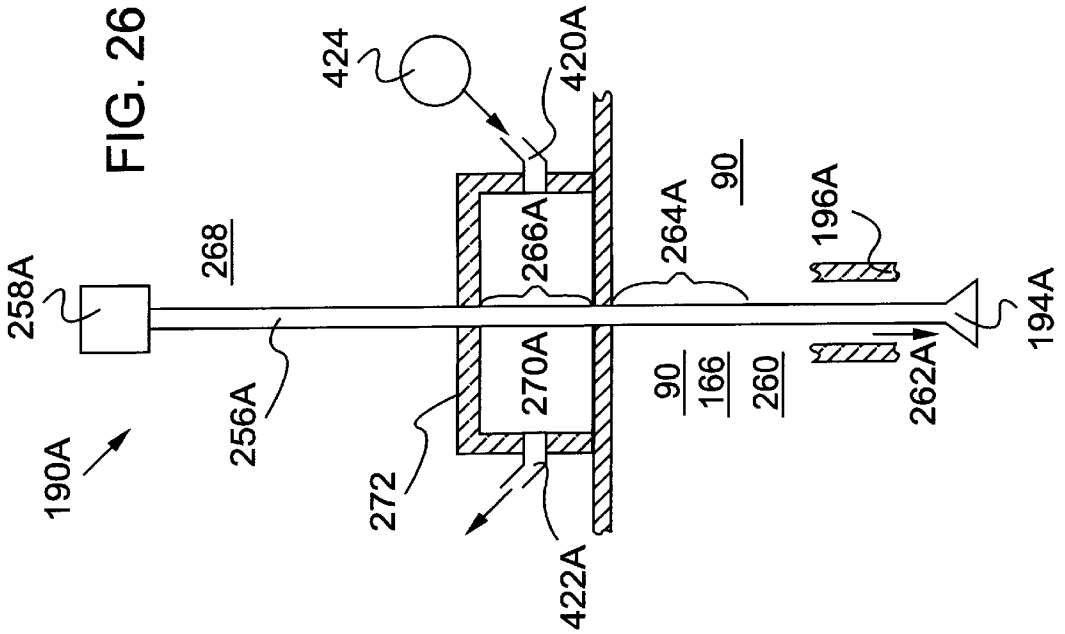
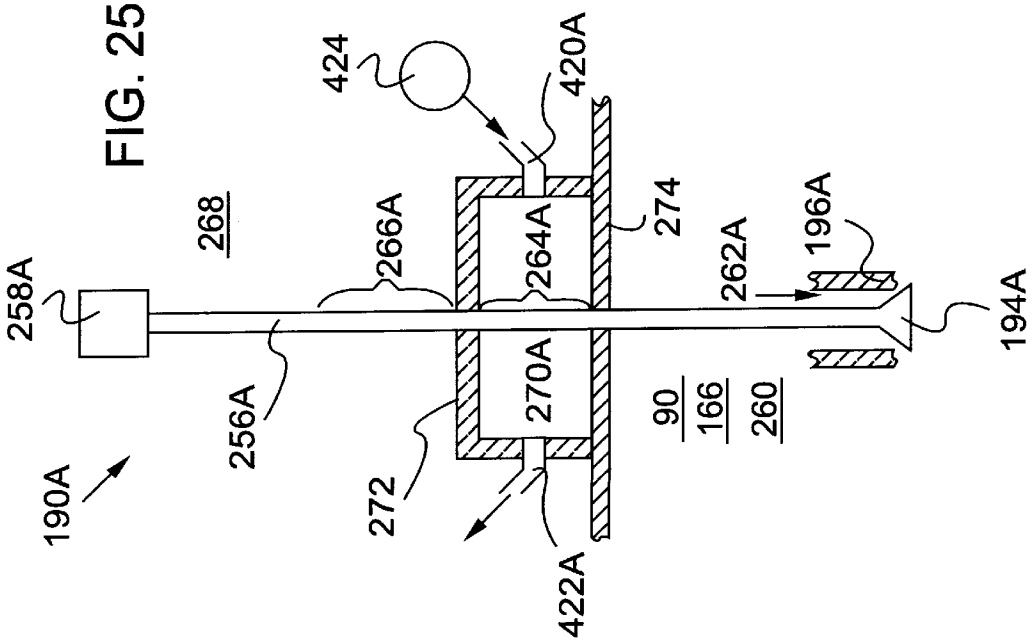

424
420A
266A
264A
90
196A
258A
268
194A
270A
90
166
260
262A
256A
272
190A
422A

FIG. 25


424
420A
268
266A
264A
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262A
196A
258A
194A
270A
90
166
260
256A
272
190A
422A

APPARATUS AND METHOD FOR PROVIDING CONTAINER FILLING IN AN ASEPTIC PROCESSING APPARATUS

This application claims benefit to U.S. provisional application Serial No. 60/118,404, filed 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 apparatus and method for providing container product filling in an aseptic processing apparatus.

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 sterilization tunnel are also known.

Liquid product fillers are known in the art. Generally, a container is placed under a filler head. The filler head opens and dispenses the liquid product. When the container is filled to a desired level, the filler head closes and stops the flow of liquid product into the container. Commonly, in line aseptic fillers use completely mechanical devices for measuring and dosing product into containers. These devices include a first apparatus for measuring the amount of material to be dispensed, and a second apparatus which functions as a filling nozzle. Typically, the first apparatus includes a piston cylinder apparatus for measuring the amount of material. The amount of material measured by the piston cylinder apparatus is limited by the diameter and stroke of the piston. The first and second apparatus include complicated mechanical members which are difficult to sterilize, clean, and maintain.

Typically, rotary fillers include multiple filling stations and allow about 7 to 15 seconds for filling. Some of the rotary bottle filers use electronic measuring devices for dosing the desired amount of product into a bottle. In order to meet FDA (Food and Drug Administration) "aseptic" standards and 3A Sanitary Standards, all surfaces of the filler that come into contact with the liquid product must be sterilized. Before filling commences, a plurality of interior parts of the filler must be removed, sterilized, and replaced. This time consuming and expensive process is necessary in order to ensure the complete sterilization of all surfaces that come into contact with the liquid product.

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 an apparatus and method for providing container product filling in an aseptic processing apparatus. Additionally, the present invention provides both a "Clean In Place" (CIP) process for cleaning, and a "Sterilizing in Place" for sterilizing all of the interior surfaces of the filler without having to disassemble the filler. The filler apparatus includes a smooth filling tube which is easy to clean and sterilize. The filler apparatus is used in a system 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 filler apparatus in order to meet various FDA aseptic standards and 3A Sanitary Standards and Accepted Practices.

The present invention generally provides an apparatus comprising:

- a valve for controlling a flow of product;
- a first sterile region surrounding a region where the product exits the valve;
- a second sterile region positioned proximate said first sterile region;
- a valve activation mechanism for controlling the opening or closing of the valve by extending a portion of the valve from the second sterile region into the first sterile region and by retracting the portion of the valve from the first sterile region back into the second sterile region.

The present invention generally provides a method comprising the steps of:

- controlling a flow of product using a valve;
- surrounding a region where the product exits the valve with a sterile region;
- providing a second sterile region positioned proximate said first sterile region; and

controlling the opening or closing of the valve by extending a portion of the valve from the second sterile region into the first sterile region and by retracting the portion of the valve from the first sterile region back into the second sterile region.

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 plan view of an aseptic processing apparatus in accordance with a preferred embodiment of the present invention;

FIG. **2** 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 sterilization 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 sterilization tunnel;

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

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

FIG. **17** is a plan view of a daisy chain of lids;

FIG. **18** is a plan view of another embodiment of a daisy chain of lids with holes for receiving pins of a drive wheel;

FIG. **19** is another embodiment of the lid sterilization and heat sealing apparatus including a pin drive apparatus;

FIG. **20** is perspective view of the heat sealing and gripper apparatus;

FIG. **21** is a schematic diagram of a sterilization control system for the interior bottle sterilization apparatus;

FIG. **22** is a side view of a main product filler apparatus;

FIG. **23** is a cross-sectional view of a valve in a closed position in a first sterile region;

FIG. **24** is a cross-sectional view with a portion of a valve stem displaced from a non-sterile region into the first sterile region;

FIG. **25** is a cross-sectional view of the valve in a closed position in a first sterile region, and with the portion of the valve stem located in a second sterile region; and

FIG. **26** is a cross-sectional view of the valve in an open position where the portion of the valve located in the second sterile region has been displaced into the first sterile region.

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 United States 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 an aseptic processing apparatus **10** 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 (hydrogen peroxide and peroxyacetic acid) 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 unscrambler **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 ster-

ilization. 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 above 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 entire 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 **67** 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 the sterilization 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 a sterilization 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 sterilization 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 **121** and a plurality of probes **123**. Each probe **123** includes any practical means for transferring the sterilant from the probe **123** to the interior surface **119** of the bottle **12**. For example, an opening or a plurality of openings may be used for ejecting the sterilant onto the interior surface **119**. Preferably, in the present invention, an applicator spray nozzle **122** is included in each probe **123**. The applicator spray nozzle **122** provides uniform sterilant application without droplet formation on the interior surface **119** of the bottle **12**. A separate measuring device **121** and the probe **123** are used for each of the twelve bottle **12** locations in the conveying plate **94**. Each sterilant measuring device **121** may include a spoon dipper **304** (e.g., approximately 0.5 ml each) as illustrated in FIG. **21**. Each bottle **12** is supplied with the same measured quantity of sterilant, preferably in the form of a hot vapor fog. A pump **306** provides a sterilant (e.g., hydrogen peroxide) from a sterilant supply tank **310** to a reservoir **124**. An overflow pipe **308** maintains the sterilant liquid level in the reservoir **124** by returning excess sterilant to the sterilant supply tank **310**. The spoon dipper **304** connected to an air cylinder **316** is submerged into the reservoir **124** and is lifted above the liquid level. Thus, a measured volume of liquid hydrogen peroxide (e.g., approximately 0.5 ml) is contained in each spoon dipper **304**.

Each spoon dipper **304** may include a conductivity probe that is configured to send a signal to the control system **550** indicating that the spoon dipper **304** is full. A tube **312** (e.g., having a diameter of about 1/16") is positioned in the center of the spoon dipper **304**. A first end of the tube **312** is positioned near the bottom of the spoon dipper **304**. A second end of the tube **312** is connected to an atomizing venturi **314**.

A pressurized air source **318** is connected by a conduit **320** to a flow adjust valve **322**. A conduit **324** connects the flow adjust valve **322** to a regulator valve **326**. A conduit **328** connects the regulator valve **326** with a solenoid actuated valve **330**. A conduit **332** connects the solenoid actuated valve **330** with the air cylinder **316**. The control system **550** controls the solenoid actuated valve **330** which controls the compressed air supplied to the air cylinder **316**. Compressed air supplied to the air cylinder **316** lowers or lifts the spoon dipper **304** into or out of the liquid sterilant.

A conduit **334** connects the flow adjust valve **322** with the regulator valve **336**. A conduit **338** connects the regulator valve **336** with a sterile air filter **340**. A conduit **342** connects the sterile air filter **340** with a solenoid actuated valve **344**. A conduit **346** connects the solenoid actuated valve **344** with the atomizing venturi **314**. When the spoon dipper **304** is full, and a signal is received from the control system **550**, the solenoid actuated valve **344** is opened allowing pressurized sterile air to enter the atomizing venturi **314** through the conduit **346**. The pressurized air flow causes a vacuum to be generated in the second end of the tube **312** causing liquid hydrogen peroxide to be pulled out of the spoon dipper **304**.

A first supply of sterile air is supplied through conduit **346**. The pressurized air supplied through conduit **346** is used to atomize the hydrogen peroxide sterilant in the atomizing venturi **314**. Atomization of the liquid hydrogen peroxide may be provided by other means such as by using ultrasonic frequencies to atomize the liquid hydrogen peroxide.

A conduit **348** connects with the atomizing venturi **314**, passes through a heat exchanger **350** (e.g., double tube heat exchanger), and connects with a probe **123** including the applicator spray nozzle **122**. A conduit **352** connects a steam supply **354** with a valve **356**. A conduit **358** connects the valve **356** with a regulator valve **360**. A conduit **382** connects the regulator valve **360** with the heat exchanger **350**.

A second supply of hot sterile air is supplied to the atomized sterilant through a conduit **378**. A humidity control apparatus **362** maintains the humidity level of the air entering a blower **364**. A conduit **366** connects the blower **364** with a heater **368**. A conduit **370** connects the heater **368** with a sterile filter **372**. A conduit **374** connects the sterile filter **372** with a flow adjust valve **376**. The conduit **378** connects the flow adjust valve **376** with the conduit **348**. A conduit **380** connects the sterile filter **372** with a bypass valve **382**. The blower **364** operates continuously supplying humidity controlled air to the heater **368**. The flow of heated sterile air is controlled with the flow adjust valve **376** and travels through conduit **378**.

Exiting conduit **378**, the second supply of hot sterile air enters the conduit **348** to mix with the atomized hydrogen peroxide from the atomizing venturi **314**. Excess flow of heated sterile air travels through conduit **380** and passes through the bypass valve **382**. The second supply of hot sterile air assists in obtaining a uniform concentration of hydrogen peroxide in the air stream in conduit **348** and provides enough momentum to ensure that all portions of the bottle **12** interior **118** are contacted by hydrogen peroxide. Furthermore, the second supply of hot sterile air is continuously blowing, whereas the first supply of sterile air and hydrogen peroxide in conduit **346** is intermittent corresponding to the movement of the bottles **12**. Since the second supply of hot sterile air is continuous, hydrogen peroxide does not have the ability to fall out of the air stream and deposit in the delivery conduit **348** in the form of drops. This ensures that the delivery of hydrogen peroxide is consistent from one bottle **12** application to the next and does not allow a drop to be directed into the bottle **12** interior **118**.

The mixture of heated sterile air and atomized hydrogen peroxide in conduit **348** passes through the double tube heat exchanger **350**. The double tube heat exchanger **350** adds additional heat to the atomized hydrogen peroxide. Heat is supplied to the double tube heat exchanger **350** from the steam supply **354** controlled by the regulator valve **360**. Generally, hydrogen peroxide has chemical stabilizers in it that may cause a white powder precipitate to form on the inner surfaces of the double tube heat exchanger **350**. This occurs when the temperature differential between the supplied steam heat and the gas to be heated is large. In the present invention, the temperature of the atomized hydrogen peroxide is typically about the same as the supplied steam heat so that a minimal amount of precipitate occurs. Another embodiment of the invention eliminates the need for the double tube heat exchanger **350** because the temperature of the atomized hydrogen peroxide is already at the desired temperature.

The temperature of the atomized gas entering the interior **118** of the bottle **12** is in the range of about 100° C. to 120° C. This temperature is limited to prevent the plastic bottles **12** from melting. The droplet size occurring on the interior surface **119** of the bottles **12** is in the range of about 300 to 500 micrometers. The initial concentration level of hydrogen peroxide on the interior surface **119** of the bottle **12** is about 35%.

As illustrated in FIG. **21**, the control system **550** monitors the temperatures at locations denoted as "T" in the interior bottle sterilization apparatus **116**. The temperartures "T" are measured in the conduit **348**, in the heater **368**, and in the conduit **370**. Additionally, the control system **550** monitors the pressures at locations denoted as "P" as illustrated in FIG. **21**. The pressures "p" are measured in the conduit **328**, conduit **338**, and in the conduit **382**.

The control system **550** monitors and controls a spray apparatus **126** that includes the probe **123** including the applicator spray nozzles **122** FIG. **10**. Each applicator spray nozzle **122** sprays the sterilant into the interior **118** of a corresponding bottle **12** as a hot vapor fog. The probe **123** including applicator spray nozzles **122** are designed to extend through the bottle openings **16**. The probe **123** including 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 probe **123** including 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 sterilization 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 sterilization 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 supply sources (e.g., conduits **140**, **142**, and **144**) into the sterilization 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**. For example, with the sterilant hydrogen peroxide, the concentration level of hydrogen peroxide is about 1000 ppm (parts per million) in the fourth sterilization zone **165**. The hydrogen peroxide sterilant level is about 3 ppm in the first sterilization zone **164**. The lowest concentration level of sterilant is in the second sterilization zone **166**. In the second sterilization zone **166**, the hydrogen peroxide sterilant concentration level is less than 0.5 ppm and typically about 0.1 ppm. 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. The hydrogen peroxide sterilant concentration level is about 0.1 ppm in the third sterilization zone **172**.

As illustrated in FIG. **3**, a gas such as hot sterile air enters the first sterilization zone **164** at a rate of about 2400 cfm (cubic feet per minute). The temperature of the hot sterile air is about 230° F. The hot sterile air enters the first sterilization zone **164** through conduit **148**. Additional hot sterile air enters the second sterile zone through sterile air conduits **140**, **142**, and **144** at a total rate of about 1000 cfm (FIG. **3**). Also, hot sterile air enters at a rate of about 1800 cfm through ports **67** and **68** leading into the infeed and sterilization apparatus **60**. A portion of the hot sterile air exits the sterilization tunnel **90** at a rate of about 1500 cfm through a plurality of exhaust ports **153** located in the first sterilization zone **164** (FIG. **15**). A portion of the hot sterile air exits the sterilization tunnel **90** at a rate about 100 cfm through an opening **282** (FIG. **14**). The bottles **12** exit the sterilization tunnel **90** through the opening **282**. The continuous flow of sterile air flow out through the opening **282** prevents contaminants from entering the sterilization tunnel **90**.

As illustrated in FIG. **3**, the hot sterile air is drawn out of the fourth sterilization zone **165** of the sterilization tunnel **90** through the bottom opening **62** in the bottle infeed and sterilization apparatus **60**. Next, the hot sterile air from the infeed and sterilization apparatus together with the fourth sterilization zone **165** exits out of the exhaust conduit **70** of the infeed and sterilization apparatus at a rate of about 3600 cfm. This outflow of hot sterile air from the bottle infeed and sterilization apparatus **60** prevents contaminants from entering the bottle infeed sterilization apparatus **60** and the sterilization tunnel **90**.

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**. In these twelve stations, a third supply of hot sterile air is provided through the sterile air supply system **146**. The sterile air supply system **146** supplies hot sterile air to a plurality of nozzles **150** in the activation and drying apparatus **152**. The hot sterile air flow in each bottle **12** is about 40 SCFM. 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 sterilization 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**, **13**, and **22**. 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. **22**, 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**, at least one volumetric measuring device **188** (two are shown as **188**A, **188**B), and at least one filling nozzle **190** (two are shown as **190**A, **190**B). The product tank **182** includes a single product inlet **250** with a valve cluster (not shown) including a sterile barrier to separate the product supply system (not shown) from 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. Pressurized steam or sterile air is supplied into the product tank **182** through the inlet **252**. The product level **254** in the product tank **182** is measured by the level sensor **184**. The control system **550** maintains the product level and pressure in the product tank **182**. This supplies each filling nozzle **190** (e.g. **190**A, **190**B) with a constant pressure that ensures proper product delivery to the bottles **12**.

Filling nozzles **190**A, **190**B are provided at stations **23**, **25**, respectively. Additionally, there are a plurality of corresponding volumetric measuring devices **188**A and **188**B to measure the volume of product entering each bottle **12** at stations **23** and **25**, respectively. In accordance with the present invention, the volumetric measuring devices **188**A and **188**B are preferably electronic measuring devices such as a magnetic flow meter which measures the volume of product flow, or a mass flow meter which measures the weight of product flow. The electronic measuring devices provide filling accuracies of about 0.5%. 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 included in the filling nozzles **190**A and **190**B, respectively. The amount of product delivered to the bottles **12** is controlled by the duration of time that the plurality of valves **194**A and **194**B are open. The control system **550** controls the duration of time. Thus, any desired quantity of product may be selected by controlling the duration of time that the valves **194**A and **194**B are open.

The activation mechanisms for valves **194**A and **194**B include valve stems **256**A and **256**B attached to actuators **258**A and **258**B, respectively. Each actuator **258**A, **258**B may include any suitable actuating apparatus (e.g. hydraulic, pneumatic, electrical, etc.). Preferably, in the present invention, the actuators **258**A and **258**B include air cylinders controlled by the control system **550**. The actuators **258**A and **258**B are attached to the valve stems **256**A and **256**B, respectively. The actuators **258**A and **258**B displace the valve stems **256**A and **256**B in an upward and downward direction.

FIG. **23** illustrates the valve stem **256**A attached to the valve **194**A. A first sterile region **260** surrounds the nozzle **196**A through which product **262**A exits. The first sterile region **260** is connected to, and is at the same sterilization level as, the second sterilization zone **166** (FIG. **3**) of the sterile tunnel **90**. The valve **194**A is in a closed position against nozzle **196**A blocking the flow of product **262**A into a bottle **12** (not shown) located in the first sterile region **260**. A first portion **264**A of the valve stem **256**A is surrounded by a non-sterile region **268**, for example, the area located outside of the sterile tunnel **90**. Thus, the first portion **264**A of the valve stem **256**A is exposed with contaminants.

As illustrated in FIG. **24**, the actuator **258**A has displaced the valve stem **256**A in a downward direction. The valve **194**A is removed from the nozzle **196**A allowing product **262**A to flow into a bottle **12** (not shown). The first portion **264**A of the valve stem **256**A has entered the first sterile region **260**. This may create a problem because the first portion **264**A of the valve stem **256**A may carry contaminants from the non-sterile region **268** into the first sterile region **260**. In order to overcome this difficulty, the present invention has introduced a second sterile region **270** as illustrated in FIG. **25**.

The second sterile region **270**A is enclosed by a housing **272** and by a wall **274**. The wall **274** separates the second sterile region **270**A from the first sterile region **260**. The first sterile region **260** is connected to, and is at the same sterilization level, as the second sterilization zone **166** of the sterile tunnel **90**. A sterilizing media **424** is supplied to the second sterile region **270**A through the inlet conduit **420**A. An outlet conduit **422**A may be added to allow the sterilizing media **424** to leave the second sterile region **270**A. The sterilizing media **424** may include any suitable sterilant (e.g. steam, hydrogen peroxide, oxonia, etc.). The non-sterile region **268** lies outside of the housing **272**. A second portion **266**A of the valve stem lies in the non-sterile region **268**. As illustrated in FIG. **25**, the valve **194**A is in a closed position against the nozzle **196**A blocking the flow of product **262**A into a bottle **12** (not shown) in the first sterile region **260**. The first portion **264**A of the valve stem **256**A is surrounded by the second sterile region **270**A. Thus, the first portion **266**A of the valve stem **256**A is maintained in a sterile condition.

As illustrated in FIG. **26**, the actuator **258**A has displaced the valve stem **256**A in a downward direction. The valve **194**A is removed from the nozzle **196**A allowing product **262**A to flow into a bottle **12** (not shown). The first portion **264**A of the valve stem **256**A has entered the first sterile region **260**. In the present invention, the first portion **264**A of the valve stem **256**A has not introduced contaminants into the first sterile region **260** because the first portion **264**A of the valve stem **256**A was pre-sterilized in the second sterile region **270**A before entering the first sterile region **260**. The second portion **266**A of the valve stem **256**A has entered the second sterile region **270**A from the non-sterile region **268**. The second portion **266**A of the valve stem **256**A is sterilized in the second sterile region **270**A removing any contaminants. Therefore, the second sterile region **270**A removes any contaminants from the valve stem **256**A before any portion of the valve stem **256**A enters the first sterile region **260**. Thus, contaminants are prevented from entering the sterile tunnel **90** through the filling nozzles **190**A and **190**B, and the valves **194**A and **194**B, respectively.

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 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 (FIG. **22**) 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 in the cups **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**. As shown in FIG. **13**, 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. 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. A bottle **12** moves into position under a nozzle **196**. The bottle stops and the valve **194** opens allowing product **262** to enter the bottle **12**. The volumetric measuring device **188** measure the amount of product entering the bottle **12**. Next, when the desired bottle **12** fill level is achieved, the valve **194** is closed. The control system **550** controls the valve opening and closing. Additionally, the control system **550** does not allow product **262** to flow if a bottle **12** is not present. The bottle **12** filling operation is completed for six bottles at station **23** and for six bottles at station **25**. The filling cycle is repeated for each cycle of the aseptic processing apparatus **10**. In the present invention the bottle filling time is about 1.5 seconds. Another embodiment of the present invention adds a second main product filler apparatus **160**B located at, for example, stations **27** and **29** (FIG. **22**). In this embodiment, the bottles **12** are partially filled by the first main product filler apparatus **160** at stations **23** and **25**. Next, the bottles are moved to the second main product filler apparatus **160**B where the filling of each bottle is completed at stations **27** and **29**. For example, in filling each **16** fluid ounce bottle **12**, the first main product filler apparatus **160** would fill the first 8 ounces in about 1.5 seconds. Next, the second main product filler apparatus **160** would fill the remaining 8 ounces in each bottle **12** in another about 1.5 seconds. The second main product filler **160**B allows the operation to be kept to about 1.5 seconds at each main product filler apparatus **160**, **160**B. This allows the conveying apparatus **100** to move the bottles through the aseptic processing apparatus **10** at speeds greater than about 350 bottles **12** per minute.

FIGS. **3**, **13**, **16** and **19** illustrate the lid sterilization and heat sealing apparatus **162**. A lid **200** is applied to each of the twelve bottles **12** at station **33**. 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 **203** that holds them together to form a long continuous chain of lids **200**, hereinafter referred to as a "daisy chain" **202**. The daisy chain **202** of lids is illustrated in FIGS. **17**. 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**. The concentration of hydrogen peroxide can range from about 30 to 40%, however, preferably the concentration is about 35%. Each lid **200** remains in the hydrogen peroxide bath **204** for at least about 6 seconds. 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 temperature is about 135° C. The hot air knives **208** also remove excess hydrogen peroxide from the lids **200**. A plurality of heated platens **205** further dry 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 sterilization tunnel **90** via the lidding operation.

Once sterilized, the lids **200** enter the sterilization 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. Sealing may also be accomplished without having to provide the mechanical crimp on the lid **200**.

Another embodiment of a lid sterilization and heat sealing apparatus **552** is illustrated in FIG. **19**. As illustrated in FIG. **18**, the daisy chain **215** of lids **200** includes a hole **207** located in each interconnecting band **203**. Each hole **207** receives a pin **209** of a drive sprocket **211**.

The daisy chain **215**A, **215**B of lids **200** is placed on each of a plurality of reels **210** (e.g. **210**A and **210**B). For the twelve bottle configuration of the present invention, six of the reels **210**, each holding a daisy chain **215**A, **215**B of lids **200**, are located on each side of a heat sealing apparatus **214**. Each daisy chain **215**A, **215**B of lids **200** winds off of a corresponding reel **210** and is sterilized preferably using a hydrogen peroxide bath **204**. The concentration of hydrogen peroxide can range from about 30 to 40%, however, preferably the concentration is about 35%. The lids **200** remain in the hydrogen peroxide bath **204** for at least about 6 seconds. 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 **215**A, **215**B. The hot sterile air temperature is about 135° C. The hot air knives **208** also remove excess hydrogen peroxide form the lids **200**. A plurality of heated platens **205** further dry 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 sterilization tunnel **90** via the lidding operation. The drive sprocket **211**A includes a plurality of pins **209** that engage with the holes **207** of the daisy chain **215**A. The drive sprocket **211**A rotates in a counterclockwise direction and indexes and directs the daisy chain **215**A, through a plurality of guides **217**A. The guides **217**A may include a plurality of rollers **221**A to further guide and direct an end **219**A of the daisy chain **215**A over the bottle **12**A. The drive sprocket

211B includes a plurality of pins **209** that engage with the holes **207** of the daisy chain **215**B. The drive sprocket **211**B rotates in a clockwise direction and indexes and directs the daisy chain **215**B through a plurality of guides **217**B. The guides **217**B may include a plurality of rollers **221**B to further guide and direct an end **219**B of the daisy chain **215**B over the bottle **12**B.

Once sterilized, the lids **200** enter the sterilization tunnel **90** where they are separated from the daisy chain **215**A, **217**B and placed on the bottle **12**A, **12**B. At station **33**, the lids **200** are applied to the bottles **12**. As illustrated in FIGS. **13** and **20**, 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**A, **12**B. Although lidding for a bottle has been described, it should be appreciated that lidding of other containers (e.g. jars) can be provided by the present invention. FIG. **20** illustrates a perspective view of the heat sealing apparatus **214**, the daisy chain **215**A, the gripper apparatus **554**, the bottle **12**A, and the conveying plate **94**. The lid **200** is located above the bottle opening **16**. The gripper apparatus **554** includes a grip **223** for capturing the bottle **12**A by a bottle lip **225**. The gripper apparatus **554** lifts the bottle **12**A in an upward direction so that the lid **200** is pressed between a bottle top lip **227** and the heated platen **216**. The interconnecting band **203** severs and separates the lid **200** on the bottle **12** from the next lid on the daisy chain **215**A. The heated platen **216** is in a two by six configuration to seal twelve of the bottles **12** at a time. There is a separate gripper apparatus **554** for each of the twelve bottles **12**. After each bottle **12** is sealed, its gripper apparatus **554** lowers and releases the bottle **12** and each bottle **12** continues to station **37**.

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 sterilization 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 the opening **282** in the sterilization 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 sterilization tunnel **90**. In order to ensure that contaminated air cannot enter the sterilization tunnel **90**, the sterile air in the sterilization tunnel **90** is maintained at a higher pressure than the air outside the sterilization tunnel **90**. Thus, sterile air is always flowing out of the sterilization tunnel **90** through the opening **282**. In addition, the gripper **288** never enters the sterilization tunnel **90**, because the top portion **284** of the bottle **12** is first lifted out of the sterilization 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 sterilization tunnel **90** because each of the bottles **12** have previously been sealed within the sterilization 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 with is used to dry the main conveyor **106** and conveying plates **94**.

Stations **1** through **40** are enclosed in the sterilization tunnel **90**. The sterilization tunnel **90** is supplied with air that is pressurized and sterilized. The interior of the sterilization 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 sterilization tunnel **90**, the sterile air supply provides a predetermined number of air changes (e.g., 2.5 changes of air per minute) in the sterilization tunnel **90**.

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 sterilization 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 following steps are performed during the "Clean In Place" (CIP) process in the filler apparatus **50**;

23. Conductivity sensor to verify caustic and acid concentrations.

24. Temperature sensor to verify "Clean In Place" solution temperatures.

25. Flow meter to verify "Clean In Place" flow rates.

26. Time is monitored to ensure that adequate cleaning time is maintained.

The follow steps are performed during sterilization of the bottle filler apparatus **50**;

27. Temperature sensors for measuring steam temperatures.

28. Proximity sensors to ensure filler nozzle cleaning/sterilization cups are in position.

29. Temperature sensors for air heating and cooling.

30. Flow meter for hydrogen peroxide injection.

31. Time is monitored to ensure the minimum time periods are met (steam, hydrogen peroxide application and activation/drying).

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.

I claim:

1. Apparatus comprising:

a valve for controlling a flow of product;

a first sterile region surrounding a region where the product exits the valve;

a continuously sterilized second sterile region positioned proximate said first sterile region whereby said second sterile region is continuously sterilized during operation;

a valve activation mechanism for controlling the opening or closing of the valve by extending a portion of the valve from the continuously sterilized second sterile region into the first sterile region and by retracting the portion of the valve from the first sterile region back into the continuously sterilized second sterile region.

2. The apparatus of claim **1**, further including:

a tank for containing a pressurized supply of the product; and

a measuring device connected to the tank for measuring an amount of the product flowing from the tank to the valve.

3. Apparatus comprising:

a tank for containing a supply of a pressurized product;

a measuring device connected to the tank for measuring an amount of the product flowing from the tank to a container;

a filling nozzle connected to the measuring device for directing product flow into the container;

a valve located within the filling nozzle for controlling the flow of product;

a first sterile region surrounding a region where the product exits the valve;

a valve stem attached to the valve for controlling the opening or closing of the valve;

a sterilization chamber surrounding a first portion of the valve stem; and

a valve activation mechanism for controlling the opening or closing of the valve by extending the first portion of the valve stem from the sterilization chamber into the first sterile region and by retracting the first portion of the valve stem from the first sterile region back into the sterilization chamber.

4. The apparatus of claim **3**, wherein the container is a bottle.

5. The apparatus of claim **3**, wherein the tank is pressurized with sterile air.

6. The apparatus of claim **3**, further including a level measuring device for measuring the level of the product in the tank.

7. The apparatus of claim **6**, wherein the measuring device is a volume flow meter.

8. The apparatus of claim **7**, wherein the volume flow meter is a magnetic flow meter.

9. The apparatus of claim **6**, wherein the measuring device is a mass flow meter.

10. The apparatus of claim **3**, wherein the valve activation mechanism includes an air cylinder.

11. The apparatus of claim **3**, wherein the sterilization chamber includes a sterilant flowing through the sterilization chamber to provide sterilization and cleaning of the first portion of the valve stem.

12. The apparatus of claim **11**, wherein the sterilant is steam.

13. The apparatus of claim **11**, wherein the sterilant is hydrogen peroxide.

14. The apparatus of claim **3**, further including a removable device for blocking off an exit of the valve to allow a build-up of steam pressure inside the tank during an initial apparatus sterilization.

15. The apparatus of claim **3**, wherein the container is filled to a first level with the product exiting from the filling nozzle and wherein the container is filled to a second level with product exiting from a second filling nozzle.

16. A method comprising the steps of:

controlling a flow of product using a valve;

surrounding a region where the product exits the valve with a sterile region;

providing a continuously sterilized second sterile region positioned proximate said first sterile region whereby said second sterile region is continuously sterilized during operation; and

controlling the opening or closing of the valve by extending a portion of the valve from the continuously sterilized second sterile region into the first sterile region and by retracting the portion of the valve from the first sterile region back into the continuously sterilized second sterile region.

17. The method of claim **16**, further including the step of providing a tank for containing a supply of pressurized product flowing to the valve.

18. The method of claim **17**, further including the step of providing a measuring device for measuring the amount of pressurized product flowing from the tank to the valve.

19. The method of claim **18** further including the steps of:

exposing the valve, an interior surface of the tank, and an interior surface of the measuring device with steam;

covering an exit of the valve; and

allowing a build-up of steam pressure inside the tank to above a temperature of about 250° F., a steam pressure of about 50 psig, for about 30 minutes.

20. The method of claim **16**, further including the step of providing a second apparatus wherein the container is filled to a first level with the product exiting from the first apparatus, and the container is filled to a second level with the product exiting from the second apparatus.

21. The method of claim **20** further including the steps of:

uncovering the exit of the valve; and

providing sterile air to reduce the temperature of the valve, the interior surface of the tank, and the interior surface of the measuring device to the temperature of the product.

22. A method comprising the steps of:

controlling a flow of product using a valve;

surrounding a region where the product exits the valve with a sterile region;

providing a second sterile region positioned proximate said first sterile region;

controlling the opening or closing of the valve by extending a portion of the valve from the second sterile region

into the first sterile region and by retracting the portion of the valve from the first sterile region back into the second sterile region;

providing a tank for containing a supply of pressurized product flowing to the valve;

providing a measuring device for measuring the amount of pressurized product flowing from the tank to the valve;

exposing the valve, an interior surface of the tank, and an interior surface of the measuring device with steam;

covering an exit of the valve; and

allowing a build-up of steam pressure inside the tank to above a temperature of about 250° F., a steam pressure of about 50 psig, for about 30 minutes.

23. A method comprising the steps of:

controlling a flow of product using a valve;

surrounding a region where the product exits the valve with a sterile region;

providing a second sterile region positioned proximate said first sterile region;

controlling the opening or closing of the valve by extending a portion of the valve from the second sterile region into the first sterile region and by retracting the portion of the valve from the first sterile region back into the second sterile region;

providing a second apparatus wherein the container is filled to a first level with the product exiting from the first apparatus, and the container is filled to a second level with the product exiting from the second apparatus;

uncovering the exit of the valve; and

providing sterile air to reduce the temperature of the valve, the interior surface of the tank, and the interior surface of the measuring device to the temperature of the product.

24. Apparatus comprising:

an inline bottle filing apparatus including:

a valve for controlling a flow of product;

a first sterile region surrounding a region where the product exits the valve;

a second sterile region positioned proximate said first sterile region;

a valve activation mechanism for controlling the opening or closing of the valve by extending a portion of the valve from the second sterile region into the first sterile region and by retracting the portion of the valve from the first sterile region back into the second sterile region.

25. The apparatus of claim **24**, further comprising a sterile tunnel.

26. Apparatus comprising:

a valve for controlling a flow of product into a bottle;

a first sterile region surrounding a region where the product exits the valve;

a second sterile region positioned proximate said first sterile region;

a valve activation mechanism for controlling the opening or closing of the valve by extending a portion of the valve from the second sterile region into the first sterile region, such that the valve does not contact the bottle, and by retracting the portion of the valve from the first sterile region back into the second sterile region.

27. The apparatus of claim **26**, further comprising a sterile tunnel.

28. The apparatus of claim **27**, wherein the valve mechanism fills the bottle such that the atmospheric pressure of the interior of the bottle is the same atmospheric pressure of the sterile tunnel.

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(12) EX PARTE REEXAMINATION CERTIFICATE (9958th)

United States Patent

Taggart

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(45) Certificate Issued: Nov. 25, 2013

(54) **APPARATUS AND METHOD FOR PROVIDING CONTAINER FILLING IN AN ASEPTIC PROCESSING APPARATUS**

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B65B 1/04 (2006.01)

(52) **U.S. Cl.**
USPC **141/89**; 141/48; 141/129

(58) **Field of Classification Search**
USPC 141/89, 48, 129
See application file for complete search history.

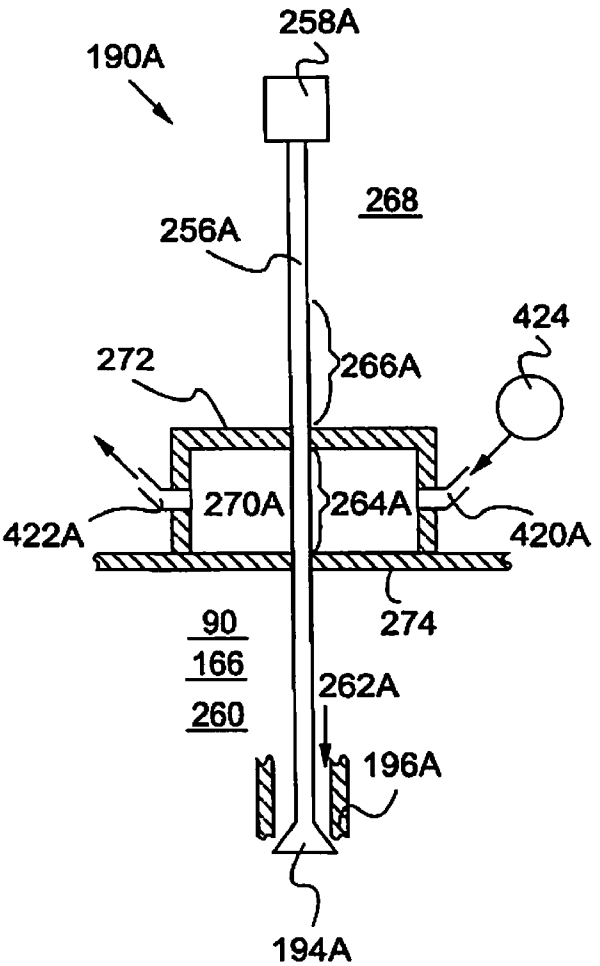
(56) **References Cited**

To view the complete listing of prior art documents cited during the proceeding for Reexamination Control Number 90/012,533, please refer to the USPTO's public Patent Application Information Retrieval (PAIR) system under the Display References tab.

Primary Examiner — Matthew C. Graham

(57) **ABSTRACT**

An apparatus and method for providing container product filling in an aseptic processing apparatus. An apparatus including a valve mechanism for controlling the opening or closing of a valve including extending a portion of the valve from a second sterile region into a first sterile region, thereby, preventing contaminants from being carried into the first sterile region.



EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

Claim **23** is cancelled.

Claims **1**, **3**, **16**, **22**, **24** and **26** are determined to be patentable as amended.

Claims **2**, **4-15**, **17-21**, **25** and **27-28**, dependent on an amended claim, are determined to be patentable.

1. Apparatus *for aseptically filling a series of bottles* comprising:

a valve for controlling a flow of *low-acid food* product *at a rate sufficient to dispense the food product at a rate of more than 350 bottles per minute in a single production line*;

a first sterile region surrounding a region where the product exits the valve;

a continuously sterilized second sterile region positioned proximate said first sterile region whereby said second sterile region is continuously sterilized during operation;

a valve activation mechanism for controlling the opening or closing of the valve by extending a portion of the valve from the continuously sterilized second sterile region into the first sterile region and by retracting the portion of the valve from the first sterile region back into the continuously sterilized second sterile region.

3. Apparatus *for aseptically filling a series of bottles* comprising:

a tank for containing a supply of a pressurized *low-acid food* product;

a measuring device connected to the tank for measuring an amount of the product flowing from the tank to a container;

a filling nozzle connected to the measuring device for directing product flow into the container;

a valve located within the filling nozzle for controlling the flow of product *and dispensing the food product at a rate of more than 350 bottles per minute in a single production line*;

a first sterile region surrounding a region where the product exits the valve;

a valve stem attached to the valve for controlling the opening or closing of the valve;

a sterilization chamber surrounding a first portion of the valve stem; and

a valve activation mechanism for controlling the opening or closing of the valve by extending the first portion of the valve stem from the sterilization chamber into the first sterile region and by retracting the first portion of the valve stem from the first sterile region back into the sterilization chamber.

16. A method *for aseptically filling a series of bottles* comprising the steps of:

controlling a flow of *low-acid food* product using a valve;

surrounding a region where the product exits the valve with a sterile region;

providing a continuously sterilized second sterile region positioned proximate said first sterile region whereby said second sterile region is continuously sterilized during operation; and

controlling the opening or closing of the valve by extending a portion of the valve from the continuously sterilized second sterile region into the first sterile region and by retracting the portion of the valve from the first sterile region back into the continuously sterilized second sterile region*; and*

dispensing the food product at a rate of more than 350 bottles per minute in a single production line.

22. A method *for aseptically filling a series of bottles* comprising the steps of:

controlling a flow of *low-acid food* product using a valve;

surrounding a region where the product exits the valve with a sterile region;

providing a second sterile region positioned proximate said first sterile region;

controlling the opening or closing of the valve by extending a portion of the valve from the second sterile region into the first sterile region and by retracting the portion of the valve from the first sterile region back into the second sterile region;

providing a tank for containing a supply of pressurized product flowing to the valve;

providing a measuring device for measuring the amount of pressurized product flowing from the tank to the valve;

exposing the valve, an interior surface of the tank, and an interior surface of the measuring device with steam;

covering an exit of the valve; **[**and**]**

allowing a build-up of steam pressure inside the tank to above a temperature of about 250° F., a steam pressure of about 50 psig, for about 30 minutes; *and*

dispensing the food product at a rate of more than 350 bottles per minute in a single production line.

24. Apparatus comprising:

an inline bottle filing apparatus *for aseptically filling a series of bottles at a rate of more than 350 bottles per minute in a single production line* including**[**:**]**

a valve for controlling a flow of *low-acid food* product;

a first sterile region surrounding a region where the product exits the valve;

a second sterile region positioned proximate said first sterile region;

a valve activation mechanism for controlling the opening or closing of the valve by extending a portion of the valve from the second sterile region into the first sterile region and by retracting the portion of the valve from the first sterile region back into the second sterile region.

26. Apparatus *for aseptically filling a series of bottles* comprising:

a valve for controlling a flow of *low-acid food* product into a bottle *at a rate of more than 350 bottles per minute in a single production line*;

a first sterile region surrounding a region where the product exits the valve;

a second sterile region positioned proximate said first sterile region;

a valve activation mechanism for controlling the opening or closing of the valve by extending a portion of the valve from the second sterile region into the first sterile region,

such that the valve does not contact the bottle, and by retracting the portion of the valve from the first sterile region back into the second sterile region.

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(12) **United States Patent**
Taggart

(10) **Patent No.: US 6,536,188 B1**
(45) **Date of Patent: Mar. 25, 2003**

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

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 205 days.

(21) Appl. No.: **09/306,552**

(22) Filed: **May 6, 1999**

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(52) **U.S. Cl.** **53/425**; 53/426; 53/79; 141/1; 141/4; 422/24; 422/29

(58) **Field of Search** 53/426, 425, 403, 53/405, 79; 141/1, 4, 64, 236; 422/29, 24, 302, 28, 292

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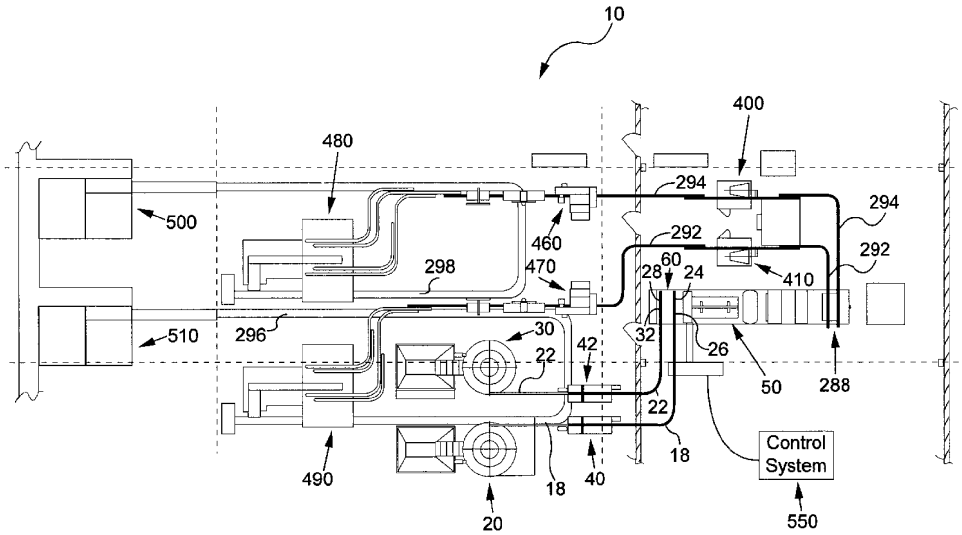
(74) *Attorney, Agent, or Firm*—Schmeiser, Olsen & Watts

(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



EXHIBIT
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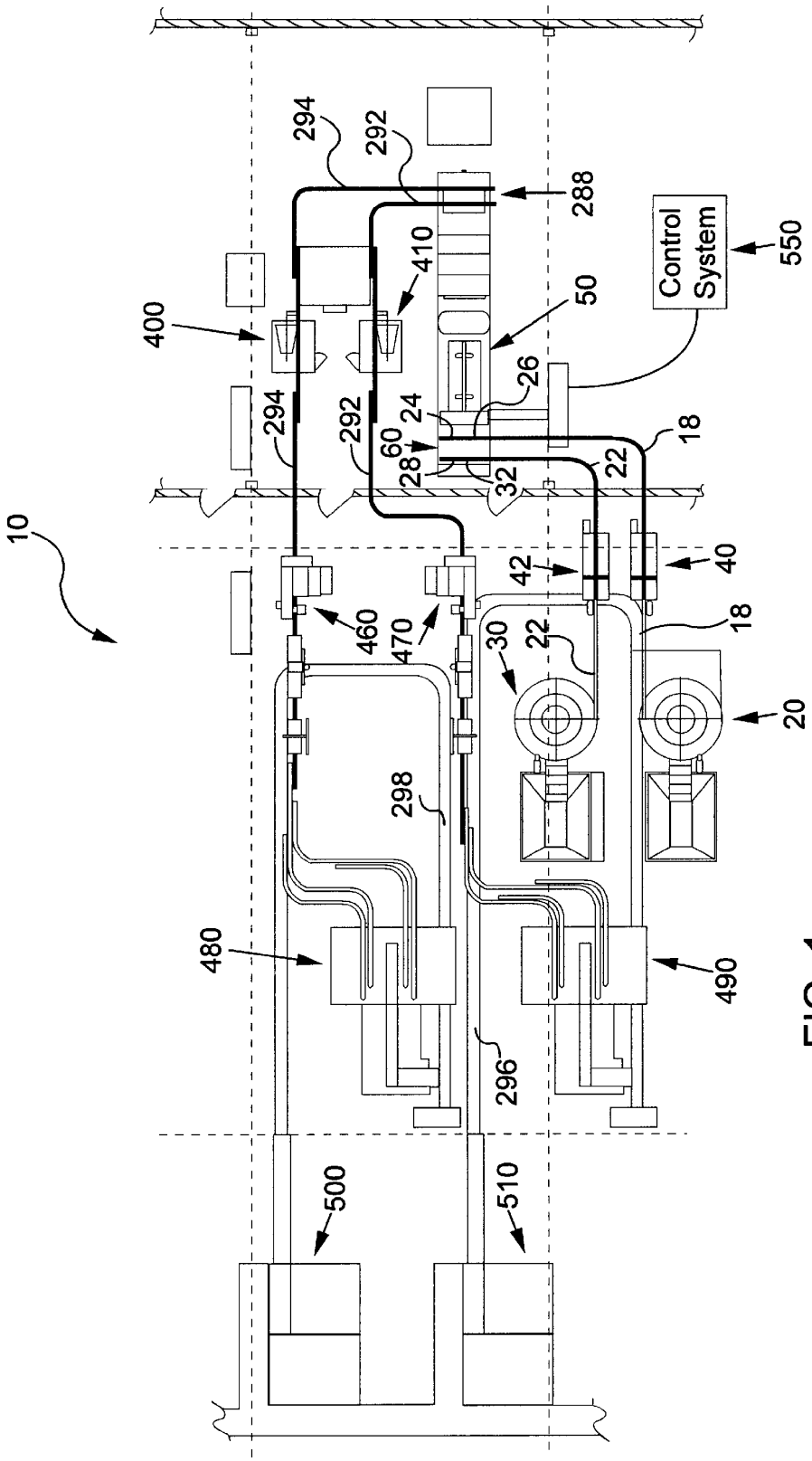
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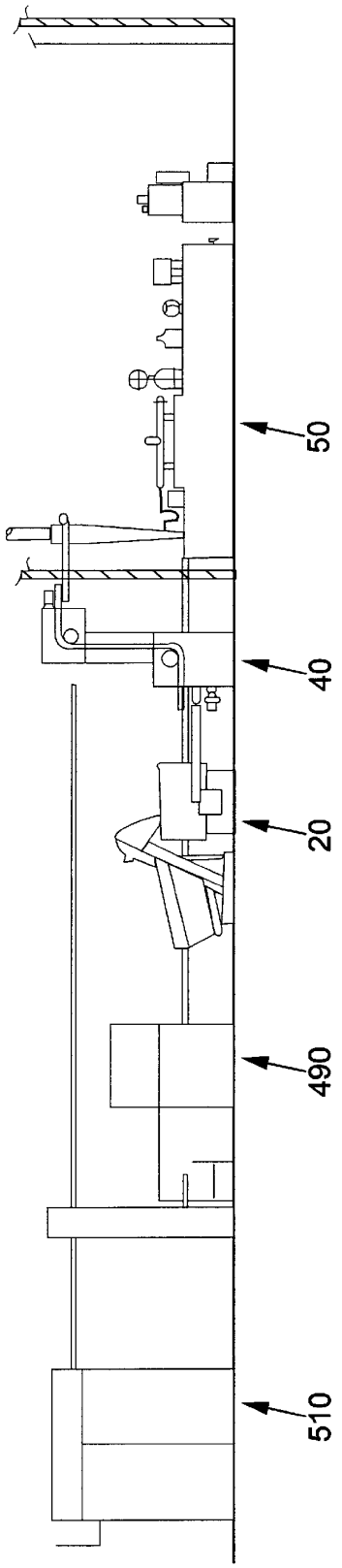
FIG. 1



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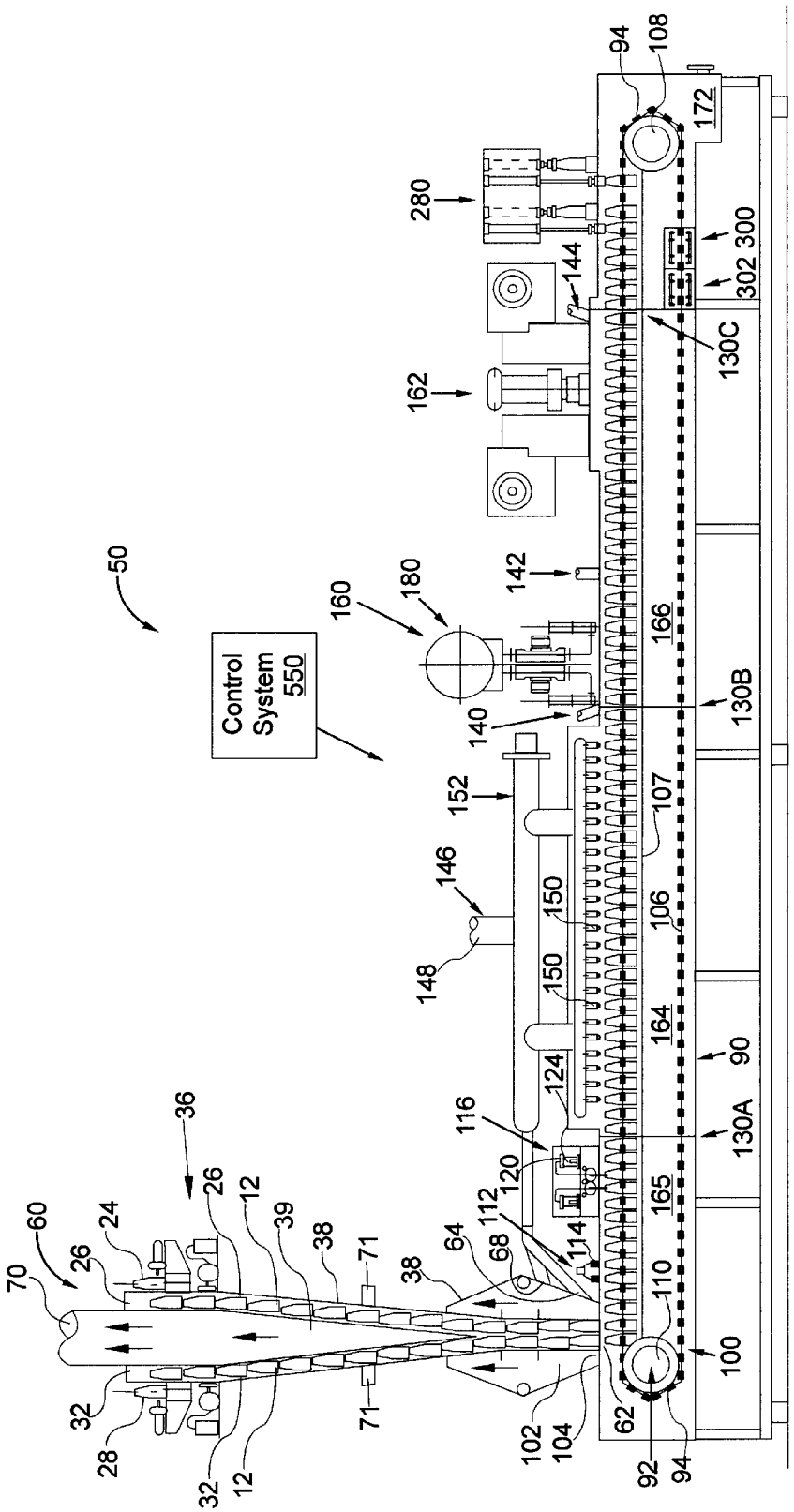
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152
107
106
164
165
166
160
180
142
140
162
280
144
172
94
108
302
300
130C
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130A
110
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62
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94
102
104
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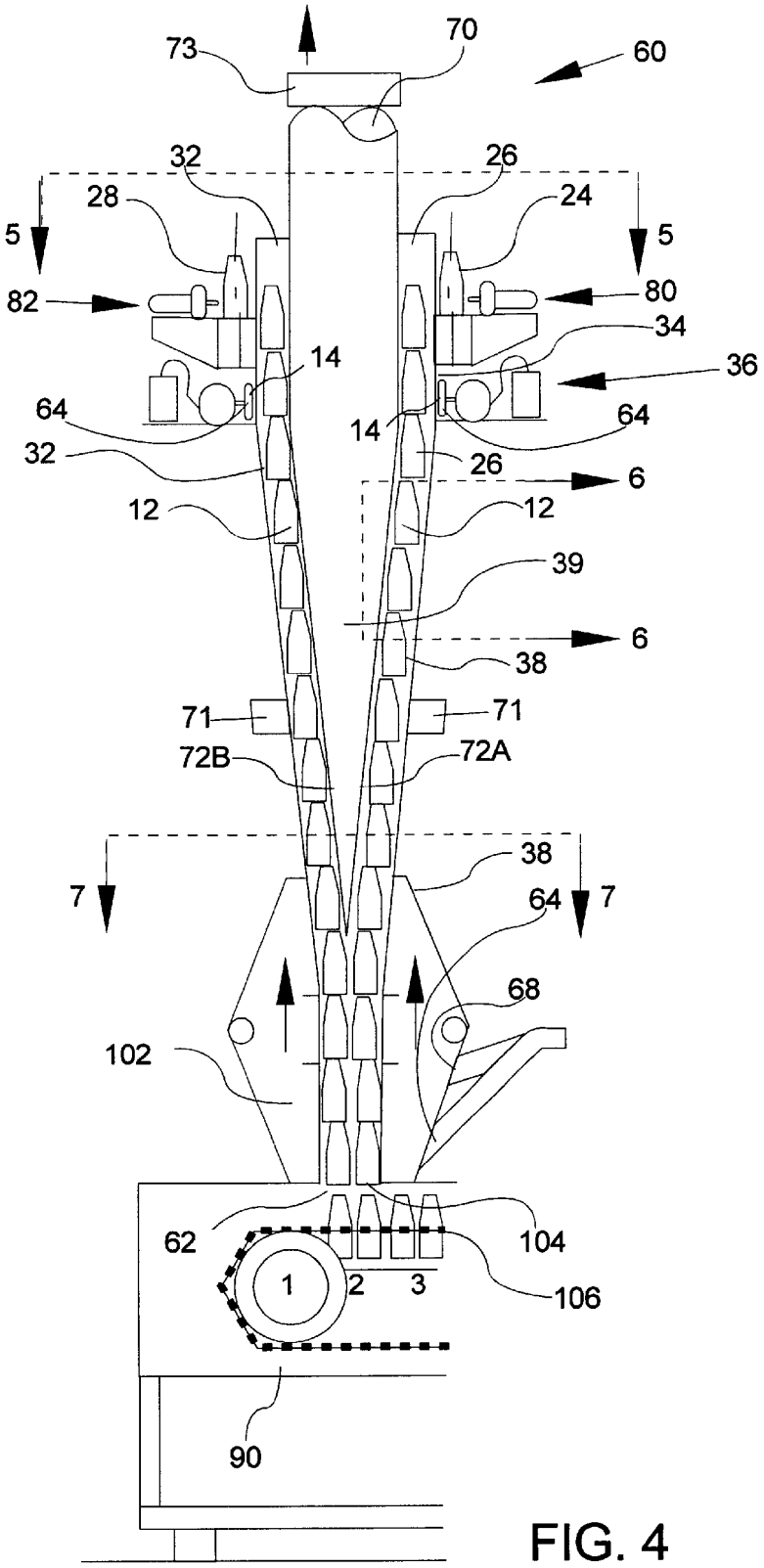
FIG. 3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12
39
6
38
71
71
72B
72A
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104
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3
106
90

FIG. 4

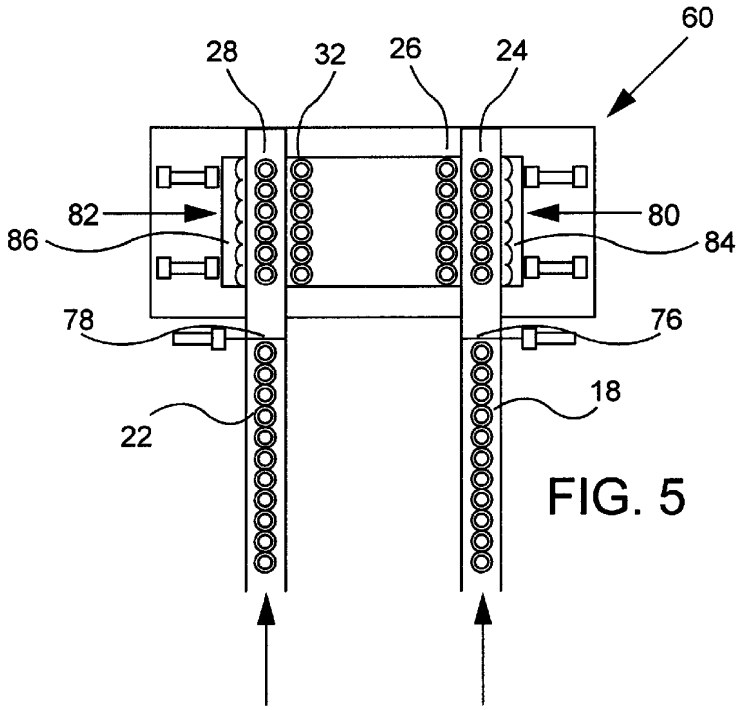


FIG. 5

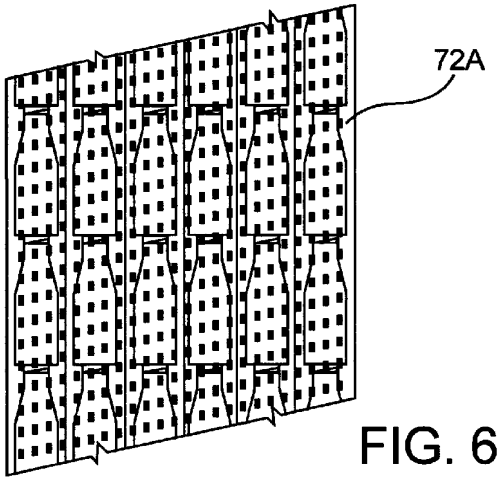


FIG. 6

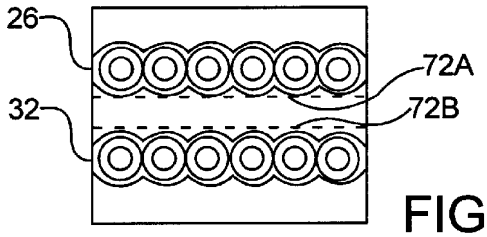


FIG. 7

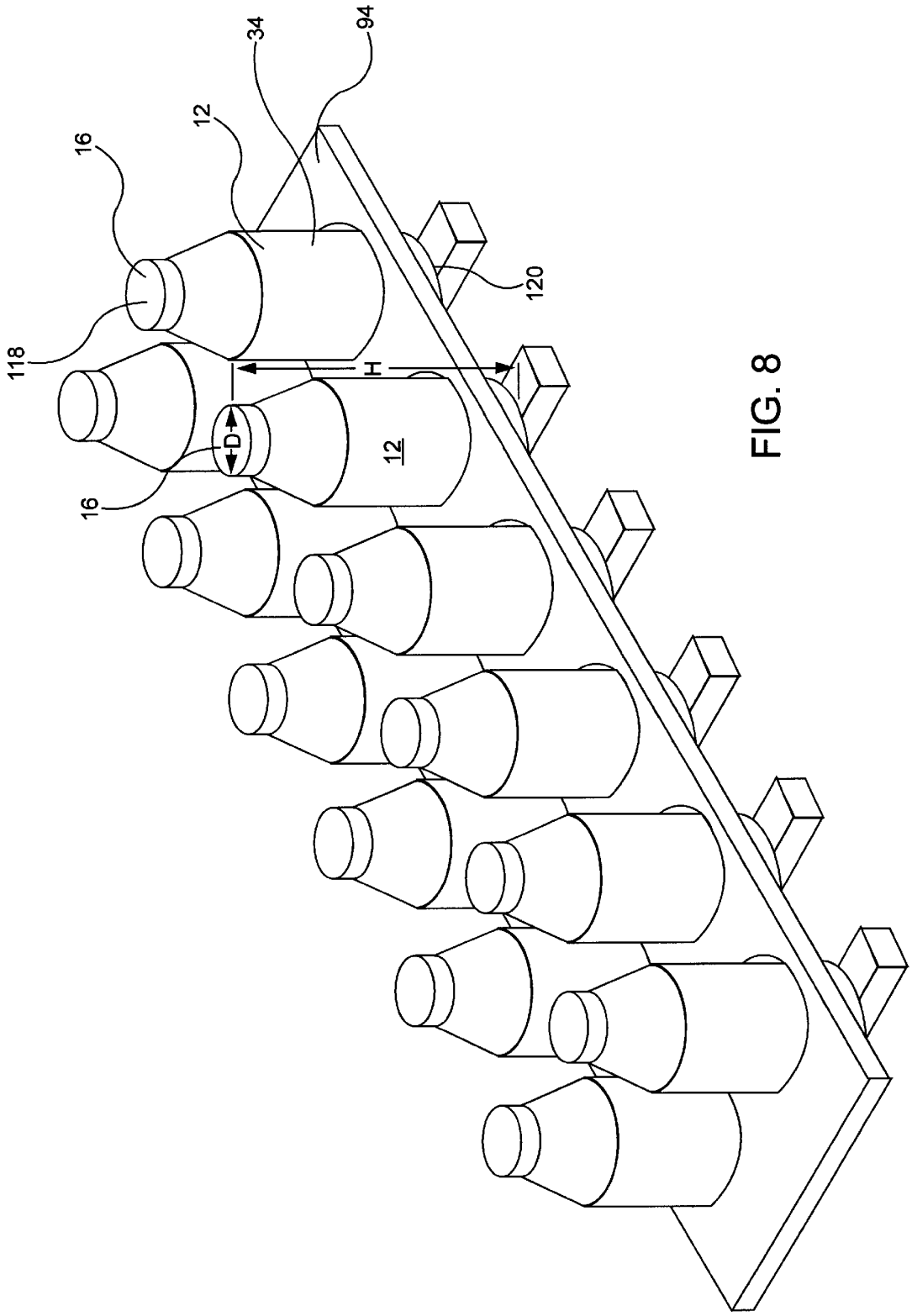


FIG. 8

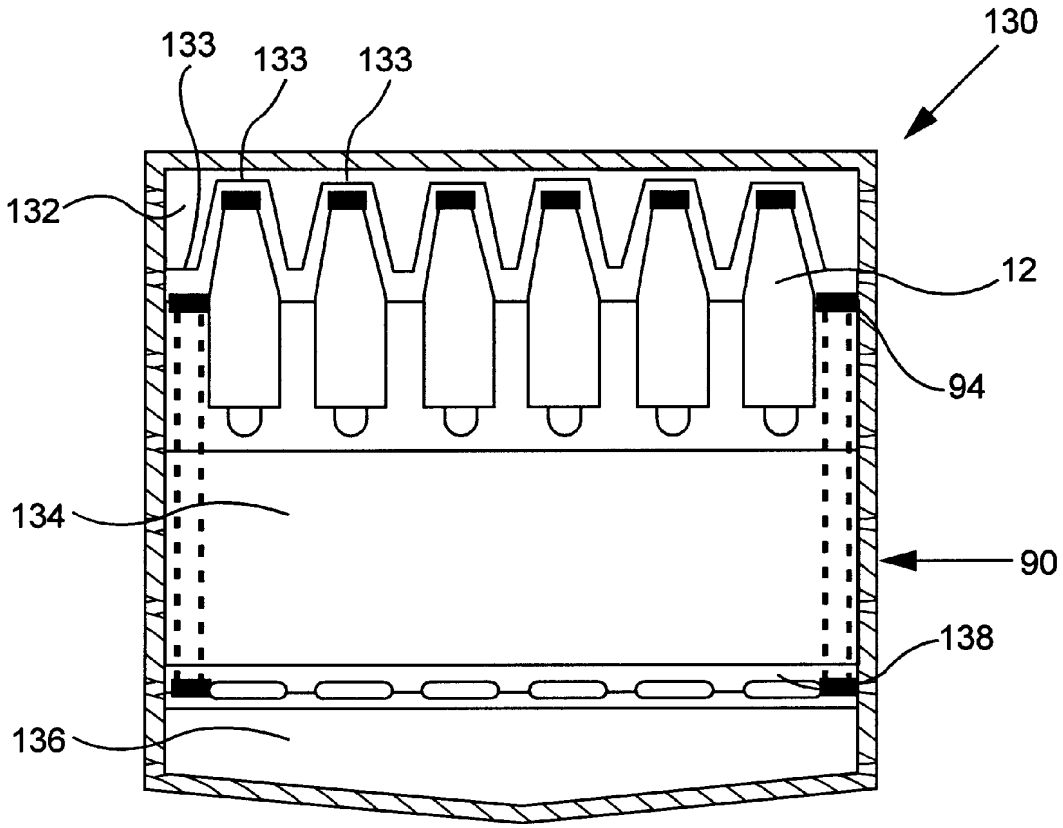
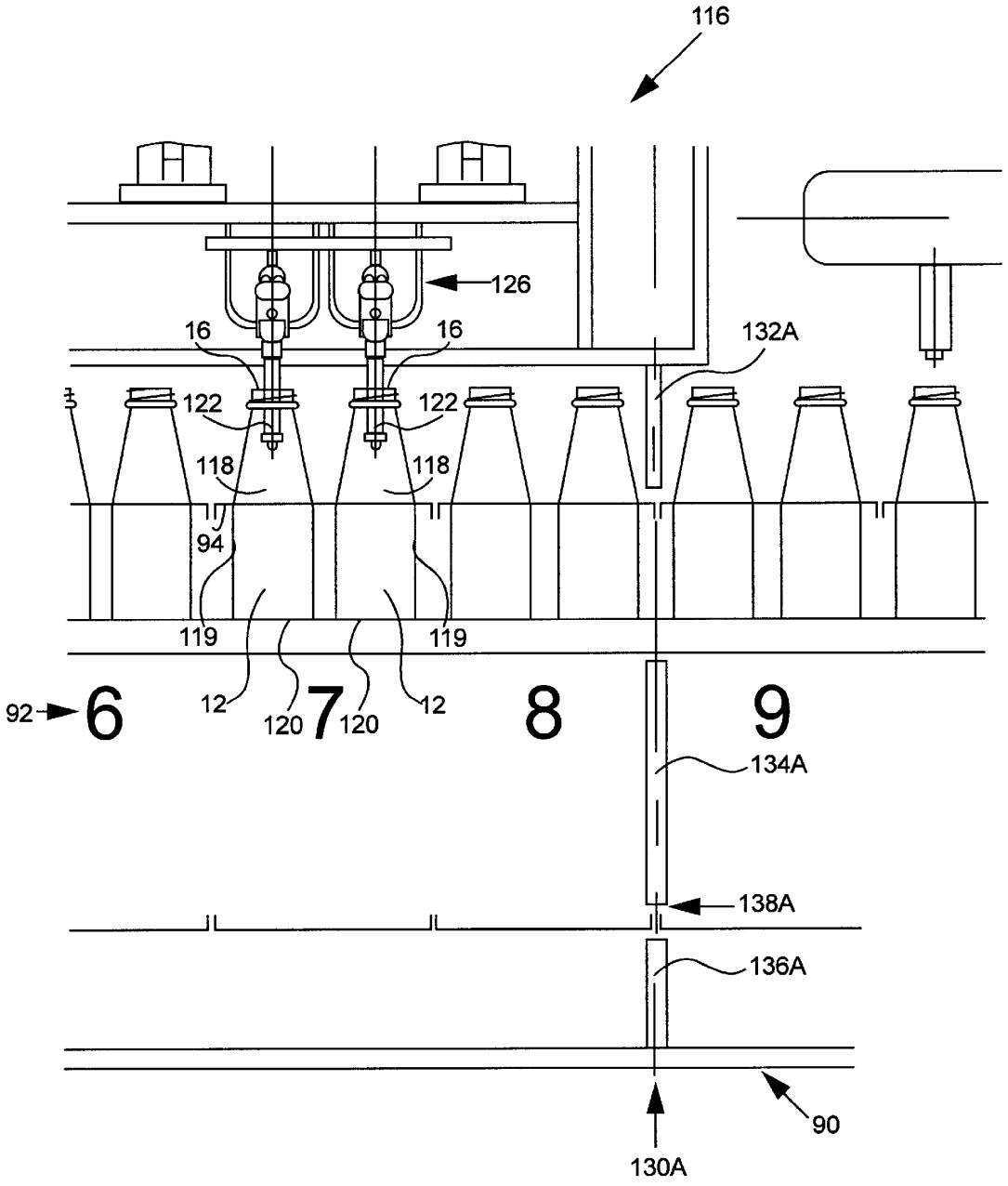


FIG. 9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132A
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134A
138A
136A
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130A

FIG. 10

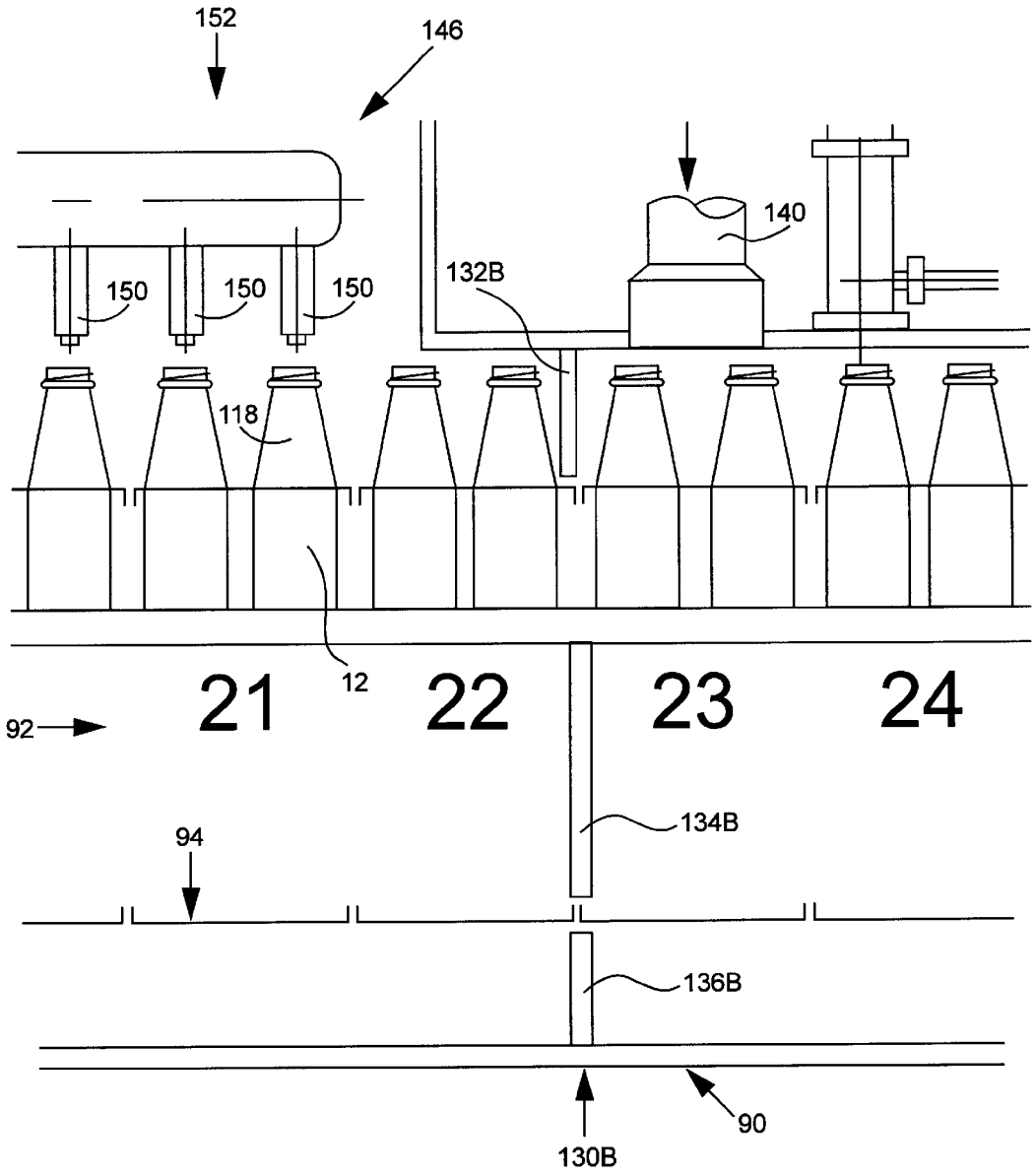
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FIG. 11

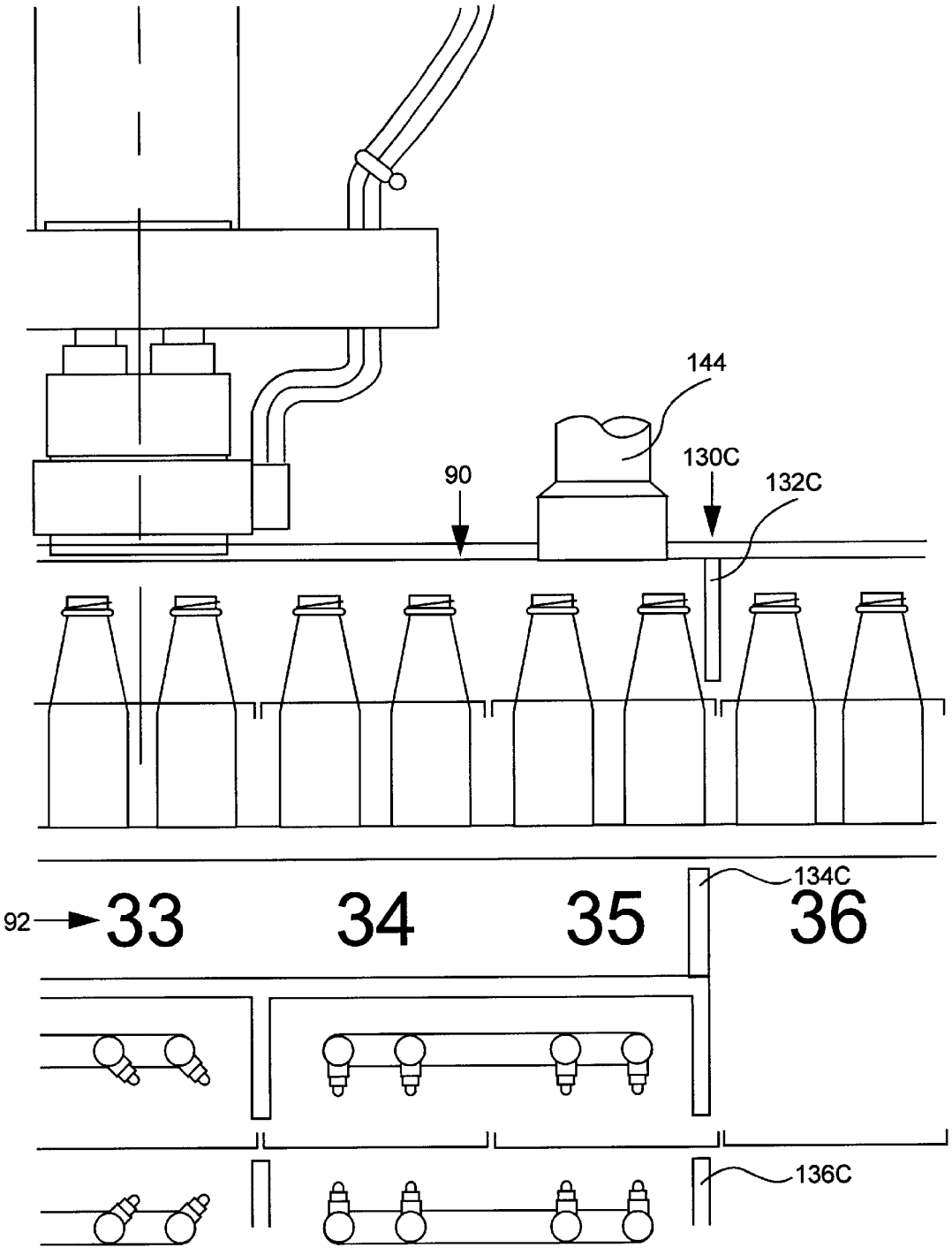
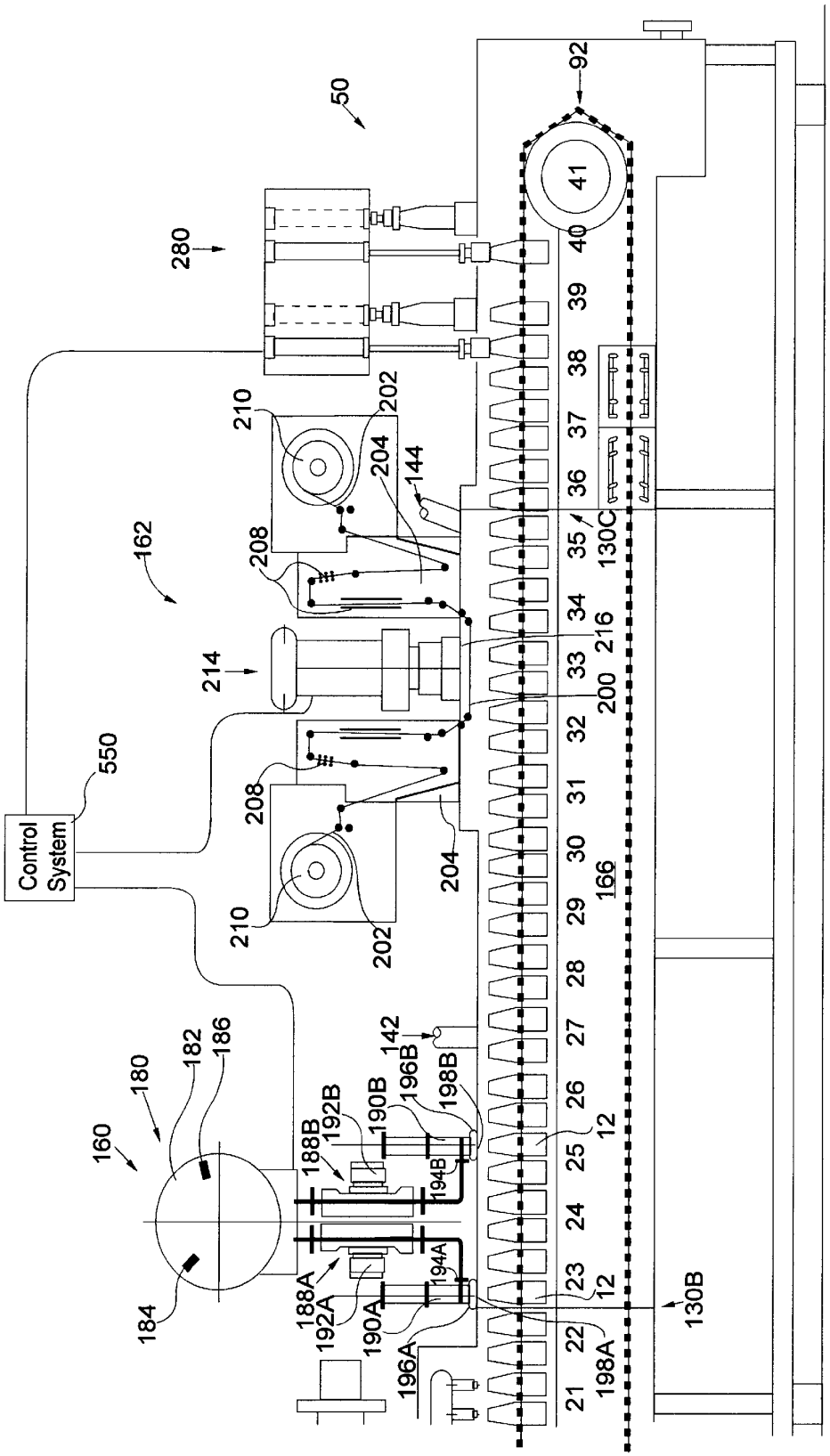


FIG. 12


Control System
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130B
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214
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202
204
144
208
216
200
166
142
160
180
182
186
184
188B
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198B
194B
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192A
190A
196A
194A
198A
12

FIG. 13

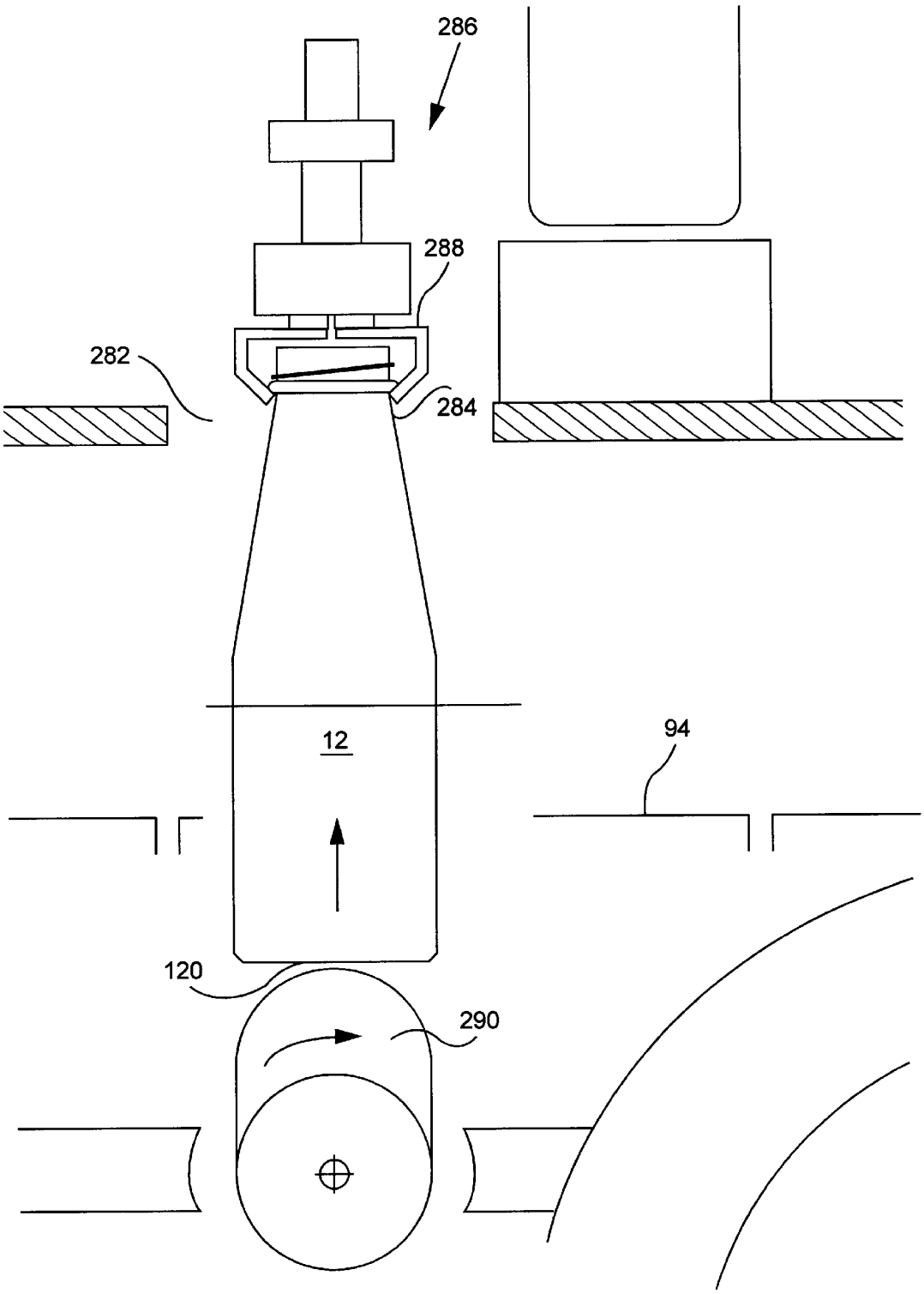


FIG. 14

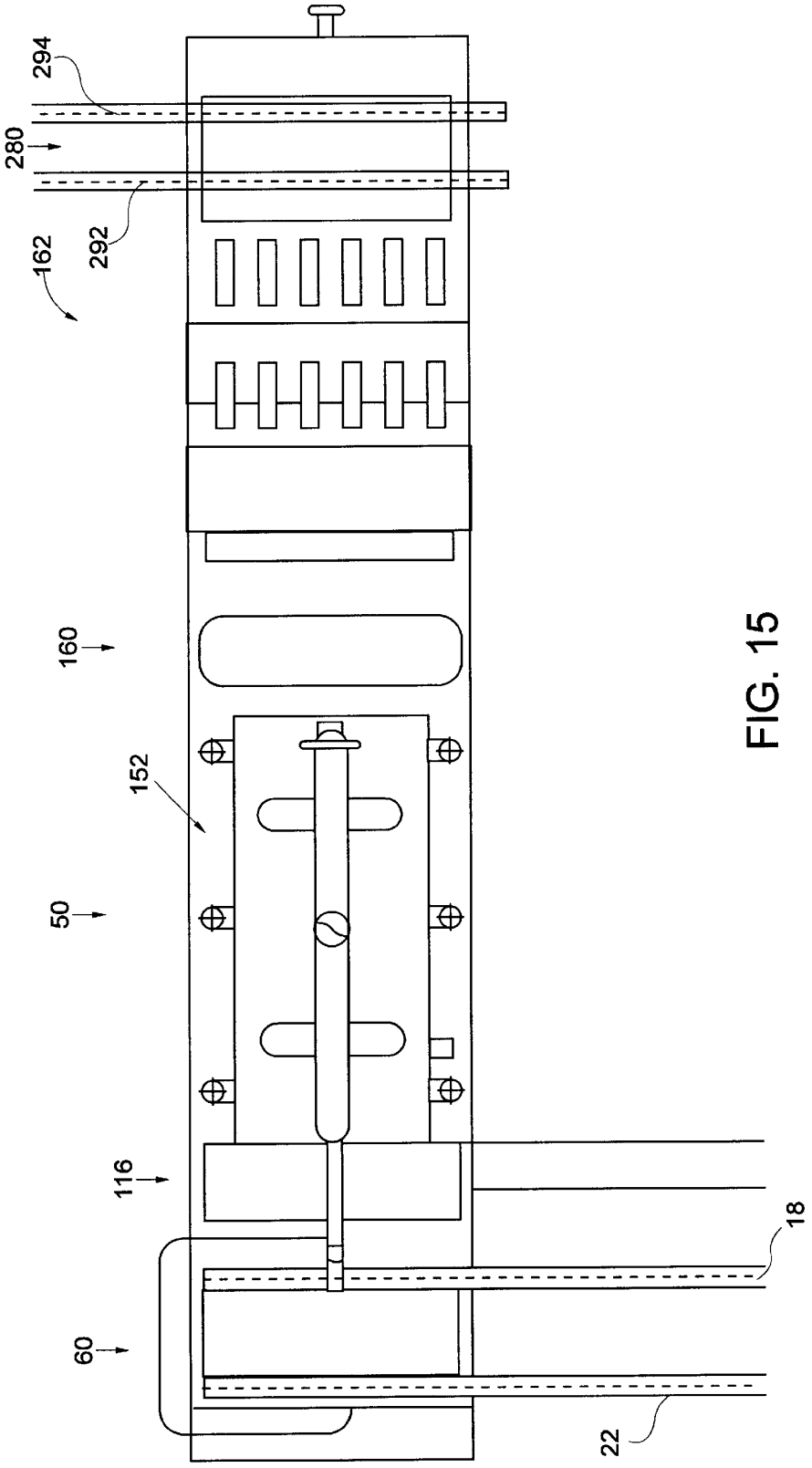
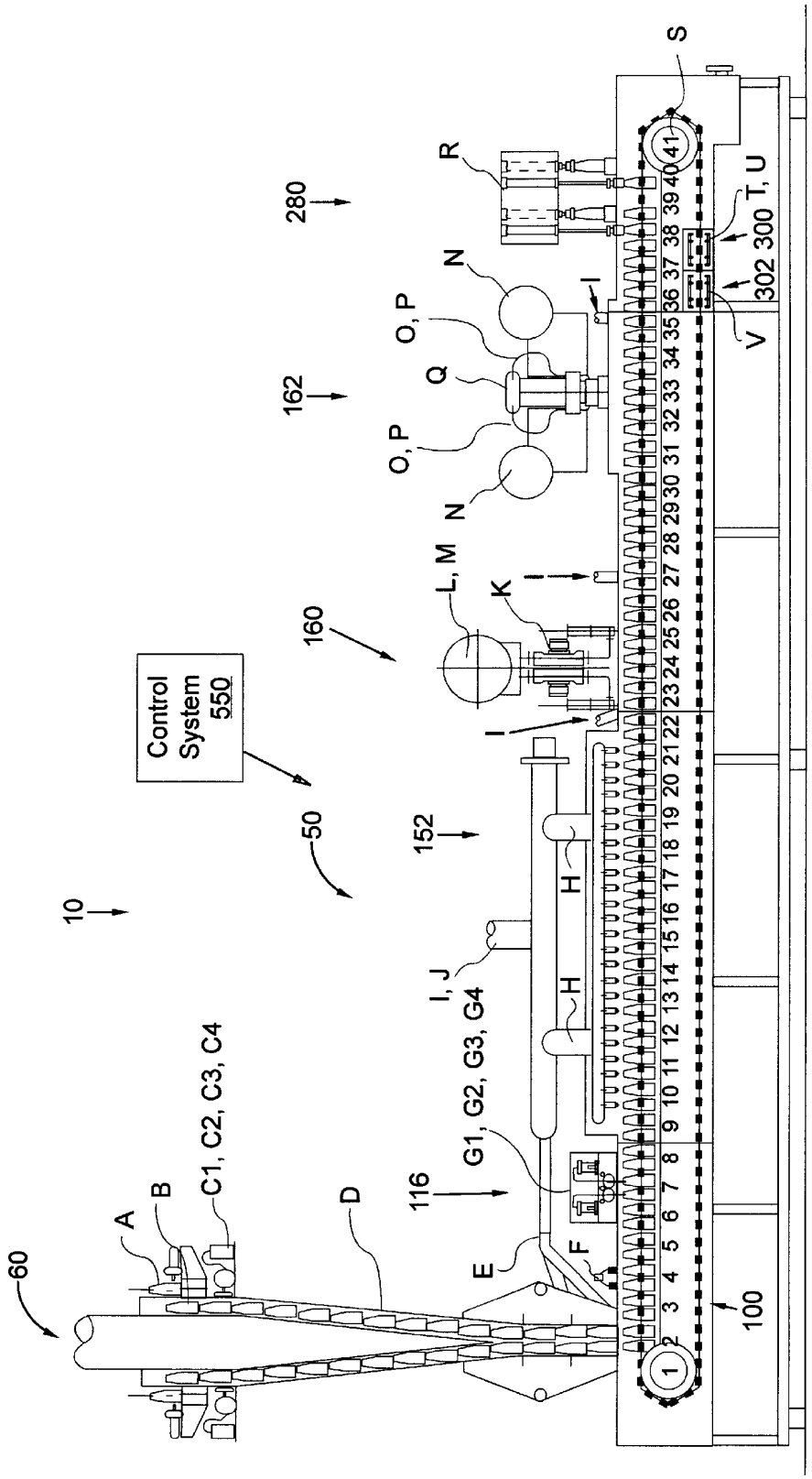


FIG. 15


Control System 550
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152
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302 300
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B
C1, C2, C3, C4
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F
G1, G2, G3, G4
H
H
I, J
I
K
L, M
N
O, P
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FIG. 16

METHOD AND APPARATUS FOR ASEPTIC PACKAGING

This application claims the benefit of Provisional Application No. 60/118,404, filed 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 **3**A 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 **3**A 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**.

C**1**. A conductivity sensor to ensure that the measuring cup used by the sterilant application apparatus **36** is full.

C**2**. A conductivity sensor to ensure that the measuring cup used by the sterilant application apparatus **36** is emptied in a predetermined time.

C**3**. A pressure sensor to ensure that the pressure of the air used by the sterilant application apparatus **36** is within predetermined atomization requirements.

C**4**. 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**.

G**1**. A conductivity sensor to ensure that the measuring cup used by the interior bottle sterilization apparatus **116** is full.

G**2**. A conductivity sensor to ensure that the measuring cup used by the interior bottle sterilization apparatus **116** is emptied in a predetermined time.

G**3**. A pressure sensor to ensure that the pressure of the air used by the interior bottle sterilization apparatus **116** is within predetermined atomization requirements.

G**4**. 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 aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the plurality of bottles to a level producing at least about a 6 log reduction in spore organisms;

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.

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

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

4. The method according to claim **3**, wherein the plastic is polyethylene terepthalate.

5. The method according to claim **3**, wherein the plastic is high density polyethylene.

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

7. The method according to claim **1**, wherein the plurality of bottles has an opening size to height ratio of less than one.

8. The method according to claim **1**, further including disinfecting the interior of the plurality of bottles with a hot hydrogen peroxide spray.

9. The method according to claim **8**, wherein disinfecting the interior of the plurality of bottles includes the application of the hot hydrogen peroxide spray for about 1 second and the activation and removal of the hot hydrogen peroxide using hot aseptically sterilized air for about 24 seconds.

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

11. The method according to claim **1**, wherein disinfecting is provided by hydrogen peroxide.

12. The method according to claim **1**, wherein disinfecting is provided by oxonia.

13. The method according to claim **1**, wherein disinfecting the outside surfaces of the plurality of bottles is provided by oxonia.

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

15. The method for aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the plurality of bottles;

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 wherein disinfecting the outside surfaces of the plurality of bottles is provided by hydrogen peroxide.

16. The method according to claim **15**, wherein disinfecting the outside surface of the plurality of bottles includes about 1 second for the application of the hot hydrogen peroxide spray and about 24 seconds for the activation and removal of the hot hydrogen peroxide using hot aseptically sterilized air.

17. The method for asepctically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

filling the aseptically disinfected plurality of bottles with the aseptically sterilized foodstuffs wherein the aseptically sterilized foodstuffs are sterilized to a level producing at least about 12 log reduction in *Clostridium botulinum;* and

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

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

providing a plurality of bottles;

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, further including disinfecting the interior of the plurality of bottles with a hot hydrogen peroxide spray wherein the residual level of hydrogen peroxide is less than about 0.5 ppm.

19. A device for aseptically bottling aseptically sterilized foodstuffs having at least about a 12 log reduction in *Clostridium botulinum* comprising:

means for providing a plurality of bottles;

means for aseptically disinfecting the plurality of bottles;

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

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

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

providing a plurality of bottles;

aseptically disinfecting the plurality of bottles to a level producing at least about a 6 log reduction in spore organisms;

filling the aseptically disinfected plurality of bottles with the aseptically sterilized foodstuffs wherein the aseptically sterilized foodstuffs are sterilized to a level producing at least about a 12 log reduction in *Clostridium botulinum;* and

filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute, further including disinfecting the interior of the plurality of bottles with a hot hydrogen peroxide spray wherein the residual level of hydrogen peroxide is less than about 0.5 ppm.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,536,188 B1
DATED : March 25, 2003
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 16,
Line 42, delete "asepctically" and insert -- aseptically --.

Signed and Sealed this

Tenth Day of June, 2003

JAMES E. ROGAN
Director of the United States Patent and Trademark Office

US006536188C1

(12) EX PARTE REEXAMINATION CERTIFICATE (9834th)

United States Patent
Taggart

(10) Number: US 6,536,188 C1
(45) Certificate Issued: Sep. 12, 2013

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

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

(73) Assignee: **Steuben Foods, Inc.**, Elma, NY (US)

Reexamination Request:
No. 90/011,072, Jun. 29, 2010
No. 90/011,357, Nov. 29, 2010

Reexamination Certificate for:
Patent No.: **6,536,188**
Issued: **Mar. 25, 2003**
Appl. No.: **09/306,552**
Filed: **May 6, 1999**

Certificate of Correction issued Jun. 10, 2003

Related U.S. Application Data

(60) Provisional application No. 60/118,404, filed on Feb. 2, 1999.

(51) **Int. Cl.**
B65B 55/02 (2006.01)

(52) **U.S. Cl.**
USPC **53/425**; 53/426; 53/79; 141/1; 141/4; 422/24; 422/29

(58) **Field of Classification Search**
None
See application file for complete search history.

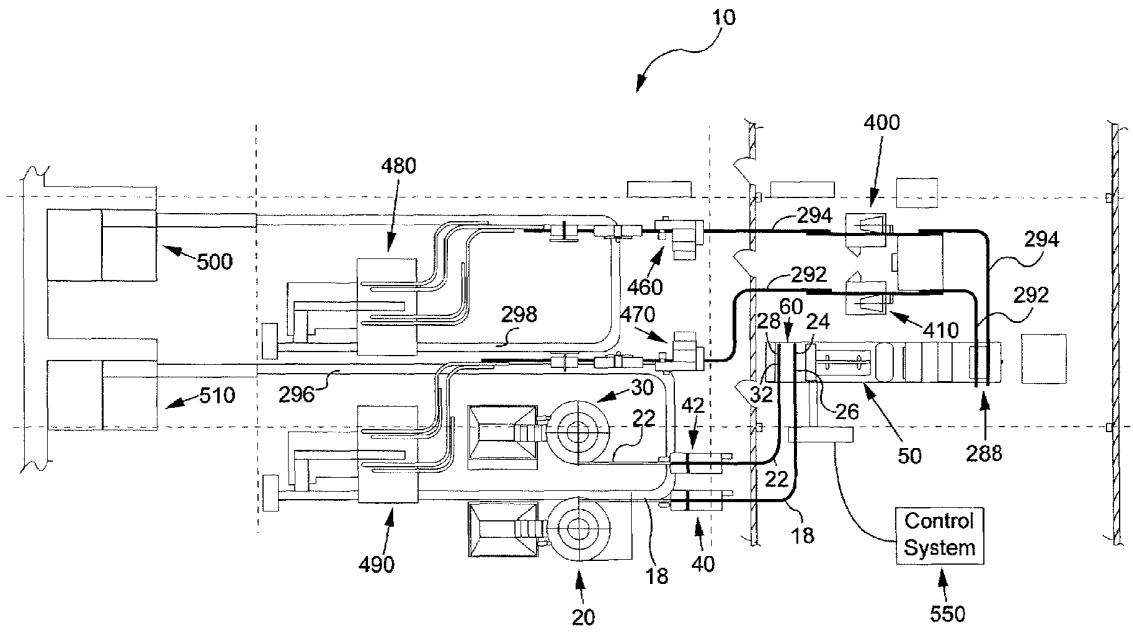
(56) **References Cited**

To view the complete listing of prior art documents cited during the proceedings for Reexamination Control Numbers 90/011,072 and 90/011,357, please refer to the USPTO's public Patent Application Information Retrieval (PAIR) system under the Display References tab.

Primary Examiner — Glenn K Dawson

(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.



EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

ONLY THOSE PARAGRAPHS OF THE SPECIFICATION AFFECTED BY AMENDMENT ARE PRINTED HEREIN.

Column 1, lines 55-67:

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**]** *teraphthalate* (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.

Column 4, lines 39-55:

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**]** *teraphthalate* (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.

Column 3, lines 16-24:

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 step of filling the aseptically disinfected bottling further comprises: filling the aseptically disinfected bottling at a rate greater than 360 bottles per minute.*

Column 10, line 31-Column 11, line 8:

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 apparatus provides for filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute and for filling the aseptically disinfected bottling at a rate greater than 360 bottles per minute.*

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims **9** and **19** is confirmed.

Claims **1-8**, **10-15**, **17**, **18** and **20** are cancelled.

Claim **16** is determined to be patentable as amended.

New claims **21-40** are added and determined to be patentable.

16. **[**The method according to claim 15,**]** *A method for aseptically bottling aseptically sterilized foodstuffs comprising the steps of:*

providing a plurality of bottles;

aseptically disinfecting the inside surface and the outside surface of each bottle with a hot hydrogen peroxide spray;

filling the aseptically disinfected plurality of bottles with aseptically sterilized foodstuffs at a rate greater than 100 bottles per minute;

wherein disinfecting the outside surface of **[**the plurality of bottles**]** *each bottle* includes about 1 second for the application of the hot hydrogen peroxide spray and

about 24 seconds for the activation and removal of the hot hydrogen peroxide using hot aseptically sterilized air.

21. The device for aseptically bottling aseptically sterilized foodstuffs having at least about a 12 log reduction in Clostridium botulinum of claim 19, wherein the means for aseptically disinfecting the plurality of bottles, disinfects to a level producing at least about a 6 log reduction in spore organisms.

22. The device for aseptically bottling aseptically sterilized foodstuffs having at least about a 12 log reduction in Clostridium botulinum of claim 21, wherein the interior of the plurality of filled bottles does not have a residual level of hydrogen peroxide of about 0.5 ppm or more.

23. The device for aseptically bottling aseptically sterilized foodstuffs having at least about a 12 log reduction in Clostridium botulinum according to claim 19, wherein the means for aseptically disinfecting the plurality of bottles further comprises aseptically disinfecting the plurality of bottles with use of a hot sterilant which heats the bottles at a temperature below the bottle softening and deformation temperature for at least 5 seconds.

24. The device for aseptically bottling aseptically sterilized foodstuffs having at least about a 12 log reduction in Clostridium botulinum according to claim 23, wherein the sterilant is one of oxonia and hydrogen peroxide.

25. An apparatus for aseptically bottling aseptically sterilized low-acid foodstuffs having at least about a 12 log reduction in Clostridium botulinum, the apparatus comprising:

a control system for controlling aseptic bottling conditions, wherein the control system automatically adjusts operational parameters, generates error messages or logs error messages;

means for providing a plurality of bottles, the means including a bottle infeed;

means for aseptically disinfecting the plurality of bottles including a plurality of nozzles;

means for aseptically filling the aseptically disinfected plurality of bottles with aseptically sterilized foodstuffs including a plurality of filling nozzles, and

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

26. An apparatus for aseptically bottling aseptically sterilized low-acid foodstuffs having at least about a 12 log reduction in Clostridium botulinum, the apparatus comprising:

a control system for controlling aseptic bottling conditions, wherein the control system further comprises a pressure sensor, a temperature sensor and a concentration sensor;

means for providing a plurality of bottles, the means including a bottle infeed;

means for aseptically disinfecting the plurality of bottles including a plurality of nozzles;

means for aseptically filling the aseptically disinfected plurality of bottles with aseptically sterilized foodstuffs including a plurality of filling nozzles, and

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

27. An apparatus for aseptically bottling aseptically sterilized low-acid foodstuffs having at least about a 12 log reduction in Clostridium botulinum, the apparatus comprising:

a control system for controlling aseptic bottling conditions, wherein the control system further comprises a conductivity sensor, a pressure sensor, a volumetric measuring device, a level sensor, a proximity sensor, and a speed sensor;

means for providing a plurality of bottles, the means including a bottle infeed;

means for aseptically disinfecting the plurality of bottles including a plurality of nozzles;

means for aseptically filling the aseptically disinfected plurality of bottles with aseptically sterilized foodstuffs including a plurality of filling nozzles, and

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

28. An apparatus for aseptically bottling aseptically sterilized low-acid foodstuffs having at least about a 12 log reduction in Clostridium botulinum, the apparatus comprising:

a control system for controlling aseptic bottling conditions, wherein the control system includes a temperature sensor;

means for providing a plurality of bottles, the means including a bottle infeed;

means for aseptically disinfecting the plurality of bottles including a plurality of nozzles;

means for aseptically filling the aseptically disinfected plurality of bottles with aseptically sterilized foodstuffs including a plurality of filling nozzles, and

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

29. The apparatus according to claim 28, wherein the control system regulates an air temperature.

30. An apparatus for aseptically bottling aseptically sterilized low-acid foodstuffs having at least about a 12 log reduction in Clostridium botulinum, the apparatus comprising:

a control system for controlling aseptic bottling conditions;

means for providing a plurality of bottles, the means including a bottle infeed;

means for aseptically disinfecting the plurality of bottles including a plurality of nozzles,

wherein the means for aseptically disinfecting the plurality of bottles further comprises means for applying sterilant to the plurality of bottles and a means for removing sterilant from the plurality of bottles;

means for aseptically filling the aseptically disinfected plurality of bottles with aseptically sterilized foodstuffs including a plurality of filling nozzles, and

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

31. The apparatus according to claim 30, wherein a temperature sensor ensures a heat of the sterilant in the means for applying sterilant to the plurality of bottles is heated to a correct temperature for activating the sterilant.

32. The apparatus according to claim 30, wherein a pressure sensor ensures a pressure of air used by the means for applying sterilant to the plurality of bottles is within predetermined atomization requirements.

33. The apparatus according to claim 30, wherein a temperature sensor ensures a heating element used by the means for applying sterilant is heated to a predetermined temperature before the sterilant is applied to an interior surface of each bottle.

34. The apparatus according to claim 30, wherein the control system ensures a minimum bottle temperature of 131° F. is held for at least 5 seconds during removal of the sterilant.

35. The apparatus according to claim 30, wherein the control system ensures the sterilant is applied for about 1 second and hot sterile air is introduced for about 24 seconds.

36. The apparatus according to claim 35, wherein the control system ensures the 24 seconds allows for the bottles to heat up to about 131° F. for at least 5 seconds.

37. The apparatus according to claim 35, wherein the means for aseptically filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute aseptically fills the aseptically disinfected plurality of bottles at a rate greater than 360 bottles per minute.

38. An apparatus for aseptically bottling aseptically sterilized low-acid foodstuffs having at least about a 12 log reduction in Clostridium botulinum, the apparatus comprising:

a control system for controlling aseptic bottling conditions;

means for providing a plurality of bottles, the means including a bottle infeed;

means for aseptically disinfecting the plurality of bottles including a plurality of nozzles;

means for aseptically filling the aseptically disinfected plurality of bottles with aseptically sterilized foodstuffs including a plurality of filling nozzles, and

means for aseptically filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute;

wherein a heating element heats air used in the apparatus to about 230° F.

39. An apparatus for aseptically bottling aseptically sterilized low-acid foodstuffs having at least about a 12 log reduction in Clostridium botulinum, the apparatus comprising:

a control system for controlling aseptic bottling conditions, wherein the control system monitors a flow rate of air;

means for providing a plurality of bottles, the means including a bottle infeed;

means for aseptically disinfecting the plurality of bottles including a plurality of nozzles;

means for aseptically filling the aseptically disinfected plurality of bottles with aseptically sterilized foodstuffs including a plurality of filling nozzles, and

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

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

providing a plurality of bottles;

aseptically disinfecting the plurality of bottles to a level producing at least a 6 log reduction in spore organisms;

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;

wherein the step of aseptically disinfecting of the plurality of bottles further includes a measuring device for measuring a quantity of sterilant, and wherein the sterilant is peroxyacetic acid and hydrogen peroxide; and wherein the peroxyacetic acid and hydrogen peroxide uses a concentration sensor to ensure that the concentration of the peroxyacetic acid and hydrogen peroxide is maintained at a predetermined level.

* * * * *

US006702985B1

(12) **United States Patent**
Taggart et al.

(10) **Patent No.: US 6,702,985 B1**
(45) **Date of Patent: Mar. 9, 2004**

(54) **APPARATUS AND METHOD FOR PROVIDING CONTAINER INTERIOR STERILIZATION IN AN ASEPTIC PROCESSING APPARATUS**

(75) Inventors: **Thomas D. Taggart**, South Wales, NY (US); **Daniel Newitt**, West Chicago, IL (US)

(73) Assignee: **Steuben Foods, Inc.**, 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.: **09/354,478**

(22) Filed: **Jul. 15, 1999**

(51) **Int. Cl.**[7] **A61L 2/20**
(52) **U.S. Cl.** **422/28**; 422/302; 222/356
(58) **Field of Search** 422/28, 33, 292, 422/304, 302; 53/425, 432, 510, 511; 118/323, 317; 222/356

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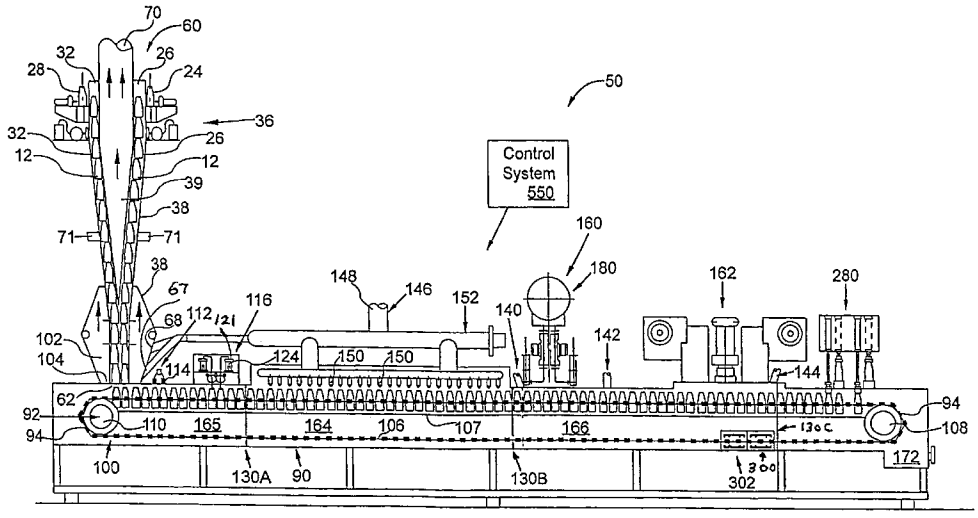
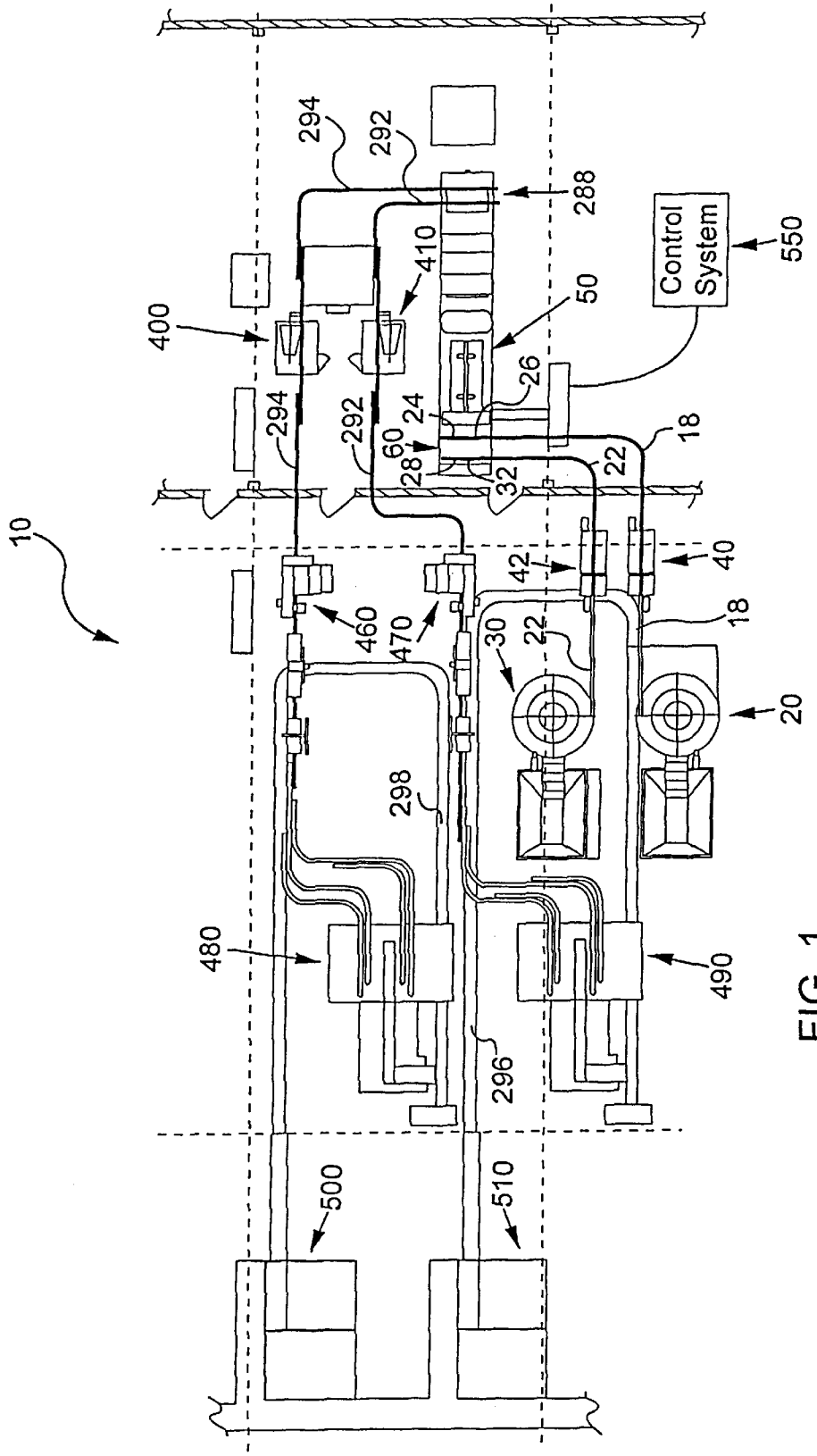
Primary Examiner—Elizabeth McKane
(74) *Attorney, Agent, or Firm*—Schmeiser, Olsen & Watts

(57) **ABSTRACT**

An apparatus and method for providing container interior sterilization in an aseptic processing apparatus. An atomized sterilant is applied to an interior surface of a container such as a bottle. A supply of hot sterile drying air is applied to the interior surface to activate and dry the sterilant.

23 Claims, 18 Drawing Sheets

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500
510

FIG. 1

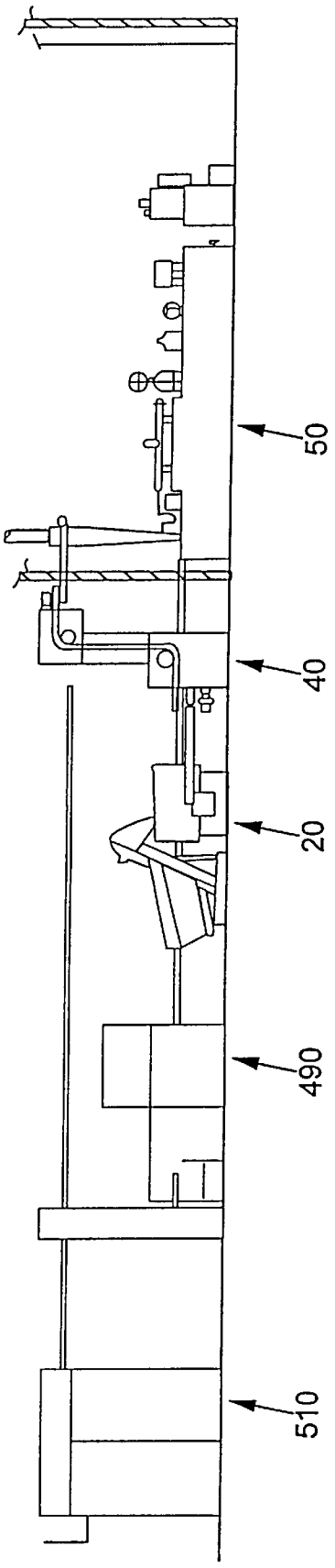


FIG. 2

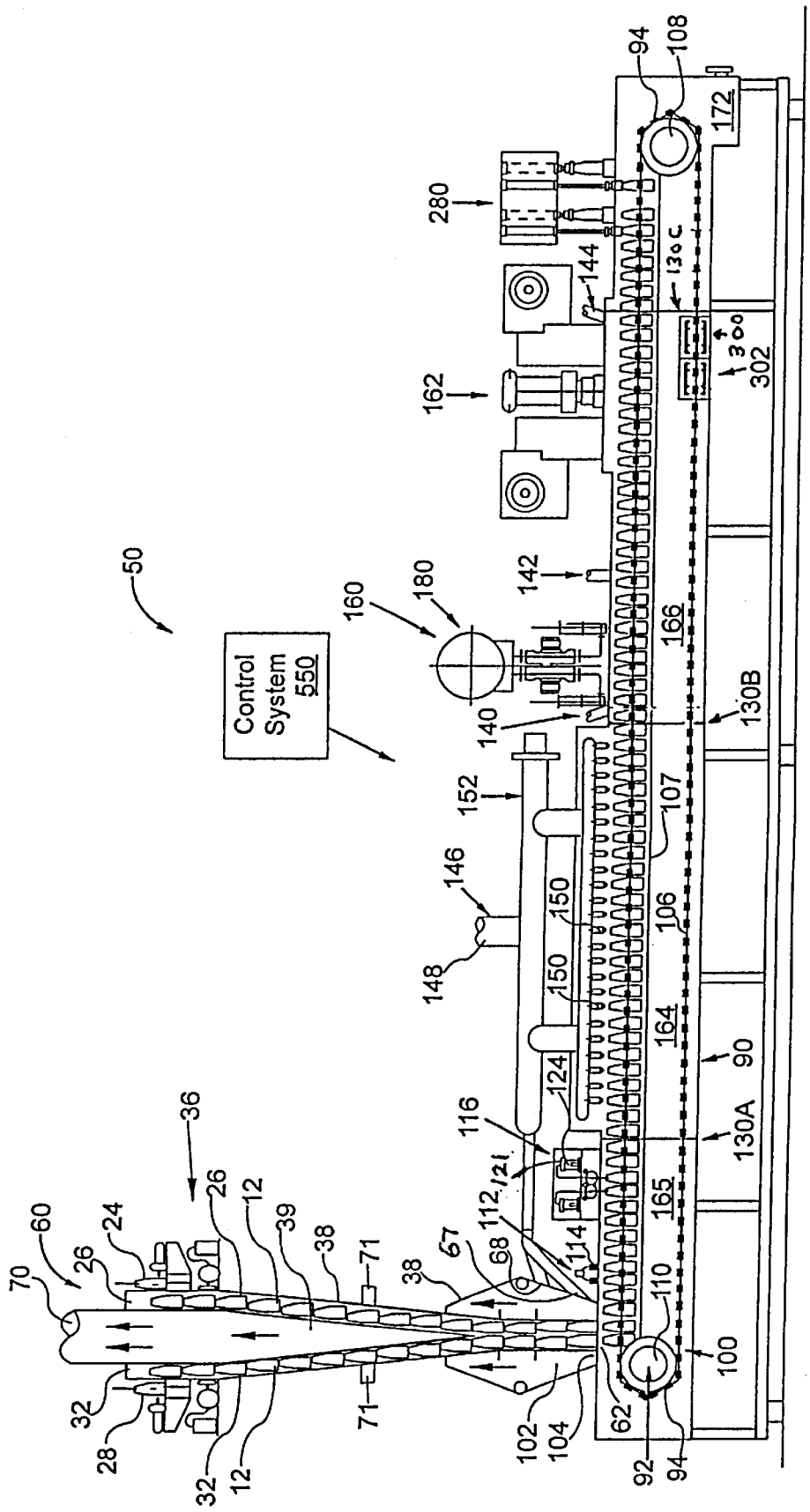

50
Control System 550
60
26
24
70
36
26
12
39
38
71
38
67
68
112
121
116
114
124
146
148
150
150
152
140
160
180
142
144
280
162
94
108
172
130C
300
302
166
130B
107
106
164
165
110
100
90
130A
62
92
94
102
104
71
32
28
32
12

FIG. 3

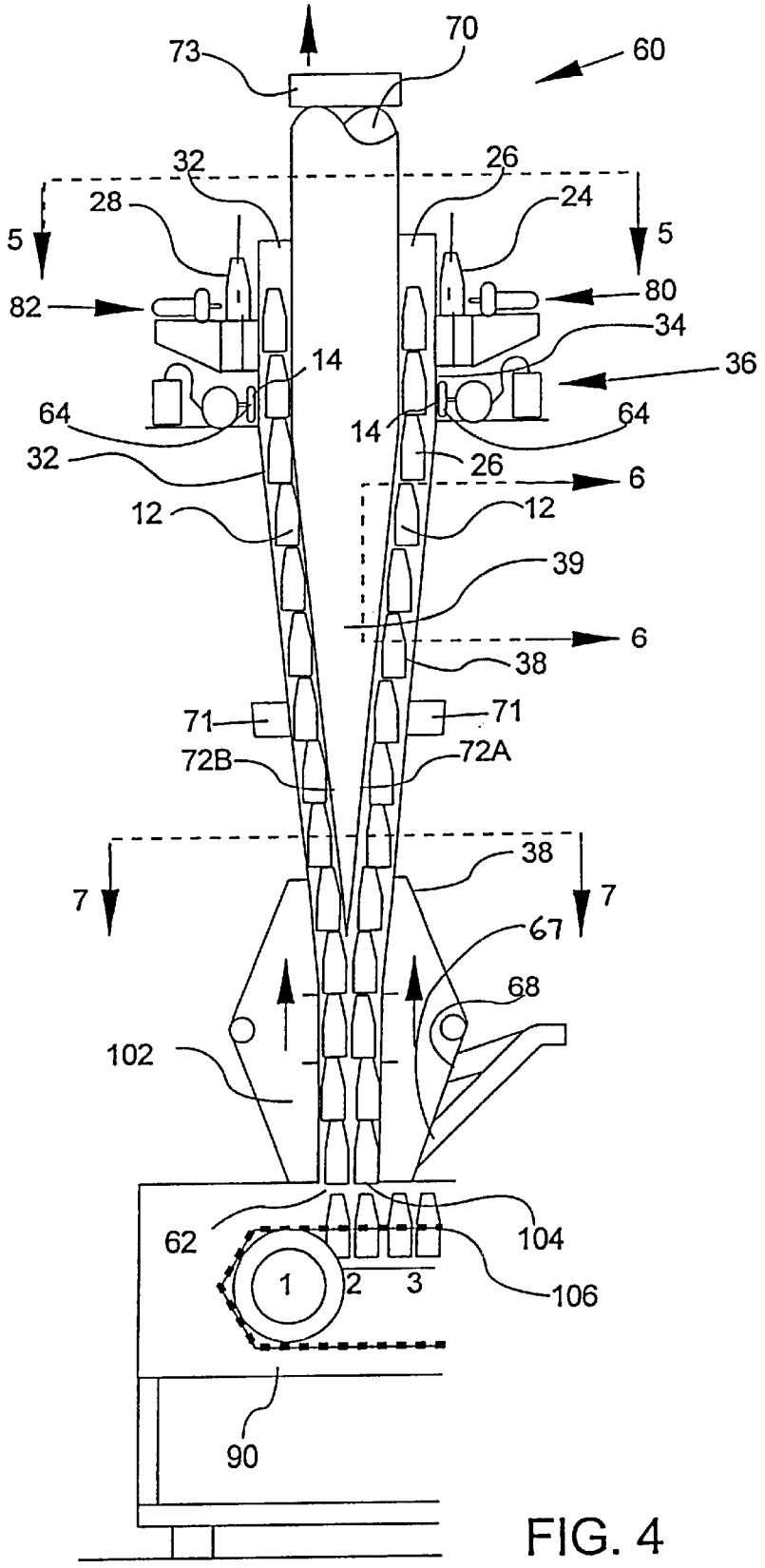

73
70
60
32
26
28
24
5
5
82
80
34
36
14
64
14
64
32
26
6
12
12
39
6
38
71
71
72B
72A
38
7
7
67
68
102
62
104
1
2
3
106
90

FIG. 4

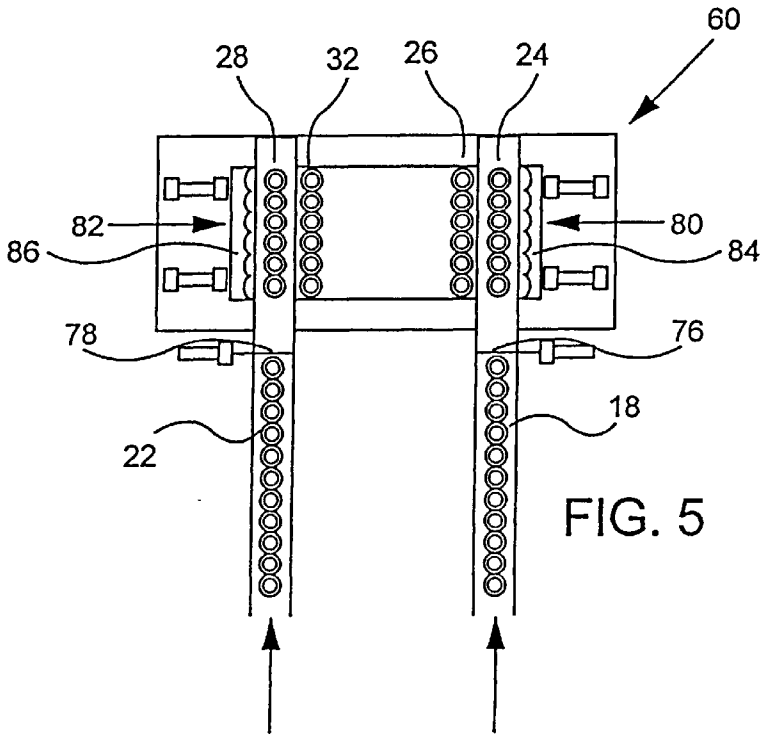


FIG. 5

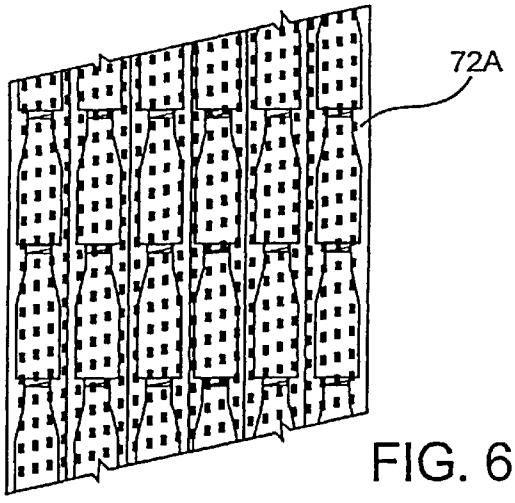


FIG. 6

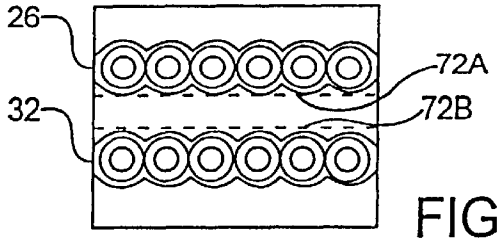


FIG. 7

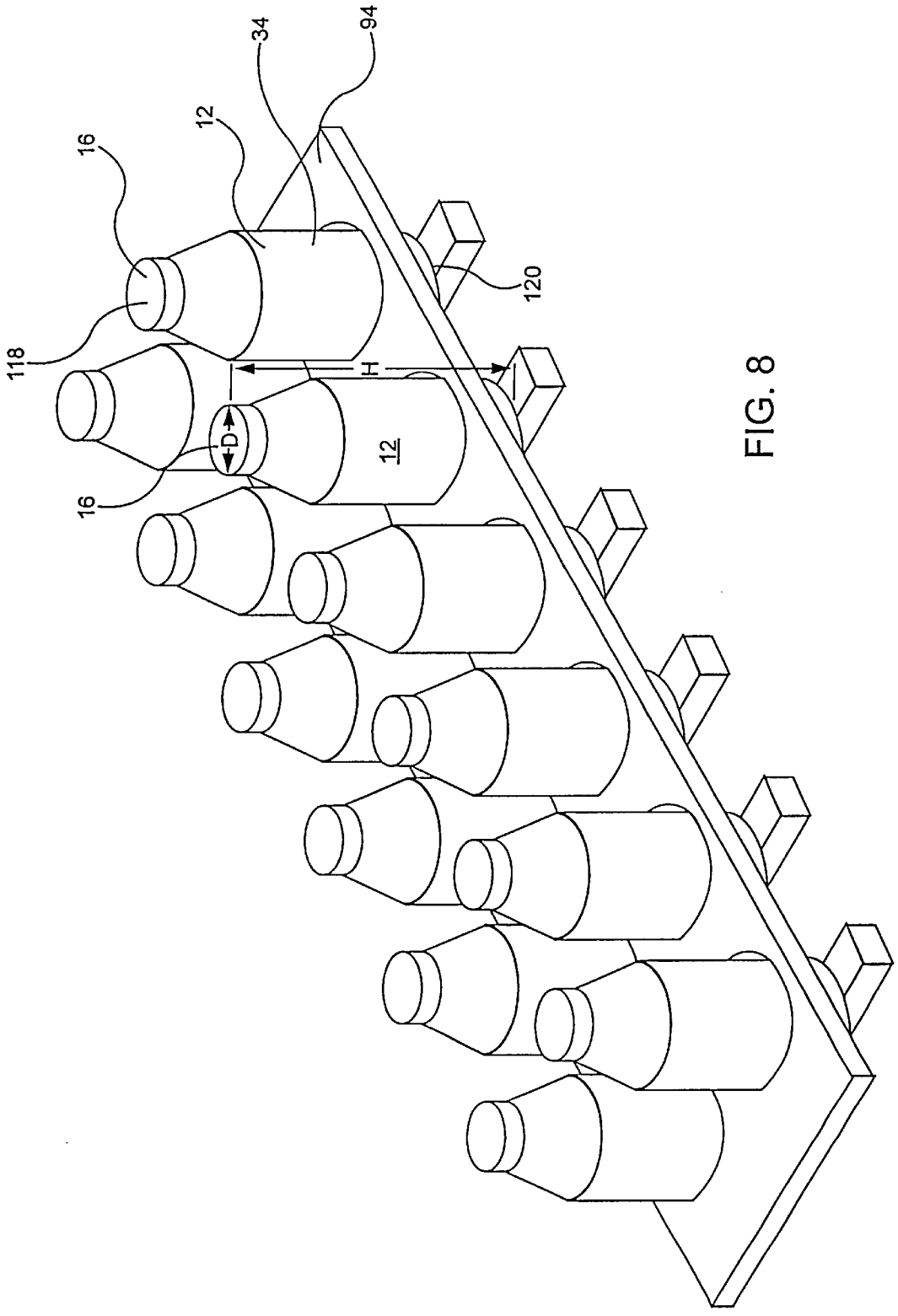


FIG. 8

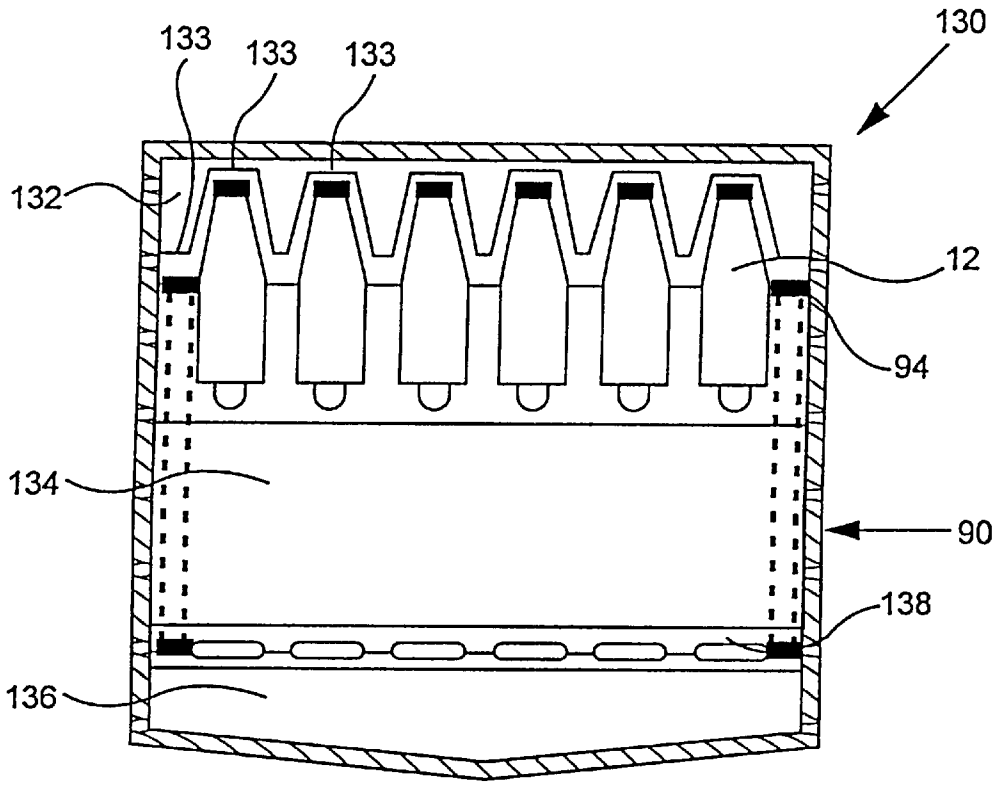


FIG. 9

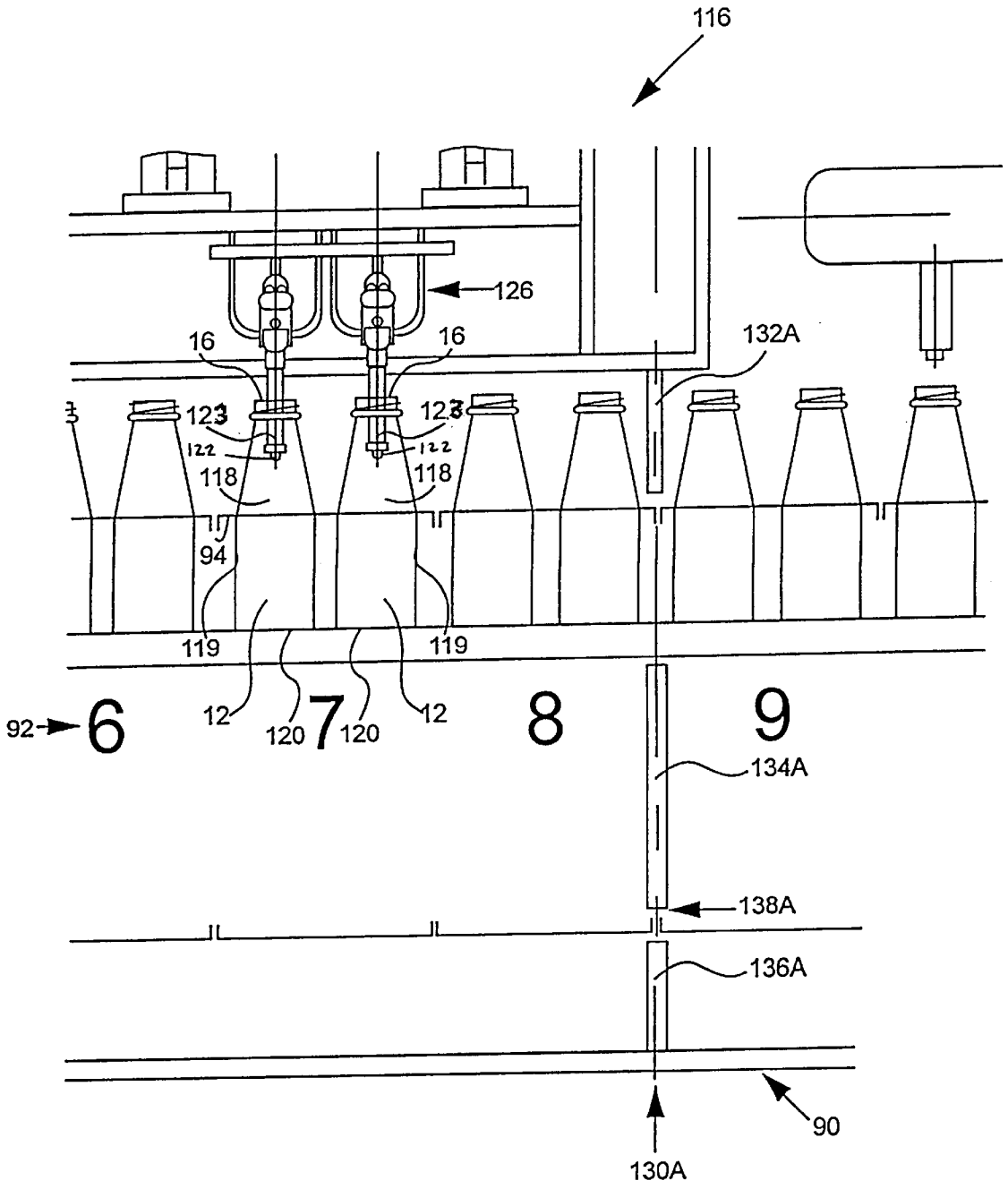

116
126
16
16
132A
123
123
122
122
118
118
94
119
119
92
6
12
120
7
120
12
8
9
134A
138A
136A
90
130A

FIG. 10

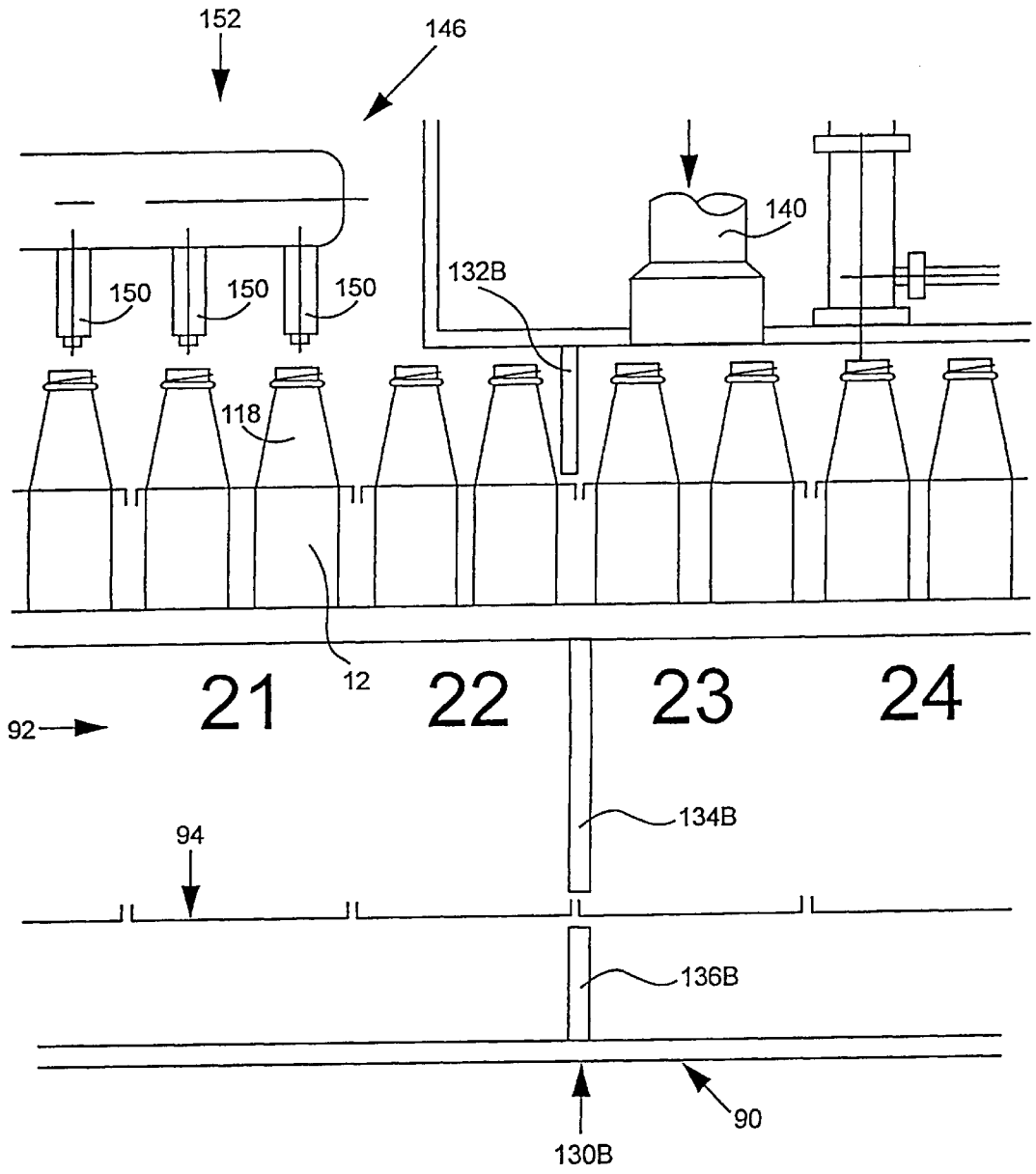

152
146
140
150
150
150
132B
118
12
21
22
23
24
92
94
134B
136B
90
130B

FIG. 11

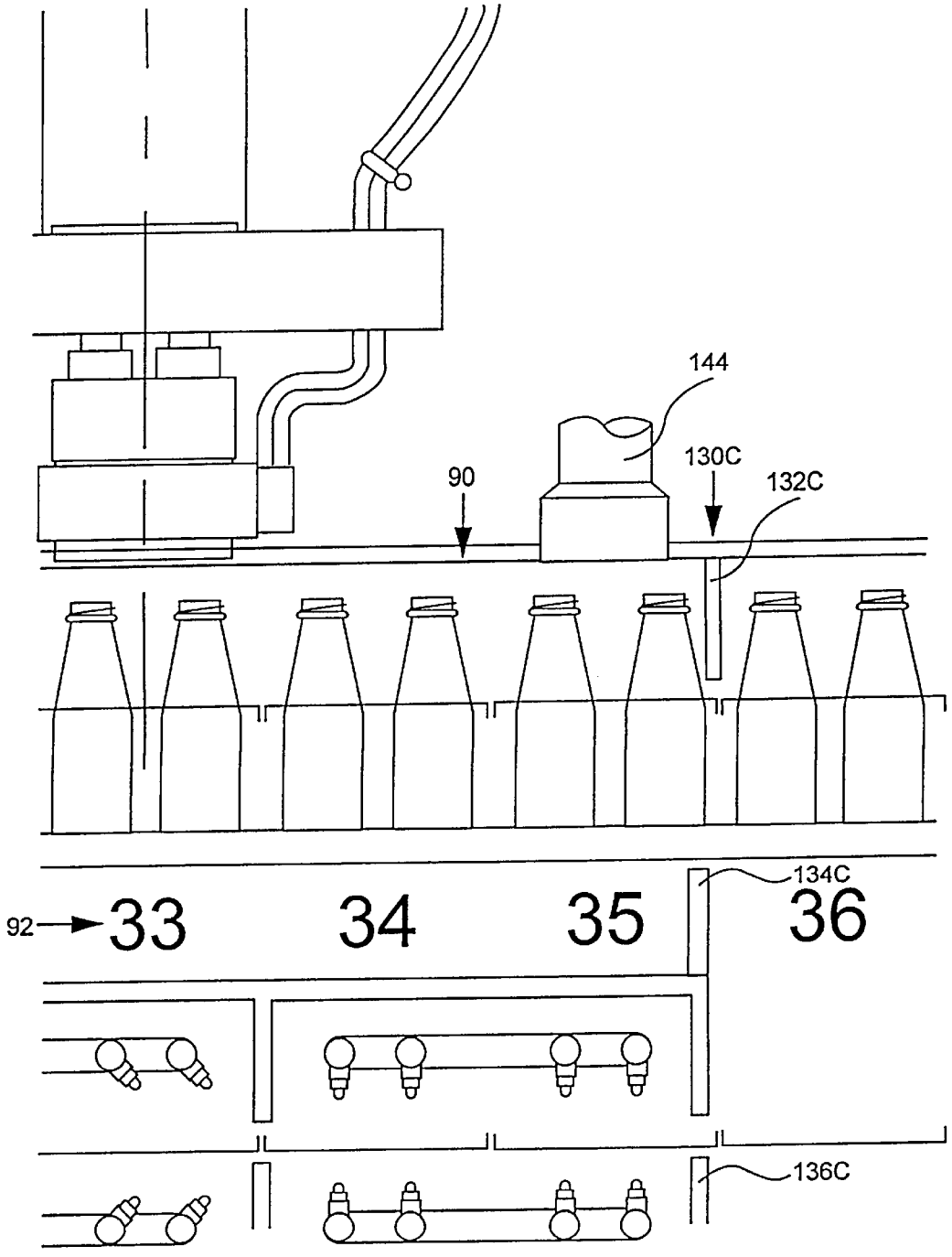


FIG. 12

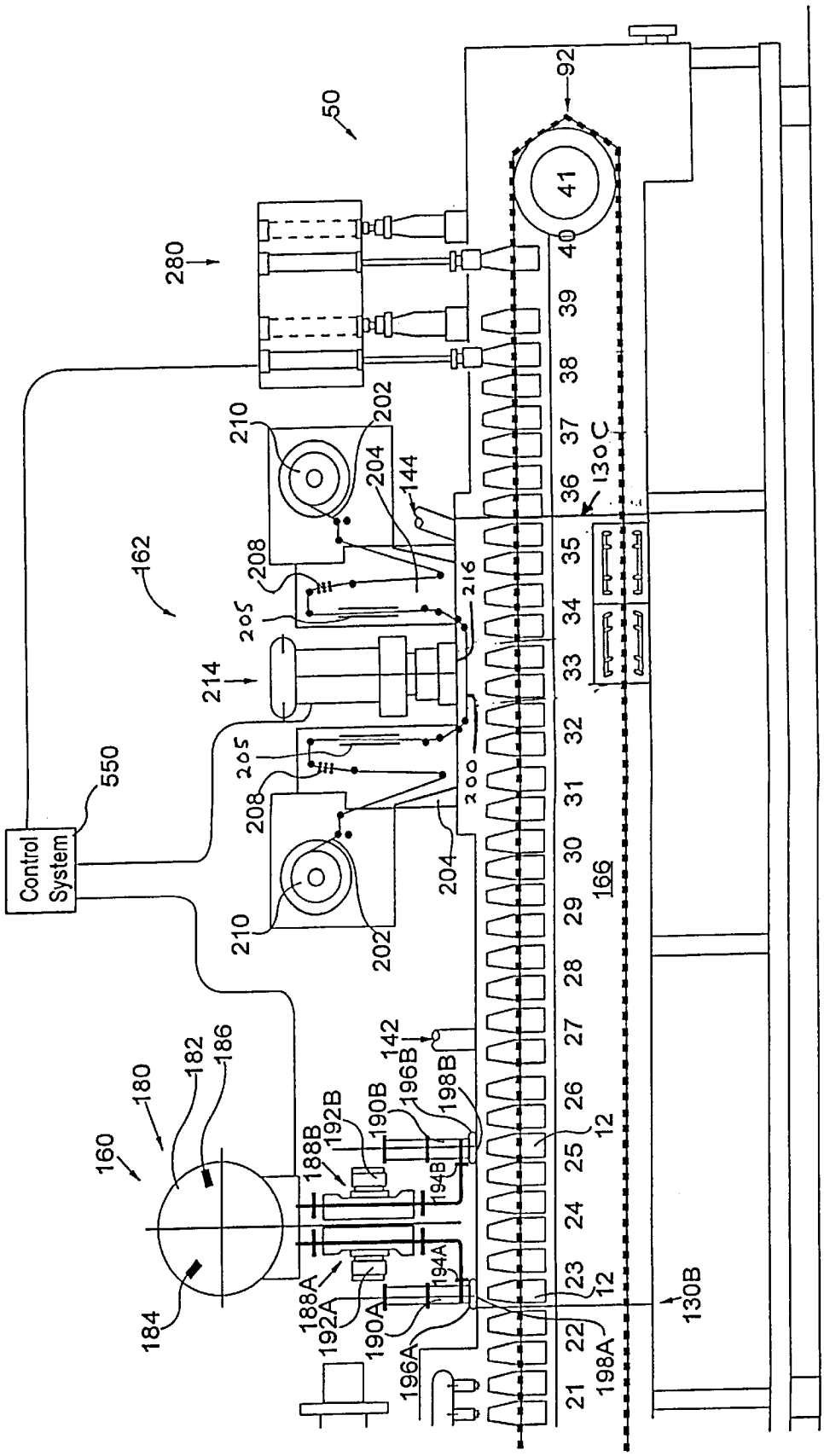

Control System
550
50
92
41
40
39
38
37
36
35
34
33
32
31
30
29
28
27
26
25
24
23
22
21
280
162
214
205
208
210
202
204
144
216
200
166
130C
130B
160
180
182
186
184
142
188A
188B
190A
190B
192A
192B
194A
194B
196A
196B
198A
198B
12

FIG. 13

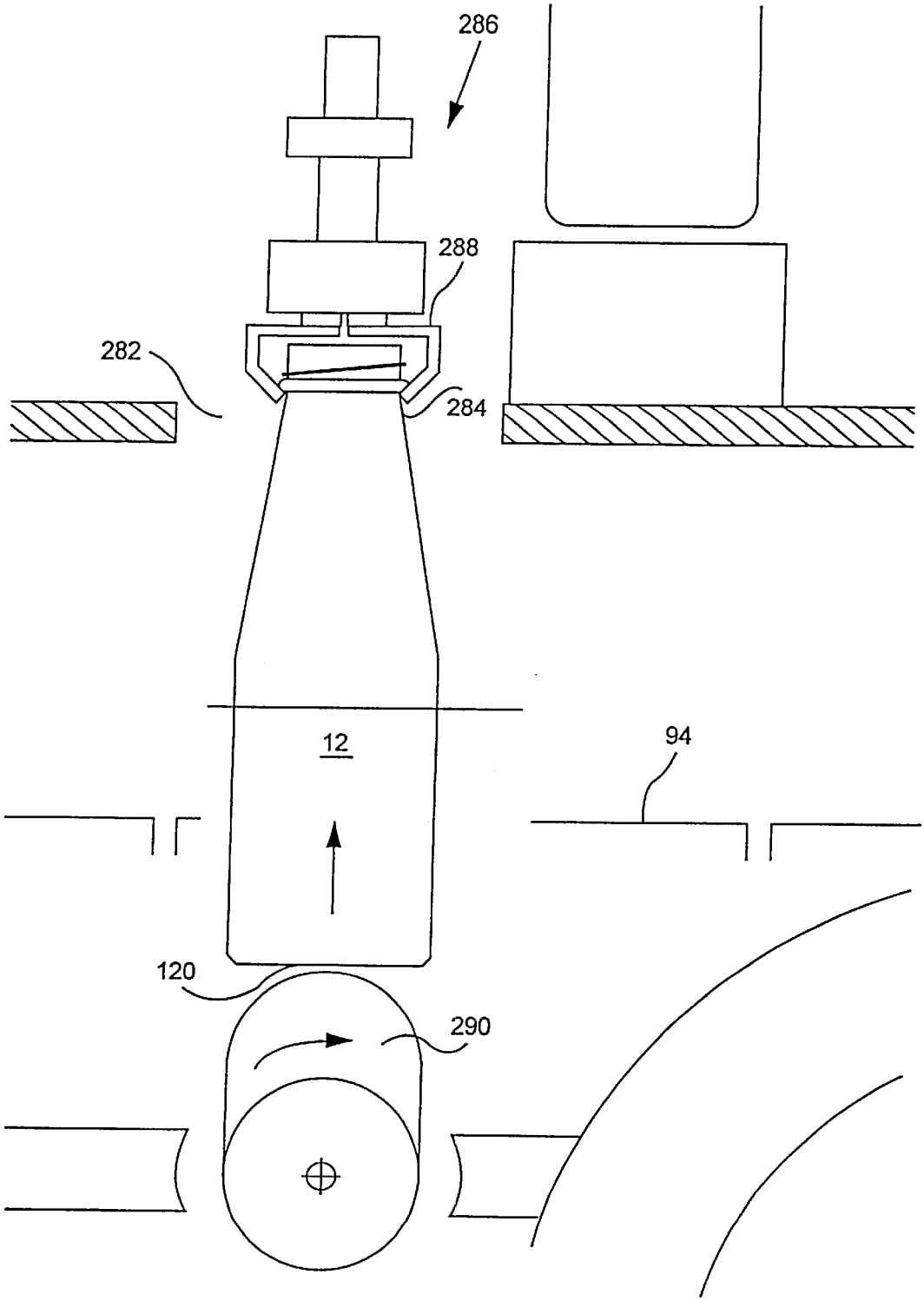


FIG. 14

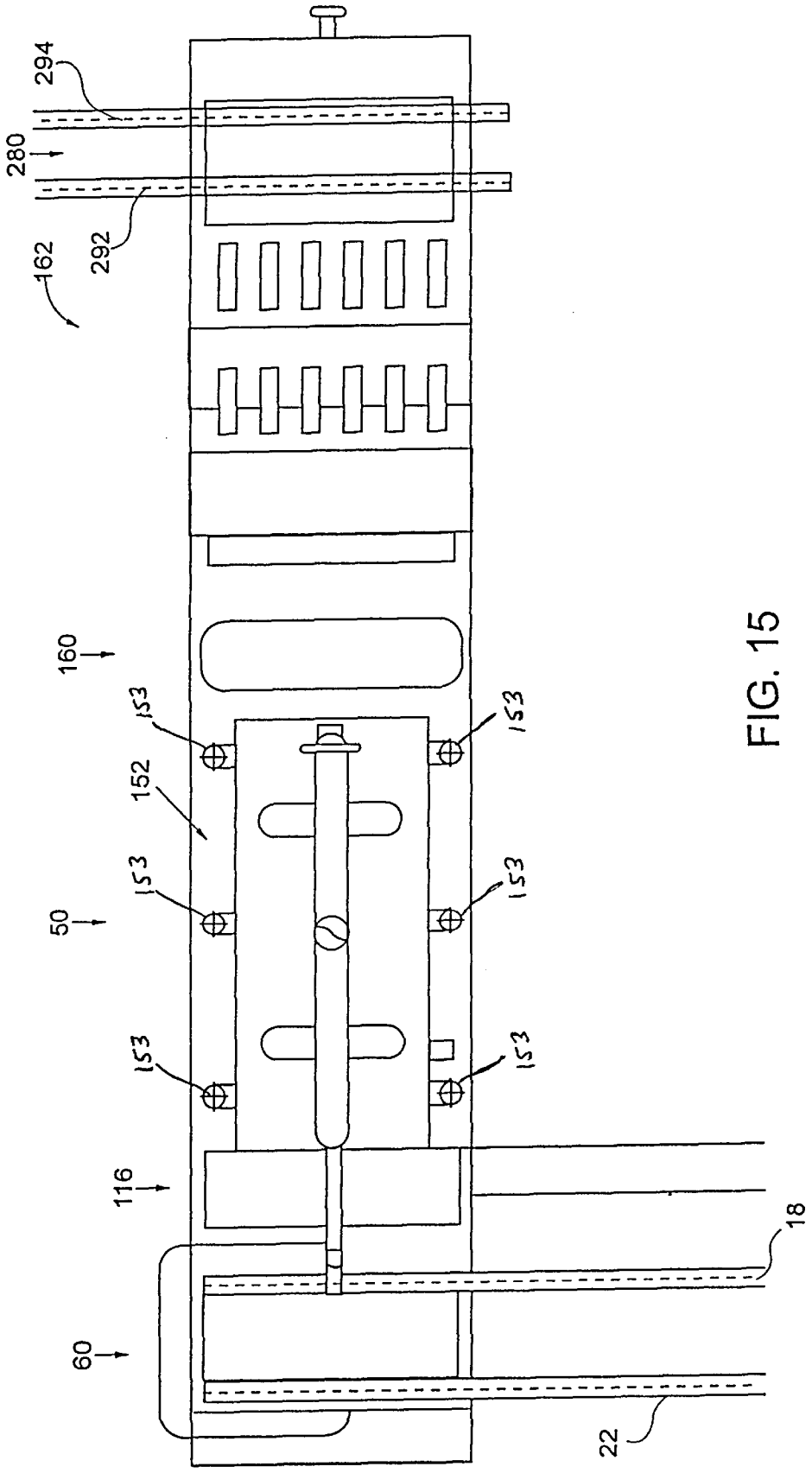


FIG. 15

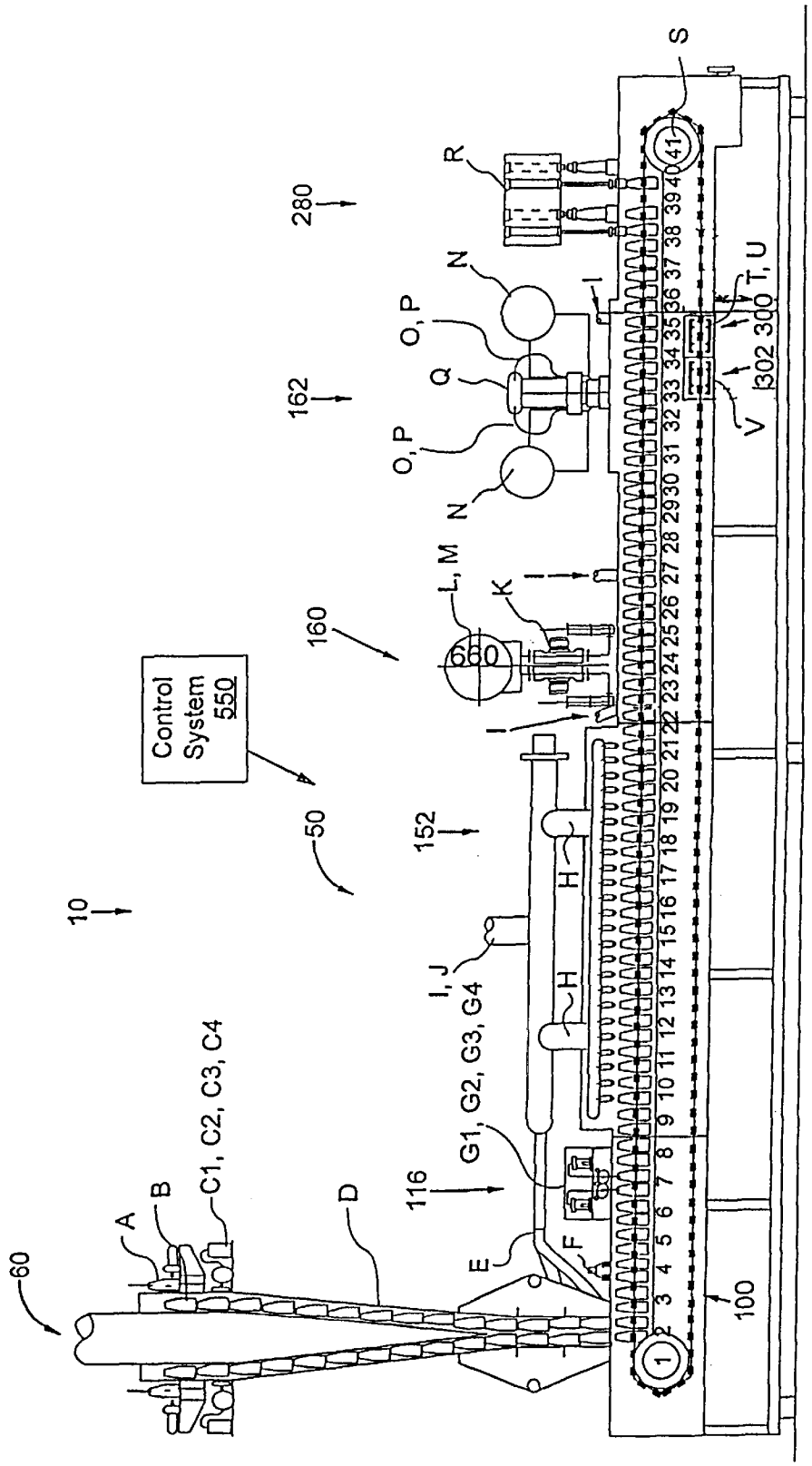

Control System 550
10
50
50
60
100
116
152
160
162
280
A
B
C1, C2, C3, C4
D
E
F
G1, G2, G3, G4
H
I, J
K
L, M
N
O, P
Q
R
S
T, U
V
300
302
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41

FIG. 16

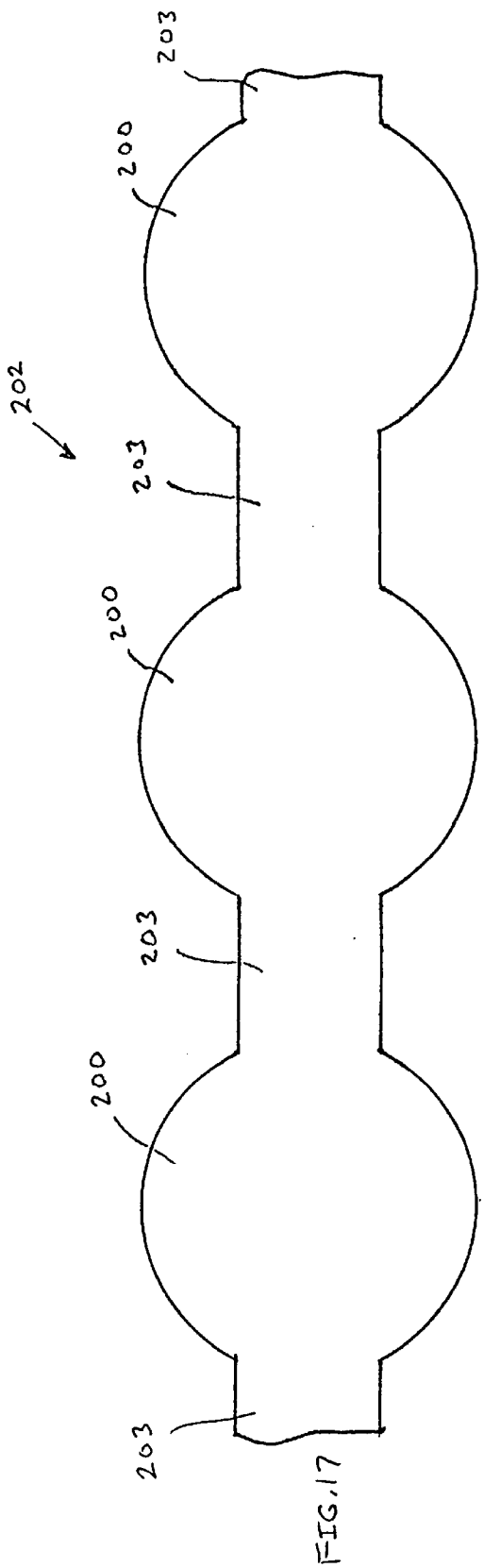

202
203
200
203
200
203
200
203

FIG. 17

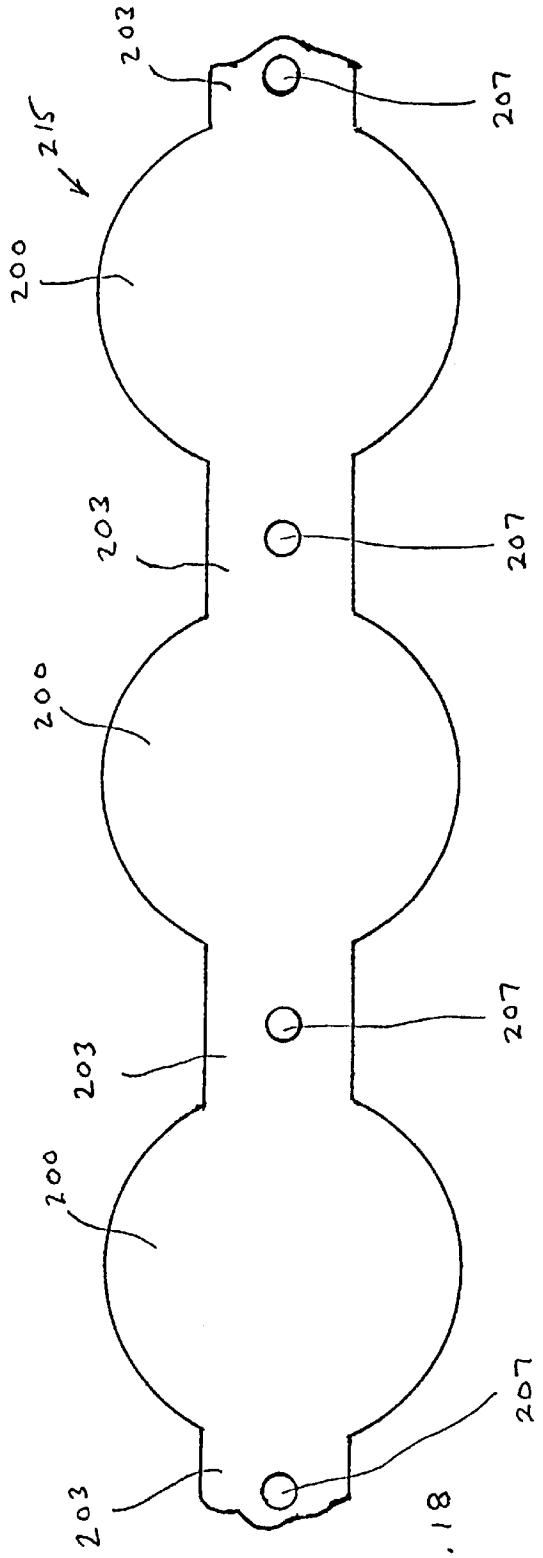

215
203
207
200
203
207
200
203
207
200
203
207

FIG. 18

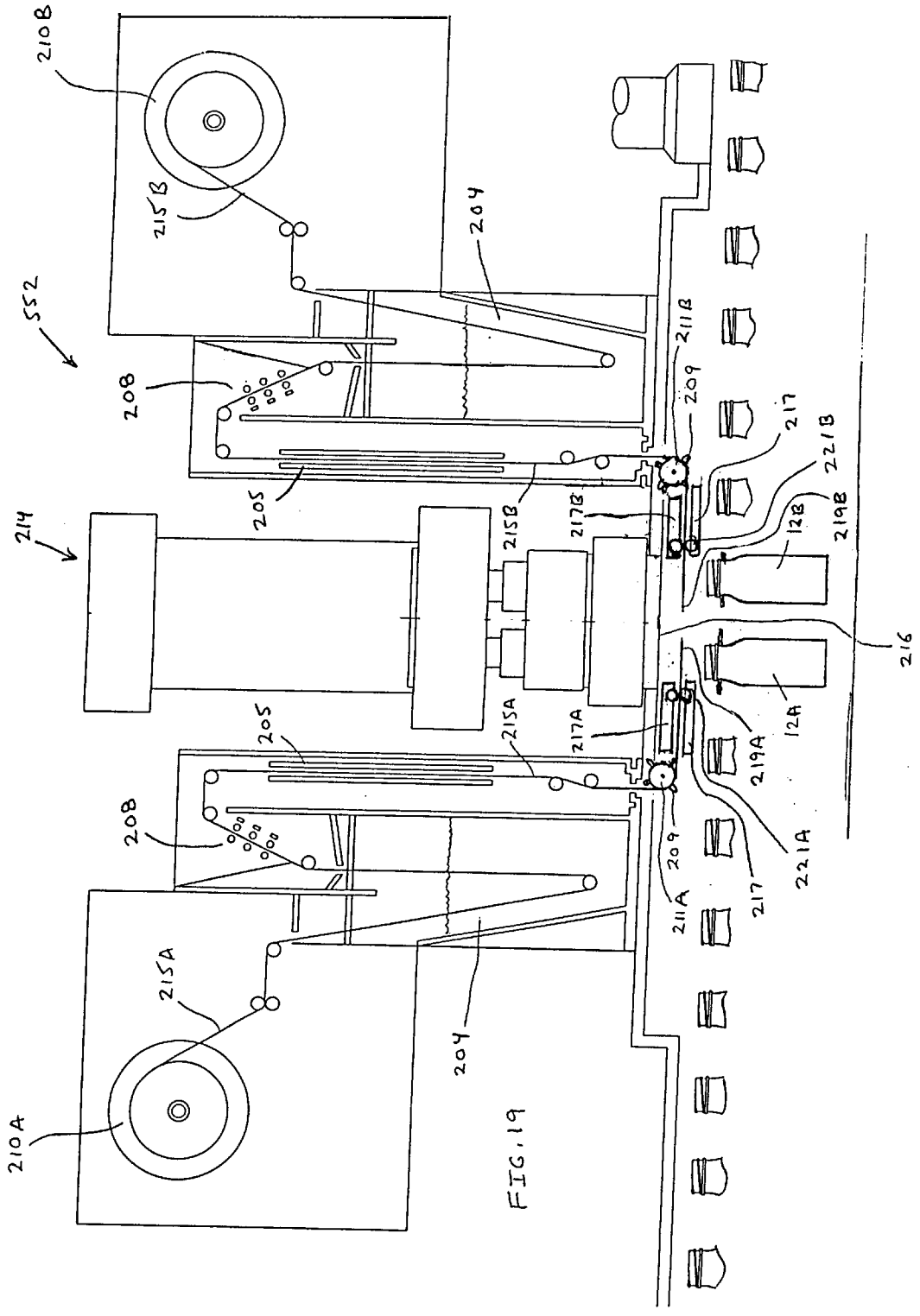

210B
215B
204
552
208
205
211B
209
217
221B
219B
214
215B
217B
128
216
205
215A
217A
12A
208
209
211A
217
221A
215A
204
210A

FIG. 19

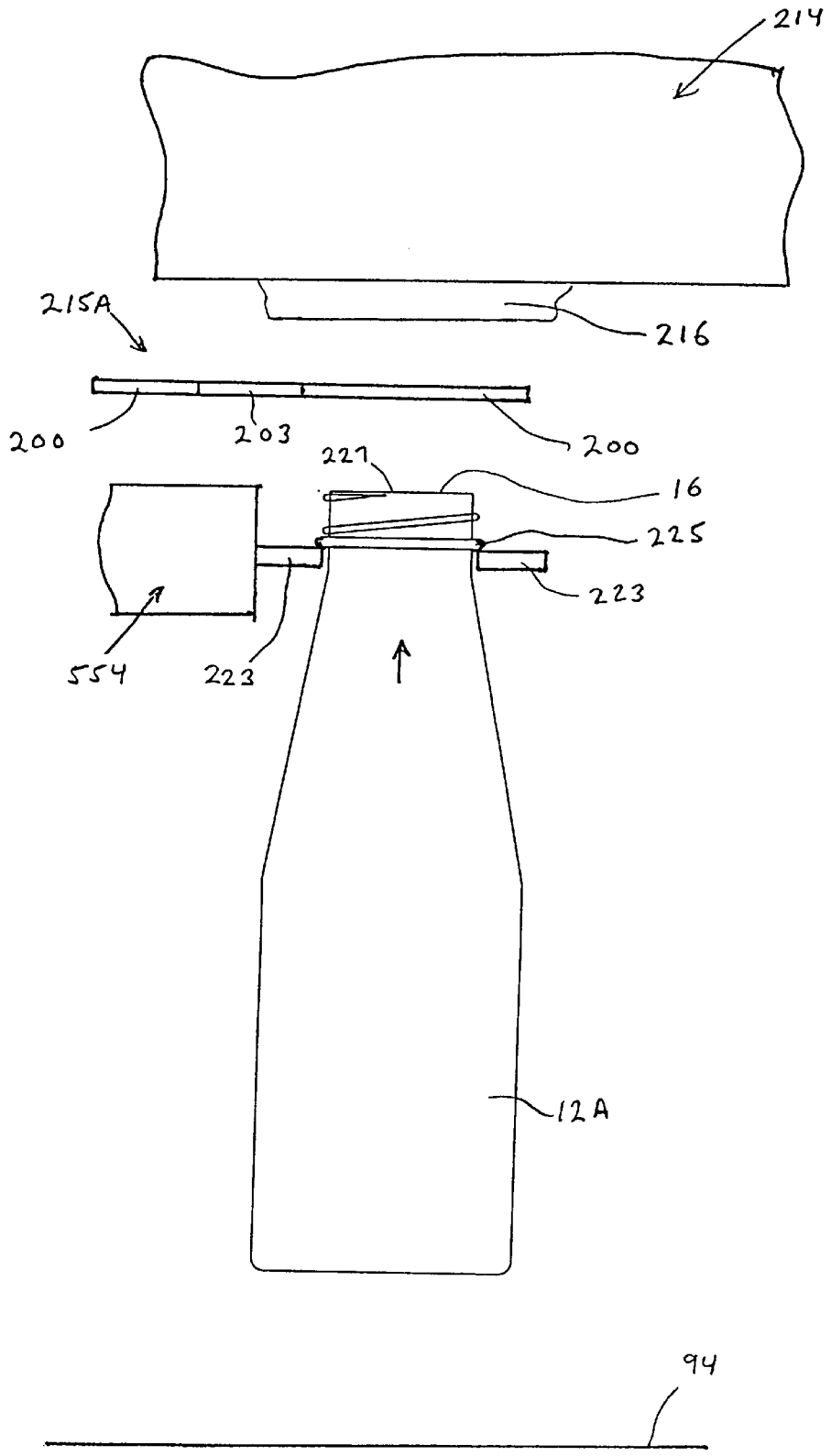


FIG.20

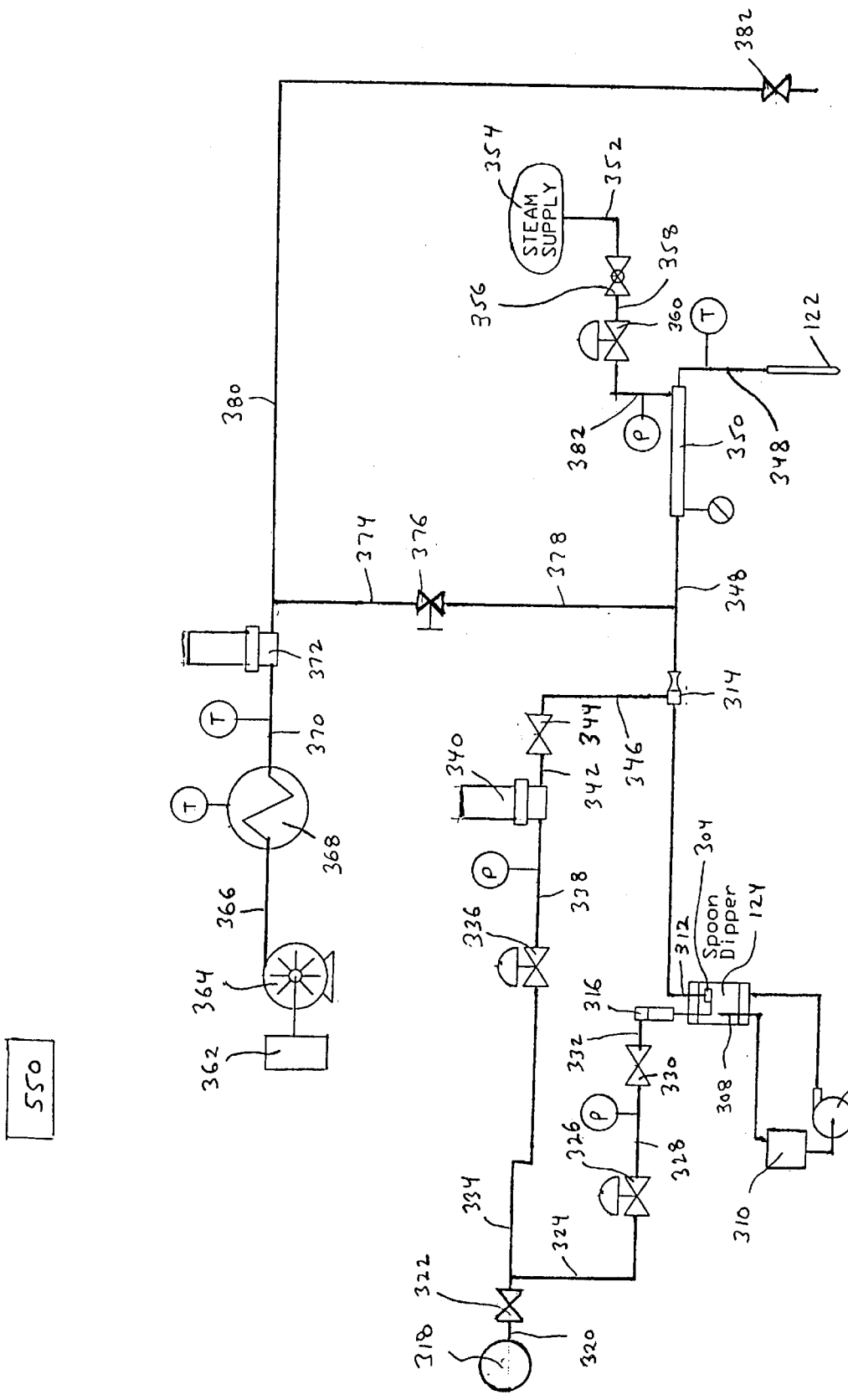

550
382
354
STEAM SUPPLY
352
358
356
360
T
122
380
P
382
350
348
374
376
378
348
372
314
T
370
340
342
344
346
T
368
304
Spoon Dipper
124
366
P
338
336
312
364
316
332
330
306
362
308
P
326
328
310
334
324
322
318
320

FIG. 21

APPARATUS AND METHOD FOR PROVIDING CONTAINER INTERIOR STERILIZATION IN AN ASEPTIC PROCESSING APPARATUS

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 apparatus and method for providing container interior sterilization in an aseptic processing apparatus.

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 sterilization tunnel are also known.

Generally, containers such as cups are sterilized using a mixture of hydrogen peroxide and a carrier gas such as air. The hydrogen peroxide vapor mixture is directed against the interior surface of the cup and a condensate film forms. Cups typically have a ratio of an opening diameter to a height of greater than 1.0. The hydrogen peroxide vapor may be easily introduced through the large opening and the vapor easily covers the interior surface of the cup. Furthermore, a hot drying gas may easily flow through and dry the interior of the cup. For containers such as bottles, with an opening to a height ratio of less than 1.0, difficulties arise in attempting to sterilize to aseptic standards the large interior surface. For example, difficulties occur when trying to rapidly introduce a sterilant through the small bottle opening onto the large interior surface. It is difficult to achieve a uniform coating of sterilant over the interior surface. Additionally, the sterilant vapor may condense and form droplets on the surface. These droplets are difficult to remove and can cause residual sterilant levels above an acceptable level. For example, for the sterilant hydrogen peroxide, the residual level must be less than 0.5 PPM in order to meet FDA standards. The small bottle opening also restricts the flow of drying gas that can enter, pass through, and exit the bottle.

Another disadvantage in the design of typical hydrogen peroxide sterilization equipment is the build up of hydrogen peroxide droplets in the delivery nozzles or other delivery apparatus. These droplets can eventually be directed into the container and become impossible to heat and evaporate, and therefore, will result in a residual level of hydrogen peroxide in the container which will be greater than the FDA allowable 0.5 PPM.

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 other fillers have 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 an apparatus and method for providing container interior sterilization in an aseptic processing apparatus. The interior container sterilization is applied in an 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. The present invention includes a plurality of sterile air supply sources. For example, a first supply source of sterile air is used to atomize a sterilant (e.g., hydrogen peroxide), within an atomizing venturi. A second supply source of sterile air is used to provide hot sterile air to the atomized sterilant leaving the atomizing venturi. A third supply source of sterile air is used to provide hot sterile air for activating and drying the sterilant on the interior surface of the container. The second supply source of heated sterile air, prevents the formation of hydrogen peroxide droplets. This results in a design that will meet the FDA regulations for each and every bottle that is manufactured. Typically, in the aseptic packaging industry, a low volume of air at a high temperature is applied to the packaging materials. This method works well when the container material can withstand relatively high temperatures such as when cups are made of polypropylene. However, this often results in deformation and softening of packaging materials formed of PET or HDPE. In order to prevent softening and deformation of the bottles, when formed from these types of plastic 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. A long exposure time is predicated by the geometry of the bottle and the softening temperature of the material used to form the bottle. In the present invention, about 24 seconds are allowed for directing hot sterile air from the third supply source of sterile air

into the interior of the bottles. In order to achieve aseptic sterilization, the bottle is maintained at about 131° F. for at least 5 seconds. Many features are incorporated into the interior bottle sterilization apparatus in order to meet the various FDA aseptic standards and the 3A Sanitary Standards and Accepted Practices.

The present invention generally provides an apparatus comprising:

a first supply source of sterile air;

a supply source of sterilant;

an atomizing system producing an atomized sterilant from the mixing of the sterile air from the first supply source of sterile air with the sterilant;

a second supply source of a hot sterile air for providing the hot sterile air to the atomized sterilant;

a probe for applying the atomized sterilant into an interior of a container; and

a third supply source of a hot sterile drying air for activating and drying the sterilant in the interior of the container.

Also provided is a method comprising:

providing a first supply of sterile air;

providing a supply of sterilant;

producing an atomized sterilant by mixing the first supply of sterile air with the sterilant;

providing a second supply of hot sterile air to the atomized sterilant;

providing a probe for applying the atomized sterilant into an interior of a container; and

supplying a third supply of hot sterile drying air for activating and drying the sterilant in the interior of the container.

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 sterilization 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 sterilization tunnel;

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

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

FIG. **17** is a plan view of a daisy chain of lids;

FIG. **18** is a plan view of another embodiment of a daisy chain of lids with holes for receiving pins of a drive wheel;

FIG. **19** is another embodiment of the lid sterilization and heat sealing apparatus including a pin drive apparatus;

FIG. **20** is a perspective view of the heat sealing and gripper apparatus; and

FIG. **21** is a schematic diagram of a sterilization control system for the interior bottle sterilization apparatus.

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 United States 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 an aseptic processing apparatus **10** 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 (hydrogen peroxide and peroxyacetic acid) 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 unscrambler **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

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 above 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 entire 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 **67** 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 the sterilization 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 a sterilization 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 is 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 sterilization 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 **121** and a plurality of probes **123**. Each probe **123** includes any practical means for transferring the sterilant from the probe **123** to the interior surface **119** of the bottle **12**. For example, an opening or a plurality of openings may be used for ejecting the sterilant onto the interior surface **119**. Preferably, in the present invention, an applicator spray nozzle **122** is included in each probe **123**. The applicator spray nozzle **122** provides uniform sterilant application without droplet formation on the interior surface **119** of the bottle **12**. A separate measuring device **121** and the probe **123** are used for each of the twelve bottle **12** locations in the conveying plate **94**. Each sterilant measuring device **121** may include a spoon dipper **304** (e.g., approximately 0.5 ml each) as illustrated in FIG. **21**. Each bottle **12** is supplied with the same measured quantity of sterilant, preferably in the form of a hot vapor fog. A pump **306** provides a sterilant (e.g., hydrogen peroxide) from a sterilant supply tank **310** to a reservoir **124**. An overflow pipe **308** maintains the sterilant liquid level in the reservoir **124** by returning excess sterilant to the sterilant supply tank **310**. The spoon dipper **304** connected to an air cylinder **316** is submerged into the reservoir **124** and is lifted above the liquid level. Thus, a measured volume of liquid hydrogen peroxide (e.g., approximately 0.5 ml) is contained in each spoon dipper **304**.

Each spoon dipper **304** may include a conductivity probe that is configured to send a signal to the control system **550** indicating that the spoon dipper **304** is full. A tube **312** (e.g., having a diameter of about 1/16") is positioned in the center of the spoon dipper **304**. A first end of the tube **312** is positioned near the bottom of the spoon dipper **304**. A second end of the tube **312** is connected to an atomizing venturi **314**.

A pressurized air source **318** is connected by a conduit **320** to a flow adjust valve **322**. A conduit **324** connects the flow adjust valve **322** to a regulator valve **326**. A conduit **328** connects the regulator valve **326** with a solenoid actuated valve **330**. A conduit **332** connects the solenoid actuated valve **330** with the air cylinder **316**. The control system **550** controls the solenoid actuated valve **330** which controls the compressed air supplied to the air cylinder **316**. Compressed air supplied to the air cylinder **316** lowers or lifts the spoon dipper **304** into or out of the liquid sterilant.

A conduit **334** connects the flow adjust valve **322** with the regulator valve **336**. A conduit **338** connects the regulator valve **336** with a sterile air filter **340**. A conduit **342** connects the sterile air filter **340** with a solenoid actuated valve **344**. A conduit **346** connects the solenoid actuated valve **344** with the atomizing venturi **314**. When the spoon dipper **304** is full, and a signal is received from the control system **550**, the solenoid actuated valve **344** is opened allowing pressurized sterile air to enter the atomizing venturi **314** through the conduit **346**. The pressurized air flow causes a vacuum to be generated in the second end of the tube **312** causing liquid hydrogen peroxide to be pulled out of the spoon dipper **304**.

A first supply of sterile air is supplied through conduit **346**. The pressurized air supplied through conduit **346** is used to atomize the hydrogen peroxide sterilant in the atomizing venturi **314**. Atomization of the liquid hydrogen peroxide may be provided by other means such as by using ultrasonic frequencies to atomize the liquid hydrogen peroxide.

A conduit **348** connects with the atomizing venturi **314**, passes through a heat exchanger **350** (e.g., double tube heat exchanger), and connects with a probe **123** including the applicator spray nozzle **122**. A conduit **352** connects a steam supply **354** with a valve **356**. A conduit **358** connects the valve **356** with a regulator valve **360**. A conduit **382** connects the regulator valve **360** with the heat exchanger **350**.

A second supply of hot sterile air is supplied to the atomized sterilant through a conduit **378**. A humidity control apparatus **362** maintains the humidity level of the air entering a blower **364**. A conduit **366** connects the blower **364** with a heater **368**. A conduit **370** connects the heater **368** with a sterile filter **372**. A conduit **374** connects the sterile filter **372** with a flow adjust valve **376**. The conduit **378** connects the flow adjust valve **376** with the conduit **348**. A conduit **380** connects the sterile filter **372** with a bypass valve **382**. The blower **364** operates continuously supplying humidity controlled air to the heater **368**. The flow of heated sterile air is controlled with the flow adjust valve **376** and travels through conduit **378**.

Exiting conduit **378**, the second supply of hot sterile air enters the conduit **348** to mix with the atomized hydrogen peroxide from the atomizing venturi **314**. Excess flow of heated sterile air travels through conduit **380** and passes through the bypass valve **382**. The second supply of hot sterile air assists in obtaining a uniform concentration of hydrogen peroxide in the air stream in conduit **348** and provides enough momentum to ensure that all portions of the bottle **12** interior **118** are contacted by hydrogen peroxide. Furthermore, the second supply of hot sterile air is continuously blowing, whereas the first supply of sterile air and hydrogen peroxide in conduit **346** is intermittent corresponding to the movement of the bottles **12**. Since the second supply of hot sterile air is continuous, hydrogen peroxide does not have the ability to fall out of the air stream and deposit in the delivery conduit **348** in the form of drops. This ensures that the delivery of hydrogen peroxide is consistent from one bottle **12** application to the next and does not allow a drop to be directed into the bottle **12** interior **118**.

The mixture of heated sterile air and atomized hydrogen peroxide in conduit **348** passes through the double tube heat exchanger **350**. The double tube heat exchanger **350** adds additional heat to the atomized hydrogen peroxide. Heat is supplied to the double tube heat exchanger **350** from the steam supply **354** controlled by the regulator valve **360**. Generally, hydrogen peroxide has chemical stabilizers in it that may cause a white powder precipitate to form on the inner surfaces of the double tube heat exchanger **350**. This occurs when the temperature differential between the supplied steam heat and the gas to be heated is large. In the present inventions the temperature of the atomized hydrogen peroxide is typically about the same as the supplied steam heat so that a minimal amount of precipitate occurs. Another embodiment of the invention eliminates the need for the double tube heat exchanger **350** because the temperature of the atomized hydrogen peroxide is already at the desired temperature.

The temperature of the atomized gas entering the interior **118** of the bottle **12** is in the range of about 100° C. to 120° C. This temperature is limited to prevent the plastic bottles **12** from melting. The droplet size occurring on the interior surface **119** of the bottles **12** is in the range of about 300 to 500 micrometers. The initial concentration level of hydrogen peroxide on the interior surface **119** of the bottle **12** is about 35%.

As illustrated in FIG. **21**, the control system **550** monitors the temperatures at locations denoted as "T" in the interior bottle sterilization apparatus **116**. The temperatures "T" are measured in the conduit **348**, in the heater **368**, and in the conduit **370**. Additionally, the control system **550** monitors the pressures at locations denoted as "P" as illustrated in FIG. **21**. The pressures "P" are measured in the conduit **328**, conduit **338**, and in the conduit **382**.

The control system **550** monitors and controls a spray apparatus **126** that includes the probe **123** including the applicator spray nozzles **122** FIG. **10**. Each applicator spray nozzle **122** sprays the sterilant into the interior **118** of a corresponding bottle **12** as a hot vapor fog. The probe **123** including applicator spray nozzles **122** are designed to extend through the bottle openings **16**. The probe **123** including 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 probe **123** including 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 sterilization 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 sterilization 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 supply sources (e.g., conduits **140**, **142**, and **144**) into the sterilization 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**. For example, with the sterilant hydrogen peroxide, the concentration level of hydrogen peroxide is about 1000 ppm (parts per million) in the fourth sterilization zone **165**. The hydrogen peroxide sterilant level is about 3 ppm in the first sterilization zone **164**. The lowest concentration level of sterilant is in the second sterilization zone **166**. In the second sterilization zone **166**, the hydrogen peroxide sterilant concentration level is less than 0.5 ppm and typically about 0.1 ppm. 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. The hydrogen peroxide sterilant concentration level is about 0.1 ppm in the third sterilization zone **172**.

As illustrated in FIG. **3**, a gas such as hot sterile air enters the first sterilization zone **164** at a rate of about 2400 cfm (cubic feet per minute). The temperature of the hot sterile air is about 230° F. The hot sterile air enters the first sterilization zone **164** through conduit **148**. Additional hot sterile air enters the second sterile zone through sterile air conduits **140**, **142**, and **144** at a total rate of about 1000 cfm (FIG. **3**). Also, hot sterile air enters at a rate of about 1800 cfm through ports **67** and **68** leading into the infeed and sterilization apparatus **60**. A portion of the hot sterile air exits the sterilization tunnel **90** at a rate of about 1500 cfm through a plurality of exhaust ports **153** located in the first sterilization zone **164** (FIG. **15**). A portion of the hot sterile air exits the sterilization tunnel **90** at a rate about 100 cfm through an opening **282** (FIG. **14**). The bottles **12** exit the sterilization tunnel **90** through the opening **282**. The continuous flow of sterile air flow out through the opening **282** prevents contaminants from entering the sterilization tunnel **90**.

As illustrated in FIG. **3**, the hot sterile air is drawn out of the fourth sterilization zone **165** of the sterilization tunnel **90** through the bottom opening **62** in the bottle infeed and sterilization apparatus **60**. Next, the hot sterile air from the infeed and sterilization apparatus together with the fourth sterilization zone **165** exits out of the exhaust conduit **70** of the infeed and sterilization apparatus at a rate of about 3600 cfm. This outflow of hot sterile air from the bottle infeed and sterilization apparatus **60** prevents contaminants from entering the bottle infeed sterilization apparatus **60** and the sterilization tunnel **90**.

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**. In these twelve stations, a third supply of hot sterile air is provided through the sterile air supply system **146**. The sterile air supply system **146** supplies hot sterile air to a plurality of nozzles **150** in the activation and drying apparatus **152**. The hot sterile air flow in each bottle **12** is about 40 SCFM. 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 it the air pressure and flow rate to ensure that an adequate flow of hot sterile air is maintained in the sterilization 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 is 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 buildup 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 in the cups **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 **203** that holds them together to form a long continuous chain of lids **200**, hereinafter referred to as a "daisy chain" **202**. The daisy chain **202** of lids is illustrated in FIGS. **17**. 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**. The concentration of hydrogen peroxide can range from about 30 to 40%, however, preferably the concentration is about 35%. Each lid **200** remains in the hydrogen peroxide bath **204** for at least 18 seconds. 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 temperature is about 135° C. The hot air knives **208** also remove excess hydrogen peroxide from the lids **200**. A plurality of heated platens **205** further dry 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 sterilization tunnel **90** via the lidding operation.

Once sterilized, the lids **200** enter the sterilization 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.

Another embodiment of a lid sterilization and heat sealing apparatus **552** is illustrated in FIG. **19**. As illustrated in FIG. **18**, the daisy chain **215** of lids **200** includes a hole **207**

located in each interconnecting band **203**. Each hole **207** receives a pin **209** of a drive sprocket **211**.

The daisy chain **215**A, **215**B of lids **200** is placed on each of a plurality of reels **210** (e.g. **210**A and **210**B). For the twelve bottle configuration of the present invention, six of the reels **210**, each holding a daisy chain **215**A, **215**B of lids **200**, are located on each side of a heat sealing apparatus **214**. Each daisy chain **215**A, **215**B of lids **200** winds off of a corresponding reel **210** and is sterilized preferably using a hydrogen peroxide bath **204**. The concentration of hydrogen peroxide can range from about **30** to 40%, however, preferably the concentration is about 35%. The lids **200** remain in the hydrogen peroxide bath **204** for at least 18 seconds. 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 **215**A, **215**B. The hot sterile air temperature is about 135° C. The hot air knives **208** also remove excess hydrogen peroxide form the lids **200**. A plurality of heated platens **205** further dry 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 sterilization tunnel **90** via the lidding operation. The drive sprocket **211**A includes a plurality of pins **209** that engage with the holes **207** of the daisy chain **215**A. The drive sprocket **211**A rotates in a counterclockwise direction and indexes and directs the daisy chain **215**A, through a plurality of guides **217**A. The guides **217**A may include a plurality of rollers **221**A to further guide and direct an end **219**A of the daisy chain **215**A over the bottle **12**A. The drive sprocket **211**B includes a plurality of pins **209** that engage with the holes **207** of the daisy chain **215**B. The drive sprocket **211**B rotates in a clockwise direction and indexes and directs the daisy chain **215**B through a plurality of guides **217**B. The guides **217**B may include a plurality of rollers **221**B to further guide and direct an end **219**B of the daisy chain **215**B over the bottle **12**B.

Once sterilized, the lids **200** enter the sterilization tunnel **90** where they are separated from the daisy chain **215**A, **217**B and placed on the bottle **12**A, **12**B. At station **33**, the lids **200** are applied to the bottles **12**. As illustrated in FIGS. **13** and **20**, 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**A, **12**B. Although lidding for a bottle has been described, it should be appreciated that lidding of other containers (e.g. jars) can be provided by the present invention. FIG. **20** illustrates a perspective view of the heat sealing apparatus **214**, the daisy chain **215**A, the gripper apparatus **554**, the bottle **12**A, and the conveying plate **94**. The lid **200** is its located above the bottle opening **16**. The gripper apparatus **554** includes a grip **223** for capturing the bottle **12**A by a bottle lip **225**. The gripper apparatus **554** lifts the bottle **12**A in an upward direction so that the lid **200** is pressed between a bottle top lip **227** and the heated platen **216**. The interconnecting band **203** severs and separates the lid **200** on the bottle **12** from the next lid on the daisy chain **215**A. The heated platen **216** is in a two by six configuration to seal twelve of the bottles **12** at a time. There is a separate gripper apparatus **554** for each of the twelve bottles **12**. After each bottle **12** is sealed, its gripper apparatus **554** lowers and releases the bottle **12** and each bottle **12** continues to station **37**.

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 sterilization 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 the opening **282** in the sterilization 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 sterilization tunnel **90**. In order to ensure that contaminated air cannot enter the sterilization tunnel **90**, the sterile air in the sterilization tunnel **90** is maintained at a higher pressure than the air outside the sterilization tunnel **90**. Thus, sterile air is always flowing out of the sterilization tunnel **90** through the opening **282**. In addition, the gripper **288** never enters the sterilization tunnel **90**, because the top portion **284** of the bottle **12** is first lifted out of the sterilization 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 sterilization tunnel **90** because each of the bottles **12** have previously been sealed within the sterilization 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 with is used to dry the main conveyor **106** and conveying plates **94**.

Stations **1** through **40** are enclosed in the sterilization tunnel **90**. The sterilization tunnel **90** is supplied with air that is pressurized and sterilized. The interior of the sterilization 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 sterilization tunnel **90**, the sterile air supply provides a predetermined number of air changes (e.g., 2.5 changes of air per minute) in the sterilization tunnel **90**.

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 sterilization 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 following steps are performed during the "Clean In Place" (CIP) process in the filler apparatus **50**;

23. Conductivity sensor to verify caustic and acid concentrations.

24. Temperature sensor to verify "Clean In Place" solution temperatures.

25. Flow meter to verify "Clean In Place" flow rates.

26. Time is monitored to ensure that adequate cleaning time is maintained.

The follow steps are performed during sterilization of the bottle filler apparatus **50**;

27. Temperature sensors for measuring steam temperatures.

28. Proximity sensors to ensure filler nozzle cleaning/sterilization cups are in position.

29. Temperature sensors for air heating and cooling.

30. Flow meter for hydrogen peroxide injection.

31. Time is monitored to ensure the minimum time periods are met (steam, hydrogen peroxide application and activation/drying).

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.

We claim:

1. Apparatus for sterilizing a container comprising:

a first supply source of sterile air;

a supply source of sterilant;

an atomizing system producing an atomized sterilant from the mixing of the sterile air from the first supply source of sterile air with the sterilant;

a second supply source providing a non-intermittent supply of hot sterile air to a conduit wherein said conduit is operationally coupled between said atomizing system and a container, and wherein said atomized sterilant is intermittently added to said conduit;

a mechanism for applying the atomized sterilant and the second supply source of hot sterile air on to the container; and

a third supply source of a hot sterile drying air for activating and drying the sterilant in the interior of the container, wherein the container is upright.

2. The apparatus of claim **1**, further including a heater for adding additional heat to the atomized sterilant.

3. The apparatus of claim **1**, wherein the container is a bottle.

4. The apparatus of claim **1**, wherein the sterilant is hydrogen peroxide.

5. The apparatus of claim **1**, wherein the atomizing system further includes an atomizing venturi.

6. The apparatus of claim **1**, wherein the second supply source of non-intermittent hot sterile air further includes a humidity control system for maintaining the humidity of the hot sterile air.

7. The apparatus of claim **1**, wherein after drying the container interior surface retains a concentration of hydrogen peroxide less than 0.5 PPM.

8. The apparatus of claim **7**, wherein the third supply source of hot sterile drying air is applied to the container for about 24 seconds.

9. The method of claim **8**, wherein the step of providing a second supply of non-intermittent hot sterile air further includes providing a humidity control system for maintaining the humidity of the non-intermittent hot sterile air.

10. The apparatus of claim **1**, wherein said atomized sterilant is only added to said conduit per each application of atomized sterilant and the second supply source of hot sterile air on to the container.

11. The apparatus of claim **1**, wherein said second supply source is provided only during operation of said apparatus.

12. The apparatus of claim **1**, wherein the supply source of sterilant further includes a spoon dipper apparatus.

13. A method for sterilizing a container comprising:

providing a first supply of sterile air;

providing a supply of sterilant;

producing an atomized sterilant by mixing the first supply of sterile air with the sterilant;

applying the atomized sterilant to the container;

supplying a third supply of hot sterile drying air for activating and drying the sterilant in the interior of the container, wherein the container is upright and plastic; and

applying the third supply of hot sterile drying air to the container for about 24 seconds, wherein the interior of the container immediately after the applying retains a concentration of hydrogen peroxide of less than 0.5 PPM.

14. The method of claim **13**, further including the step of providing a heater for adding additional heat to the atomized sterilant.

15. The method of claim **13**, wherein the container is a bottle.

16. The method of claim **13**, wherein the sterilant is hydrogen peroxide.

17. The method of claim **13**, wherein the step of producing an atomized sterilant further includes providing an atomizing venturi for mixing the first supply of sterile air with the sterilant.

18. The method of claim **13**, further comprising:

providing a conduit operationally coupled between the container and a location where said atomized sterilant is produced;

providing a second supply of non-intermittent hot sterile air to the conduit;

adding the atomized sterilant to the conduit intermittently; and further wherein the applying the atomized sterilant step includes applying a mixture of the non-intermittent hot sterile air and the atomized sterilant to the container.

19. The method of claim 18, wherein the adding the atomized sterilant is done per each said applying said mixture.

20. The method of claim 18, wherein said providing a second supply is done during operation of said method.

21. The method of claim 13, wherein providing a supply of sterilant further includes providing a spoon dipper apparatus for measuring a quantity of the sterilant.

22. Apparatus comprising:

means for supplying a first source of sterile air;

means for supplying a source of sterilant, including a spoon dipper apparatus;

means for providing an atomizing system for producing an atomized sterilant from the mixing of sterile air from the first source of sterile air with the sterilant;

means for applying a second source of hot sterile air non-intermittently to a volume;

means for applying the atomizing sterilant intermittently to the volume thereby mixing the second source of non-intermittent hot sterile air with the atomizing sterilant;

means for applying the mixture of atomized sterilant and the second source of non-intermittent hot sterile air to a container; and

means for supplying a third source of hot sterile drying air into the interior of the container for activating and drying the sterilant, wherein the container is upright.

23. The apparatus of claim 22, wherein the means for supplying a third source of hot sterile drying air further includes a means for providing a residual concentration of hydrogen peroxide less than 0.5 PPM.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

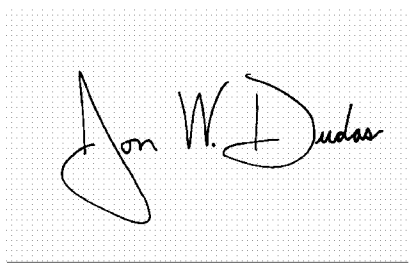
PATENT NO. : 6,702,985 B1
DATED : March 9, 2004
INVENTOR(S) : Taggart et al.

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

Column 5,
Line 40, insert -- sterilization apparatus 60 -- after the word "and".

Signed and Sealed this

Eighteenth Day of May, 2004



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

US006702985C1

(12) EX PARTE REEXAMINATION CERTIFICATE (10235th)

United States Patent

Taggart et al.

(10) Number: US 6,702,985 C1

(45) Certificate Issued: Jul. 31, 2014

(54) **APPARATUS AND METHOD FOR PROVIDING CONTAINER INTERIOR STERILIZATION IN AN ASEPTIC PROCESSING APPARATUS**

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(51) **Int. Cl.**
B67C 7/00 (2006.01)

(52) **U.S. Cl.**
CPC *B67C 7/0073* (2013.01)
USPC **422/28**; 222/356; 422/302

(58) **Field of Classification Search**
None
See application file for complete search history.

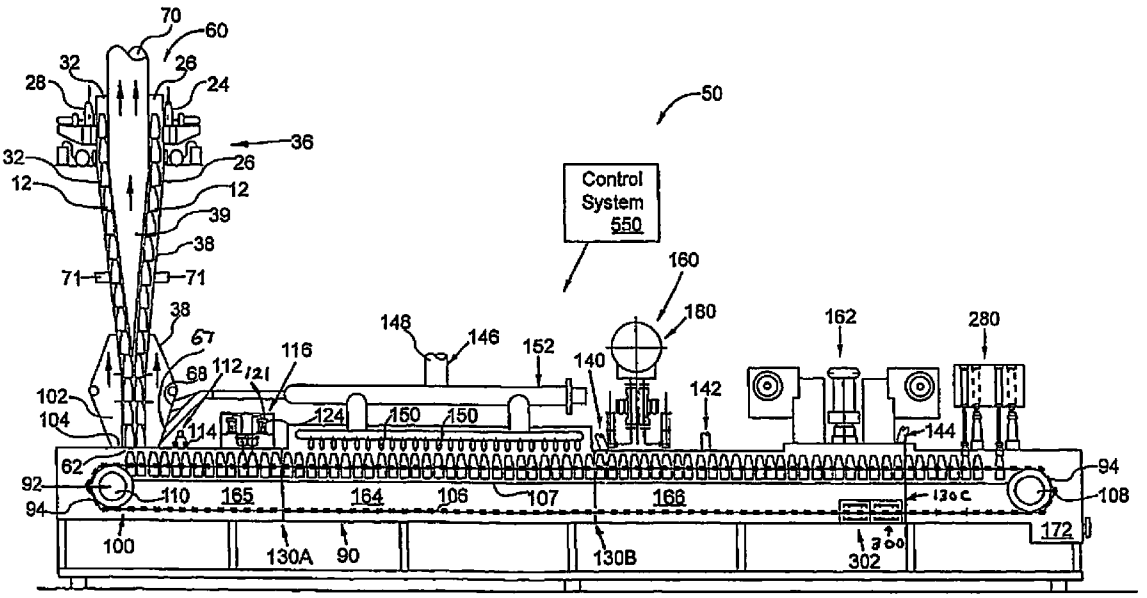
(56) **References Cited**

To view the complete listing of prior art documents cited during the proceeding for Reexamination Control Number 90/012,528, please refer to the USPTO's public Patent Application Information Retrieval (PAIR) system under the Display References tab.

Primary Examiner — Sean E Vincent

(57) **ABSTRACT**

An apparatus and method for providing container interior sterilization in an aseptic processing apparatus. An atomized sterilant is applied to an interior surface of a container such as a bottle. A supply of hot sterile drying air is applied to the interior surface to activate and dry the sterilant.



EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims **1-8** and **10-12** is confirmed.

Claims **9**, **22** and **23** are cancelled.

Claims **13** and **18** are determined to be patentable as amended.

Claims **14-17** and **19-21**, dependent on an amended claim, are determined to be patentable.

New claims **24-36** are added and determined to be patentable.

13. A method for sterilizing a container comprising:

providing a first supply of sterile air;

providing a supply of sterilant;

producing an atomized sterilant by mixing the first supply of sterile air with the sterilant;

providing a conduit operationally coupled between the container and a location where said atomized sterilant is produced;

adding the atomized sterilant to the conduit;

providing a second supply of hot sterile air to the conduit;

mixing the second supply of hot sterile air with the atomized sterilant;

applying the *mixture of* atomized sterilant *and the second supply of hot sterile air* to the container;

supplying a third supply of hot sterile drying air for activating and drying the sterilant in the interior of the container, wherein the container is upright and plastic; and

applying the third supply of hot sterile drying air to the container for about 24 seconds, wherein the interior of the container immediately after the applying retains a concentration of hydrogen peroxide of less than 0.5 PPM.

18. The method of claim **13**, **[**further comprising:

providing a conduit operationally coupled between the container and a location where said atomized sterilant is produced;

providing a second supply of non-intermittent hot sterile air to the conduit;**]**

wherein the adding the atomized sterilant *includes adding the atomized sterilant* to the conduit intermittently; and

[further**]**

wherein the **[**applying the atomized sterilant step includes applying a mixture of the non-intermittent hot sterile air and the atomized sterilant to the container**]** *providing a second supply of hot sterile air to the conduit includes providing the second supply of hot sterile air to the conduit non-intermittently.*

24. Apparatus for sterilizing a container comprising:

a first supply source of sterile air;

a supply source of sterilant;

an atomizing system producing an atomized sterilant from the mixing of the sterile air from the first supply source of sterile air with the sterilant;

a second supply source providing a non-intermittent supply of hot sterile air to a conduit wherein said conduit is operationally coupled between said atomizing system and a container, and wherein said atomize sterilant is intermittently added to said conduit;

a mechanism for applying the atomized sterilant and the second supply source of hot sterile air on to the container;

a third supply source of a hot sterile drying air for activating and drying the sterilant in the interior of the container, wherein the container is upright; and

a control system including a concentration sensor to monitor a concentration of the atomized sterilant.

25. The apparatus of claim 24, wherein the control system further includes a flow rate sensor to monitor a flow rate.

26. The apparatus of claim 24, further comprising a container conveying system configured to carry containers in a downstream direction through a zone including a sterilization apparatus, a zone including a filler apparatus, and a zone including a bottle discharge apparatus, wherein each of said zones is separate and distinct.

27. The apparatus of claim 26, wherein the zone including a sterilization apparatus, the zone including a filler apparatus, and the conveying system are configured to maintain containers on the conveying system at a substantially constant temperature for at least five seconds after application of the atomized sterilant and the second supply source of hot sterile air to the containers as the containers travel through the zone including a sterilization apparatus toward the zone including a filler apparatus.

28. Apparatus for sterilizing a container comprising:

a first supply source of sterile air:

a supply source of sterilant;

an atomizing system producing an atomized sterilant from the mixing of the sterile air from the first supply source of sterile air with the sterilant;

a second supply source providing a non-intermittent supply of hot sterile air to a conduit wherein said conduit is operationally coupled between said atomizing system and a container, and wherein said atomized sterilant is intermittently added to said conduit;

a mechanism for applying the atomized sterilant and the second supply source of hot sterile air on to the container;

a third supply source of a hot sterile drying air for activating and drying the sterilant in a interior of the container, wherein the container is upright; and

a container conveying system configured to carry containers in a downstream direction through a zone including a sterilization apparatus, a zone including a filler apparatus, and a zone including a bottle discharge apparatus, wherein each of said zones is separate and distinct.

29. The apparatus of claim 28, further comprising a control system including a flow rate sensor.

30. The apparatus of claim 29, further comprising the control system including a concentration sensor to monitor a concentration of the atomize sterilant.

31. The apparatus of claim 28, further comprising a delivery apparatus for the third supply source of hot sterile air, wherein the delivery apparatus is configured to deliver the third supply of hot sterile air upstream away from the zone including a filler apparatus.

32. The apparatus of claim 28, wherein the zone including a sterilization apparatus, the zone including a filler appara-

tus, and the conveying system are configured to maintain containers on the conveying system at a substantially constant temperature for at least five seconds after application of the atomized sterilant and the second supply source of hot sterile air to the containers as the containers travel through the zone including a sterilization apparatus toward the zone including a filler apparatus.

33. Apparatus for sterilizing a container comprising:

a first supply source of sterile air;

a supply source of sterilant:

an atomizing system producing an atomized sterilant from the mixing of the sterile air from the first supply source of sterile air with the sterilant;

a second supply source providing a non-intermittent supply of hot sterile air to a conduit wherein said conduit is operationally coupled between said atomizing system and a container, and wherein said atomized sterilant is intermittently added to said conduit;

a mechanism for applying the atomized sterilant and the second supply source of hot sterile air on to the container;

a third supply source of a hot sterile drying air for activating and drying the sterilant in the interior of the container, wherein the container is upright; and

a container conveying system configured to carry containers in a downstream direction through a zone including a sterilization apparatus, a zone including a filler apparatus, and a zone including a discharge apparatus, each of said zones being defined at least in part by one or more partitions,

wherein the zone including a filler apparatus is at a higher pressure than the zone including the sterilization apparatus and the zone including the discharge apparatus such that any gas flow leakage occurs in a direction away from the zone including the filler operation.

34. The apparatus of claim 33, further comprising a control system including a flow rate sensor.

35. The apparatus of claim 33, further comprising a control system including a concentration sensor to monitor a concentration of the atomized sterilant.

36. The apparatus of claim 33, wherein the zone including a sterilization apparatus, the zone including a filler apparatus and the conveying system are configured to maintain containers on the conveying system at a substantially constant temperature for at least five seconds after application of the atomized sterilant and the second supply source of hot sterile air to the containers as the containers travel through the zone including a sterilization apparatus toward the zone including the filler apparatus.

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 23-1790

Short Case Caption: Steuben Foods, Inc. v. Shibuya Hoppmann Corporation, et al.

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