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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NESTLÉ USA, INC.,
Petitioner,

v.

STEUBEN FOODS, INC.,
Patent Owner.

Case IPR2015-00195
Patent 6,475,435 B1

Before MICHAEL P. TIERNEY, BEVERLY M. BUNTING, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

PAULRAJ, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. *§ 318(a) and* 37 C.F.R. *§ 42.73*

I. BACKGROUND

Nestlé USA, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–10, 14, 16–21, 25, 27, 29, and 32–36 of U.S. Patent No. 6,475,435 B1 (Ex. 1001, "the '435 patent"). Paper 1 ("Pet."). Steuben Foods, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Papers 22, 30 ("Prelim. Resp."). Taking into account the Petition and Patent Owner's Preliminary Response, we determined that there was a reasonable likelihood that challenged claims 1–10, 14, 16–21, 25, 27, 29, and 32–36 are unpatentable. Pursuant to 35 U.S.C. § 314, we instituted *inter partes* review, on June 3, 2015, as to those claims of the '435 patent. Paper 38 ("Inst. Dec."); Paper 51 (redacted version).

After institution, Patent Owner filed a Patent Owner Response. Paper 57 ("PO Resp."). Petitioner filed a Reply to the Patent Owner Response. Paper 61 ("Pet. Reply"). In accordance with our authorization (Paper 69), Patent Owner filed a Sur-Reply addressing the arguments presented on pages 6–9 of Petitioner's Reply. Paper 76 ("PO Sur-Reply").

Additionally, Patent Owner filed a Motion to Exclude Evidence (Paper 73), to which Petitioner filed an Opposition (Paper 79). Patent Owner filed a Reply in Support of its Motion to Exclude (Paper 85). Petitioner also filed a Motion to Exclude Evidence (Paper 75), to which Patent Owner filed an Opposition (Paper 80). Petitioner filed a Reply to Patent Owner's Opposition to its Motion to Exclude (Paper 84).

A hearing was held on January 27, 2016, a transcript of which appears in the record. Record of Oral Hearing, Paper 92 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(c). This decision is a Final Written Decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 as to the

patentability of the challenged claims. For the reasons discussed below, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–10, 14, 16–21, 25, 27, 29, and 32–36 are unpatentable.

A. Related Proceedings

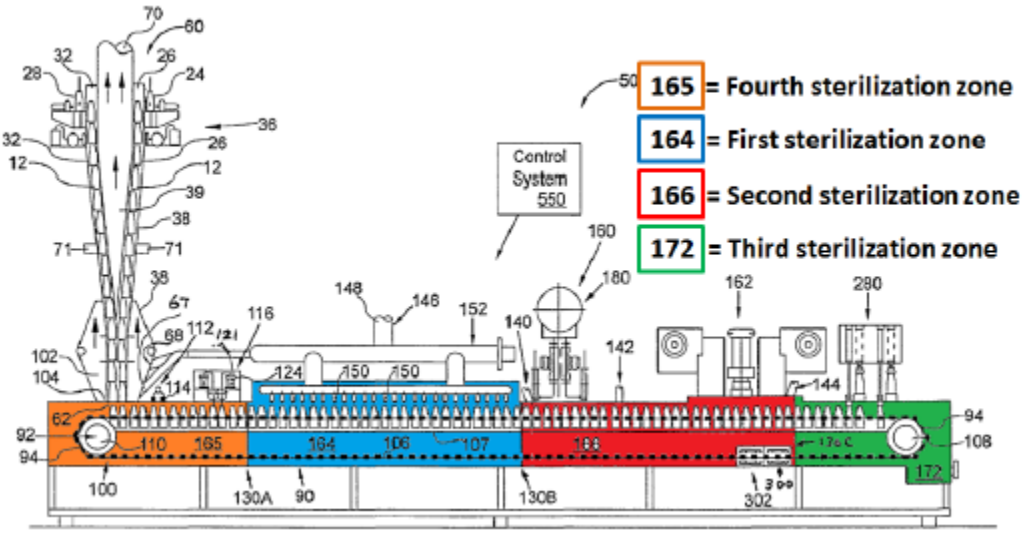
The parties identify several related matters, including the pending litigation in the U.S. District Court for the Western District of New York: *Steuben Foods, Inc. v. Nestle, USA*, No. 1:13-cv-00892 (filed Sept. 3, 2013). Pet. 58–59; Paper 8, 2–3. The '435 patent was challenged in IPR2014-00043 (terminated). Pet. 58–59; Paper 8, 2–3; *GEA Process Eng., Inc. v. Steuben Foods, Inc.*, Case IPR2014-00043 (PTAB Dec. 23, 2014) (Paper 114). The '435 patent is also the subject of *ex parte* reexamination proceedings (control nos. 90/012,135 and 90/013,458), which have been merged and are currently ongoing.

B. The '435 Patent (Ex. 1001)

The '435 patent claims the benefit of the filing date of a provisional application filed on February 2, 1999. Ex. 1001, [22], [60], 1:6–7.

The '435 patent is directed to an apparatus and method for providing sterilization zones in an aseptic packaging sterilization tunnel that surrounds a plurality of containers with pressurized gas. *Id*. at 1:12–14, 3:30–31. The sterilization tunnel comprises a plurality of sterile zones created by a plurality of partitions and a plurality of hot sterile air supply sources (e.g., conduits). *Id*. at 2:46–48, 3:20. In particular, the '435 patent describes a first sterilization zone that includes an activation and drying apparatus, a second sterilization zone that includes the main product filler apparatus and lid sterilization and heat sealing apparatus, a third sterilization zone that includes a bottle discharge apparatus, and a fourth sterilization zone that

includes an interior bottle sterilization apparatus. *Id.* at 9:29–39. An annotated version of Figure 3 of the '435 patent is reproduced below:



The Figure above shows the first sterilization zone 164 (blue), the second sterilization zone 166 (red), the third sterilization zone (green), and the fourth sterilization zone (orange). Sterile air is supplied to the sterilization tunnel via a number of interfaces, including "through conduit 148" and "conduits 140, 142, and 144." *Id.* at 10:3–9. Sterile air is applied directly to bottles via a "plurality of nozzles" to activate and dry a hydrogen peroxide (H_2O_2) sterilant. *Id.* at 10:32–45. Additionally, sterile air can exit the tunnel from various interfaces at different rates, including "through a plurality of exhaust ports 153 located in the first sterilization zone 164" at a rate of about 1500 cfm, "through an opening 282" at a rate of about 100 cfm, and "out of the exhaust conduit 70 of the infeed and sterilization apparatus at a rate of about 3600 cfm." *Id.* at 10:12–17, 10:24-28. Partitions 130A, 130B, and 130C help control sterile air flow within the sterilization tunnel, and are provided with "cut-outs" to allow bottles and the conveyer belt to pass through. *Id.* at 8:62–9:8.

The aseptic sterilant used in the apparatus may be H_2O_2 with a concentration of less than about 35%. *Id*. at 2:23–24, 5:2–4. "The sterile zones provide a plurality of sterilant concentration levels within the sterilization tunnel." *Id*. at 2:48–50, 3:20–21, 16:52. For example, the '435 patent provides an embodiment wherein the sterilant concentration is highest at about 1000 parts per million (ppm) in the bottle sterilizer zone. *Id*. at 9:38–39, 9:51–10:2. In contrast, the sterilant concentration is the lowest, less than 0.5 ppm and typically about 0.1 ppm, in the filling zone, thereby preventing unwanted high levels of sterilant to enter the food product during filling. *Id*. at 9:59–66. In addition, the sterile zones have a plurality of gas flow rates within the sterilization tunnel, wherein gas flow is in the direction from the first sterilization zone to the fourth sterilization zone. *Id*. at 2:50–51, 3:39–40, 9:48–50.

C. Illustrative Claim

Petitioner challenges claims 1–10, 14, 16–21, 25, 27, 29, and 32–36 of the '435 patent. Claims 1, 4, 17, and 33 are independent claims. Claim 1 is illustrative and is reproduced below:

> 1. Apparatus comprising:
>
> a sterilization tunnel for surrounding a plurality of containers with pressurized gas; and
>
> a plurality of zones within the sterilization tunnel having different sterilant concentration levels therein wherein the sterilant concentration levels in the plurality of zones are maintained at a ratio of at least about 5 to 1.

D. Grounds for Unpatentability

We instituted *inter partes* review of the '435 patent based upon the following grounds of unpatentability:

A. Obviousness of claims 1–10, 14, 16–21, 25, 27, 29, and 32–36 over Scholle,[1] Chambers,[2] the FDA Regulations,[3] Biewendt,[4] Kelbrick,[5] Elliott,[6] Akai,[7] and Kodera;[8]

B. Obviousness of claims 1–10, 14, 16–21, 25, 27, 29, and 32–36 over Biewendt, Chambers, the FDA Regulations, Buchner,[9] ZFL,[10] Scholle, Kelbrick, Akai, Kodera, and Elliott.

Inst. Dec. 27.

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[1] U.S. Patent No. 4,417,607 for "Apparatus and Method for Aseptically Filling Flexible Containers," issued November 29, 1983 to William R. Scholle, et. al. ("Scholle") (Ex. 1005).

[2] J. Chambers et al., Principles of Aseptic Processing and Packaging, The Food Processors Institute (2d ed. 1993) ("Chambers") (Ex. 1014).

[3] 21 C.F.R. § 178.1005 (Apr. 1, 1996) ("FDA Regulations") (Ex. 1013).

[4] H.-G. Biewendt et al., Report on the Type Testing of the Aseptic Filling and Sealing Plant for Glass Bottles for UHT Milk (1996) ("Biewendt") (Ex. 1024). Ex. 1024 replaces the version of Biewendt originally filed with the Petition (Ex. 1006).

[5] U.S. Patent No. 5,534,222 for "Method for Sterilizing Internal Surfaces of an Edible Liquid Packaging Machine," issued July 9, 1996, to William J. Kelbrick, et. al. ("Kelbrick") (Ex. 1007).

[6] P. Elliott et al., Microbiologists Evaluation of Low- Acid Aseptic Fillers, J. Food Tech. (May 1992) ("Elliott") (Ex. 1015).

[7] EP 0 384 535 for "Apparatus for supplying hydrogen peroxide for sterilization" published August 29, 1990, listing inventors Tado Akai et al. ("Akai") (Ex. 1008).

[8] U.S. Patent 4,427,772, issued January 24, 1984 to Yasuo Kodera et al. ("Kodera") (Ex. 1009).

[9] N. Buchner, Aseptic Production and Filling Methods in the Pharmaceutical and Foodstuff Industries, Pharma Technologie Journal, Concept Heidelberg (including translation) ("Buchner") (Ex. 1011).

[10] N. Buchner, Aseptic Filling of Glass and Plastic Containers, ZFL Magazine (1989) ("ZFL") (Ex. 1010).

II. DISCUSSION

A. Time Bar Under 35 U.S.C. § 315(b)

Patent Owner contends that GEA Process Engineering, Inc. ("GEA") was served with a complaint alleging infringement of the '435 patent more than one year before the Petition was filed, and because GEA is a privy of Petitioner, the Petition is time barred under 35 U.S.C. § 315(b). *See* PO Resp. 43–54. Prior to institution, Patent Owner's arguments regarding privity were based primarily on Petitioner's agreement to indemnify GEA as part of Petitioner's purchase of a bottling machine from GEA ("the Line 8 Agreement," Ex. 2046).[11] Prelim. Resp. 5–32.

The question of whether Petitioner is time-barred under § 315(b) is considered part of the determination of whether to institute an *inter partes* review. *See Achates Reference Publ'g, Inc. v. Apple Inc.*, 803 F.3d 652, 657–59 (Fed. Cir. 2015). In our Institution Decision, we determined that the district court complaint filed by Patent Owner against GEA did not time bar the Petitioner under § 315(b) because Patent Owner had not provided a sufficient factual basis upon which to conclude that Petitioner and GEA are privies.[12] *See* Inst. Dec. 6–17. In particular, we were not persuaded that the Line 8 Agreement shows that Petitioner and GEA have a substantive legal relationship or that Petitioner and GEA shared control of this *inter partes*

[11] Petitioner purchased seven bottling machines from GEA and GEA's predecessor, Procomac SpA. Paper 81, 2. These seven machines were purchased in three groupings: (1) lines 1–5, (2) line 6/7, and (3) line 8. Patent Owner explains that line 7 is sometimes referred to as line 6, and for that reason we refer to it as "line 6/7." Paper 87, 2 n.3.

[12] Patent Owner's exhibits 2001–2046 were entered prior to Institution. Patent Owner Exhibits 2047–2065 were submitted in conjunction with the Patent Owner Response (post-institution).

review and/or the related litigation in the manner required for a privity relationship. *Id.* We incorporate that analysis here, and reconsider Patent Owner's contention only to the extent it is warranted by subsequent argument and evidence.[13] *See Achates*, 803 F.3d at 658 ("The Board's reconsideration of the time-bar [in the final determination] is 'still fair[ly] characterize[ed] as part of the decision to institute.") (citations omitted).

Since our Institution Decision, the only new arguments made by Patent Owner with regard to its privity assertion relate to the purchase of certain other aseptic bottling machines, as reflected in the agreements for lines 1–6/7. According to Patent Owner, Petitioner and GEA are privies because these agreements obligate Petitioner to indemnify GEA for lines 1-6/7 in addition to the indemnification for line 8. PO Resp. 43–54. Patent Owner makes three supporting contentions.

First, Patent Owner contends that the machines purchased by Petitioner for lines 1–6/7 were made and built to Petitioner's specifications, quoting the following excerpt from Exhibit 2011:

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

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

PO Resp. 44 (citing Ex. 2011). Exhibit 2011 is printout of a website that is dated January 22, 2015, titled "GEA Procomac Bottling Plants." The Exhibit does not mention the sale of lines 1–6/7 to Petitioner. Although the Exhibit states that GEA Procomac was acquired by GEA Group in April 2007, the Exhibit neither states nor implies how long GEA Procomac had been designing and manufacturing customized bottling plants.

Second, Patent Owner asserts that Petitioner was subject to the version of the Uniform Commercial Code adopted as the California Commercial Code, citing Exhibit 2062 as proof of where Petitioner does business. PO Resp. 45. Exhibit 2062 provides no information about the purchase of lines 1–6/7. Moreover, Patent Owner's arguments regarding the California Commercial Code rely upon an alleged indemnification obligation based on Petitioner's purchase of custom-made machines. PO Resp. 46. We previously held, with respect to the Line 8 Agreement, that indemnity does not create the type of substantive legal relationship that amounts to privity. Inst. Dec. 12–15.

Third, Patent Owner asserts that Petitioner has refused to produce the joint defense agreement between GEA and Petitioner. PO Resp. 48 (citing Ex. 2013). Exhibit 2013 is an email chain regarding a request from Patent Owner's counsel to Petitioner's counsel for any agreements between Petitioner and GEA that form the basis of a joint defense privilege, and the subsequent discussion. Ex. 2013, 8. We previously denied Patent Owner's motion to authorize a request for production of the joint defense agreement (JDA) between Petitioner and GEA. Paper 21. We noted that "Patent Owner does not state what useful information is to be gained from the JDA document sought, other than proving what is already acknowledged, that a

JDA exists between Petitioner and GEA." *Id.* at 3. More importantly, our prior analysis in the Institution Decision examined the joint defense relationship between Petitioner and GEA and explained that such relationship does not demonstrate privity. Inst. Dec. 11–12.

Petitioner's new arguments and evidence do not persuasively demonstrate that the machines purchased as lines 1–6/7 were built to Petitioner's specification, nor has Patent Owner demonstrated persuasively that the purchase agreements otherwise created privity between GEA and Petitioner. Even if the agreements for lines 1–6/7 were similar to the Line 8 Agreement as Patent Owner contends, we examined the relationship created by the Line 8 Agreement in detail, and determined that Petitioner and GEA were not privies. *See* Inst. Dec. 6–17. Given this, Patent Owner has added nothing new of significance since our Institution Decision.

It is worth noting that after Patent Owner's Response was submitted, Patent Owner sought and was denied additional discovery relating to the agreements for lines 1–6/7. Paper 77 (Patent Owner's Motion for Discovery), Paper 81 (Opposition), Paper 87 (Decision denying discovery). Also of note, our order regarding oral argument limited the parties to present arguments related to privity only to the extent that additional evidence came of record after institution of trial. Paper 83. At oral hearing, Patent Owner did not present any arguments on the merits regarding privity; rather, Patent Owner proffered an email indicating the possibility that additional information would be obtained from the related litigation. Tr. 68–75; *see also* Paper 88 (entering the email as Board Exhibit 3001, and noting that the email contained nothing of substance). Since that time, Patent Owner has not sought to enter any such information into the record.

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

B. Claim Construction

We interpret the claims of an unexpired patent using the broadest reasonable construction. *See* 37 C.F.R. § 42.100(b). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Based on the evidence of record at the time, we did not construe any claim terms in our Institution Decision. Inst. Dec. 17–18. Patent Owner, in its Patent Owner Response, argues that "sterilant concentration level" and "surrounding a plurality of containers with pressurized gas" require construction. PO Resp. 4–11. Petitioner, in its Reply, challenges Patent Owner's construction of "sterilant concentration level." Reply 3–5. We construe only those terms which are in controversy, and only to the extent necessary to resolve the controversy. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). Now, with the entire record fully developed, we address the party's contentions regarding "sterilant concentration levels" below and determine that no other term requires express construction.

Sterilant Concentration Levels

Patent Owner asserts that the broadest reasonable interpretation of the phrase "sterilant concentration levels" recited in the claims is "the amount of

airborne sterilant within a given zone." PO Resp. 10. Patent Owner contends that the plain and ordinary meaning of the phrase is "the amount of sterilant in the volume of pressurized gas in a given zone," and notes that sterilant concentration level can be expressed in "parts of sterilant" per "million parts gas" (ppm). *Id.* at 4. As support for its construction, Patent Owner points to the statement in the specification that "[t]he partitions 130A, 130B, and 130C create sterilization zones 164, 165, 166, and 172 with different concentration levels of ***gas laden sterilant*** (e.g., ***hydrogen peroxide in air***)." *Id.* at 5 (citing Ex. 1001, 9:51–53). Patent Owner further asserts that the specification's subsequent reference to concentration levels of H_2O_2 in different zones in terms of "ppm" refers to airborne concentrations. *Id.* (citing Ex. 1001, 9:54–10:2). Patent Owner also relies upon its expert, Andre Sharon, Ph.D., who concurs that the skilled artisan "would read the claims as referring to the airborne sterilant concentration within the zones as opposed to the sterilant concentration in the solution in the sterilant tank, or sterilant remaining in the bottles that are within the zone." *Id.* at 6 (citing Ex. 2056, ¶ 19).

Petitioner argues that Patent Owner's proposed construction of "sterilant concentration levels" should be rejected because the term "airborne" appears nowhere in the '435 patent claims or specification. Reply 3. Moreover, Petitioner contends that Patent Owner took a different position in its infringement contentions during the related litigation. *Id.* Petitioner also contends that Patent Owner's construction is ambiguous insofar as it does not address *where* the airborne concentration should be measured. *Id.* at 5.

We determine that the broadest reasonable interpretation consistent with the specification does not limit the claimed "sterilant concentration levels" to only airborne concentrations. We recognize that the specification, in one instance, refers to zones with "different concentration levels of gas laden sterilant (e.g., hydrogen peroxide in air)." Ex. 1001, 9:51–53. The specification, however, refers elsewhere to the "residual concentration" of H_2O_2, measured in terms of ppm. *Id.* at 12:46–47 ("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.") (emphasis added); *see also id.* at 11:15–17 ("After bottle 12 has dried, the residual hydrogen peroxide remaining *on the bottle 12 surface* is less than 0.5 PPM.") (emphasis added).

Patent Owner acknowledges that "[o]ther discussions of ppm within the specification are in the context of residual sterilant on the bottle," which is measured in accordance with the FDA Regulations (21 C.F.R § 178.1005(d) (Ex. 1013)) as the concentration in distilled water, but nonetheless asserts that "[t]his is consistent with the definition of 'sterilant concentration' in the context of the claim [as] parts of sterilant per million parts of carrier gas." PO Resp. 6. However, insofar as it is undisputed that "residual" sterilant concentrations on the bottle surface are disclosed in the specification and encompassed by the claim scope, Patent Owner does not explain why the skilled artisan would have understood such a concentration would be measured as parts of sterilant per million parts of carrier gas (i.e., airborne) as opposed to parts of sterilant per million parts of distilled water in accordance with the FDA Regulations. *See* Ex. 1013, 326 ("No use of hydrogen peroxide solution in the sterilization of food packaging material

shall be considered to be in compliance if more than 0.5 part per million of hydrogen peroxide can be determined in distilled water packaged under production conditions."). In short, neither the claims nor the specification limit how or where within "the plurality of zones" the sterilant concentration levels should be assessed in order to determine whether the 5 to 1 ratio is satisfied. As such, we find no basis to limit the claimed sterilant concentration levels to only airborne concentrations.

C. Overview of the Prior Art

1. Scholle (Ex. 1005)

Scholle is directed to an "Apparatus and Method for Aseptically Filling Flexible Containers." Ex. 1005, Title. Scholle describes an apparatus in which empty "presterilized" containers are fed through an entry port into a "tunnel-like, elongated chamber" for sterilization and filling. *Id.* at Abstract, 1:52–57. The chamber is "partitioned into three compartments, including a sterilizing compartment . . . a filling compartment . . . and a drying compartment, interposed" therebetween. *Id.* at 1:57-62. The chamber also has "an entry port, through which the empty containers are fed, and a dispensing port, through which the filled containers are dispensed," which "each have a seal, formed of elastomeric material with a slit therein, to reduce the risk of contaminant migration into the elongated chamber while permitting the containers to pass therethrough." *Id.* at 1:54–57, 63–66.

In operation, "[a] supply of sterilized air is continuously input to the filling compartment to pressurize the entire elongated chamber and provide a flow of sterile air therethrough to prevent entry of contaminants." *Id.* at 1:67-2:2. Scholle teaches using "a 30-percent solution of hydrogen peroxide

in water [i.e., 300,000 ppm H_2O_2]" as a sterilant. *Id.* at 5:18-22. Spray heads "atomize the hydrogen peroxide solution into a fine mist or fog, and spray such mist into the spraying compartment [], drying compartment [], filling compartment [], and dispensing mouth [], respectively." *Id.* at 5:22–26. Additionally, the flow of sterile air within the chamber maintains a positive pressure in the filling and drying compartments, which "reduces any tendency of the hydrogen peroxide mist in the spray compartment [] to migrate through the opening" in the partition dividing the compartments. *Id.* at 5:36–43, 6:36–43.

2. Chambers (Ex. 1014)

The Chambers reference is an excerpt from a book entitled "Principles of Aseptic Processing and Packaging" (Ex. 1014). Chambers teaches that the FDA approved the use of H_2O_2 for sterilization of aseptic packaging materials in 1981, but FDA regulations placed a limit of a final concentration of not more than 0.5 ppm after packaging." *Id.* at 60. Chambers further teaches that "[m]any aseptic packaging systems use H_2O_2 at concentrations of 30 to 35%." *Id.*

3. The FDA Regulations (Ex. 1013)

The FDA Regulations relied upon as prior art are set forth in the April 1, 1996 edition of 21 C.F.R. § 178.1005 (Ex. 1013). The FDA Regulations indicate that "hydrogen peroxide is an aqueous solution containing not more than 35 percent hydrogen peroxide . . . by weight." *Id.* at 326. Further, it provides that "[n]o use of hydrogen peroxide solution in the sterilization of food packaging material shall be considered to be in compliance if more than 0.5 part per million of hydrogen peroxide can be determined in distilled

water packaged under production conditions (assay to be performed immediately after packaging)." *Id.*

4. Biewendt (Ex. 1024)

The Biewendt reference, translated from German, is entitled "Report on the Type Testing of the Aseptic Filling and Sealing Plant for Glass Bottles for UHT [Unit Heat Treatment] Milk." Ex. 1024 at 1. The reference describes a system and process for aseptic sterilization and packaging of bottles developed by Robert Bosch GmbH (the "Bosch" system). "The complete process . . . . comprises the sterilization of the plant and the bottles, filling the milk into said bottles and sealing the bottles (=Production), as well as cleaning the plant after production is completed." *Id.* at 11. The Bosch system is depicted as comprising several interconnected sections or machines, including the bottle sterilizing machine, the aseptic filling machine, an aseptic tunnel, with a relatively reduced cross-section, that connects the sterilizing and filling machines, and the aseptic sealing machine. *Id.* at 2. In the bottle sterilization machine, during transport, the bottles are "sprayed with hydrogen peroxide (H_2O_2)". *Id.* at 3. In the aseptic filling machine, prior to filling, the bottles are "universally fogged with a warm hydrogen peroxide (H_2O_2) air mixture of defined concentration for a specified time and then universally blown dry with heated air." *Id.* at 17.

"To maintain aseptic conditions until production is completed, the sterilized aseptic areas of the plant are [] supplied with sterile air by the aseptic supply unit; the pressure of the aseptic supply unit is kept continuously around 20 Pa above the atmospheric pressure." *Id.* at 13; *see*

also id. at 18 ("The housing in which the sterilized bottles are transported, filled, and sealed, which is encapsulated from the atmosphere . . . . is loaded with sterile air until production is completed; the pressure of said air is kept approx. 20 Pa above the atmospheric pressure."). The sterilization media comprises a "minimum 33% H_2O_2". *Id.* at 11. Regarding the effectiveness of this sterilization method, the reference states that "[t]esting with Merckoquant 10 001 testing strips did not show any proof of contamination with H_2O_2 residue in filled UHT milk bottles." *Id.* at 18.

5. Kelbrick (Ex. 1007)

Kelbrick is directed to a "Method for Sterilizing Internal Surfaces of an Edible Liquid Packaging Machine." Ex. 1007, Title. Kelbrick discloses aseptic sterilization of containers whereby the containers are "first sprayed with aqueous hydrogen peroxide (preferably 33% H_2O_2) by means of a spray nozzle [], followed immediately by exposure of the sprayed containers to a series of hot air nozzles . . ." *Id.* at 2:34–37.

6. Elliott (Ex. 1015)

The Elliott reference is entitled "Microbiological Evaluation of Low-Acid Aseptic Fillers." Ex. 1015 at 116. The article discusses the methods used to establish critical factors for aseptic fillers and demonstrates the need for standardization. *Id.* The article describes how the operational limits for several critical factors or a "window of operation" for container sterilization can be created "by varying the peroxide dosage/container and the heated air temperature." *Id.* One edge of the "window of operation" is created "by varying these two critical factors to give the maximum allowable peroxide residual of 0.5 ppm/container (21 CFR 178.1005)." *Id.* at 117.

7. Akai (Ex. 1008)

Akai is directed to an "Apparatus for supplying hydrogen peroxide for sterilization." Ex. 1008, Title. Akai discloses that the containers which are to be sterilized are sprayed with an aqueous solution of hydrogen peroxide. *Id.* at 2. The atomized solution is entrained by a stream of air and applied to the containers. *Id.* In order to maintain the predetermined concentration of atomized H_2O_2, which partially decomposes into a gas when heated, Akai discloses a control system comprising a sensor for detecting the concentration of atomized H_2O_2. *Id.*

8. Kodera (Ex. 1009)

Kodera is directed to an "Apparatus Having Automatic Calibration for Determining Hydrogen Peroxide Concentration." Ex. 1009, Title. Kodera describes a sterilization system to automatically determine and control the concentration of H_2O_2 in an aqueous solution of a sterilant supply. *Id.* at 5:14–17.

9. Buchner (Ex. 1011)

The Buchner article is entitled "Aseptic Production and Filling Methods in the Pharmaceutical and Foodstuff Industries." Ex. 1011, Title. Buchner describes a pilot sterilization plant for aseptic filling and sealing of bottles. *Id.* at 26. While being transported through the various stations within the plant, the bottles are sprayed with H_2O_2. *Id.* The entire plant has completely closed aseptic spaces that are subject to a slight overpressure of sterile air. *Id.* at 4. The plant can achieve a residual peroxide concentration less than 0.5 ppm. *Id.*

10. ZFL (Ex. 1010)

The ZFL reference, also authored by Buchner, is entitled "Aseptic Filling of Glass and Plastic Containers." Ex. 1010 at 295. The reference presents a newly developed filling line which is able to fill containers under aseptic conditions. *Id.* The system sterilizes containers with vaporized H_2O_2. *Id.* at 296. By adjusting sterilizing conditions such as sterilant flow rate, temperature, and peroxide concentration, the system can achieve a residual peroxide concentration in the containers of less than 0.5 ppm. *Id.* at 297.

D. Obviousness Challenges

Petitioner contends that claims 1–10, 14, 16–21, 25, 27, 29, and 32–36 would have been obvious under 35 U.S.C. § 103(a) over Scholle in view of one or more of Chambers, the FDA Regulations, Biewendt, Kelbrick, Elliott, Akai, and Kodera. Pet. 19–38. Petitioner also contends that the same claims would have been obvious over Biewendt in view of one or more of Chambers, the FDA Regulations, Buchner, ZFL, Scholle, Kelbrick, Akai, Kodera, and Elliott. *Id.* at 39–58. Petitioner relies upon the Declaration of Dennis Heldman, Ph.D (Ex. 1004) in support of these challenges.[14]

[14] Petitioner asserts that a person of ordinary skill in the art ("POSITA") would possess "an undergraduate scientific or engineering degree in a relevant field (such as microbiology or mechanical, packaging, process, or food engineering), at least five years of experience in an aseptic packaging and/or processing field (or a graduate degree conferring similar expertise), and an understanding of the relevant principles of microbiology and food science and technology." Pet. 12; Ex. 1004, ¶ 12. Patent Owner has not contested that definition in its Patent Owner Response, but its expert Dr. Sharon asserts that Petitioner's definition is only partially correct insofar as it does not recognize that the POSITA could have a mechanical engineering

Patent Owner's arguments are directed primarily to the sterilant concentration ratio requirement recited in each of the challenged independent claims 1, 4, 17, and 33. Specifically, the challenged claims all require that the sterilant concentration levels in the plurality of zones within the sterilization tunnel "are maintained at a ratio of at least about 5 to 1." Accordingly, we focus on that limitation, and treat the claims together for purpose of our analysis.

1. Scholle in view of Chambers, the FDA Regulations, Biewendt, Kelbrick, Elliott, Akai, and Kodera

Petitioner asserts that, using partitions and pressure differentials, the apparatus of Scholle (Ex. 1004) is configured to prevent the H_2O_2 sterilant from migrating from the sterilizing compartment to the drying and filling compartments, and, thus, the sterilant concentration in the sterilization compartment of Scholle is necessarily different from the concentration in the drying and filling compartments. Pet. 20 (citing Ex. 1004 ¶ 55; Ex. 1005, 6:36–41). Petitioner also points to Scholle's teaching of using a 30% solution of H_2O_2 in water (i.e., 300,000 ppm) as a sterilant (*id.* at 21 (citing Ex. 1004 ¶ 56; Ex. 1005, 5:18–22)), and asserts that the skilled artisan "would understand that to ensure consistent sterilization and residual peroxide levels, the concentration of applied sterilant must necessarily be 'maintained.'" *Id.*

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degree. Ex. 2056, ¶ 12. We note, however, that Petitioner has included mechanical engineering as a "relevant field" within its definition. Accordingly, we apply Petitioner's proposed level of skill in the art in our analysis.

Petitioner further argues that Chambers discloses that "[m]any aseptic packaging systems use H_2O_2 *at concentrations of 30 to 35%* and 80 to 90°C for 3 to 5 sec . . . followed by hot air (60 to 125°C)" to sterilize packaging materials. *Id.* (citing Ex. 1014, 17). Additionally, Petitioner asserts that the FDA limits the residual concentration of H_2O_2 to "*not more than 0.5 ppm* after packaging." *Id.* (citing Ex. 1013, 1). Based on these teachings, Petitioner argues that "it would have been obvious in view of *Chambers* and/or the *FDA Regulations* to limit residual hydrogen peroxide and, by extension, to maintain a particular sterilant concentration ratio between the 30 percent applied hydrogen peroxide and the residue in filled and capped containers." *Id.*

Patent Owner, in its Patent Owner Response, challenges whether the maintenance of a ratio of air borne sterilant concentration as between or among zones was a known result effective parameter. PO Resp. 11–18. Relying on its proposed claim construction requiring a ratio of airborne sterilant concentration of at least 5 to 1, Patent Owner argues that the maintenance of a ratio of airborne sterilant concentration as between or among zones was not a known result-effective parameter, and thus the skilled artisan would not have been concerned with optimizing the ratio of airborne sterilant concentrations in the prior art systems. *Id.* at 11–21. As discussed above, however, we do not construe the claims to require that the 5 to 1 ratio is based on a measurement of airborne sterilant concentration. Based on the arguments and evidence of record, we determine that the claimed invention is rendered obvious so long as the skilled artisan would have had sufficient motivation and a reasonable expectation of success with respect to the optimization of sterilant concentration levels measured at *any*

point within the sterilization tunnel—including the "residual" concentration on bottle surfaces—such that the 5 to 1 ratio is satisfied.

A preponderance of the evidence supports the conclusion that the skilled artisan would have found it obvious to optimize the sterilant concentration levels within the different "zones" (i.e., compartments) of Scholle's apparatus in such a manner. Several features of Scholle's apparatus facilitate such an optimization. First, a 30-percent solution of H_2O_2 in water is atomized and continuously sprayed into the spraying compartment during operation. Ex. 1005, 5:18–26, 45–49. Second, the spraying zone is separated from other compartments by a partition with a narrow opening designed "to reduce the amount of [H_2O_2] mist passing through the opening." *Id.* at 6:12-15. Third, in the drying compartment, the H_2O_2 is "evaporated" and vented out of the sterile tunnel. *Id.* at 6:33-36, 44-55. And finally, the sterile air maintains a positive pressure in the filling and drying compartments, thus reducing any tendency of the H_2O_2 mist in the spray compartment to migrate through the narrow opening into those other compartments. *Id.* at 5:36–43, 6:36-41. Although the parties dispute the particular concentration of H_2O_2 that exists in the sterilization tunnel after it is sprayed, there is no dispute that the spraying compartment in Scholle's apparatus will have a higher sterilant concentration than the filling compartment. Indeed, even if airborne concentration levels were to be considered, Patent Owner's counsel acknowledged during oral argument that "there is going to be more sterilant in the air in the spray zone than in the fill zone." Tr. 122:12–14; *see also* Ex. 1035, 122:21–123:3 (Patent Owner's expert Dr. Sharon conceding that the airborne concentration is lower in the fill zone than in the spray zone).

Furthermore, we find that the concentration of the 30% solution of H_2O_2 will remain close to 300,000 ppm in the liquid phase at some point after it is sprayed into the spraying compartment. Scholle discloses that the spray heads atomize the H_2O_2 solution into a "fine mist or fog," which coats the exterior of the containers to kill microorganisms. Ex. 1005, 5:22–23, 8:8–13. Although Dr. Sharon asserts that the skilled artisan "would be motivated to use as little sterilant in the sterilization zone as necessary to get the job done" (Ex. 2056, ¶24), he nonetheless acknowledged that, after condensation, the concentration of liquid H_2O_2 that coats the containers is "somewhere in the neighborhood" of 30%, or 300,000 ppm. Ex. 1035, Tr. 105:17–106:15. Here, we also credit Dr. Heldman's testimony who stated that although the process of atomizing H_2O_2 may "result in varying concentrations," the skilled artisan nonetheless "would understand that to ensure consistent sterilization and residual peroxide levels, the concentration of applied sterilant must necessarily be 'maintained.'" Ex. 1004 ¶¶ 51, 56.

Patent Owner argues that Dr. Heldman agreed that it would be reasonable to assume that the airborne concentration of H_2O_2 could drop by a factor of 100 between the time it is taken from the tank and put through an atomizer, and that it would be reasonable to assume that the concentration would drop by another factor of 100 once it is injected into the sterilization tunnel of Scholle. PO Resp. 26 (citing Ex. 2055, 56:2–57:24, 95:1–98:9, 188:21–190:19). As a result, Patent Owner argues that the airborne sterilant concentration in the spraying compartment could be as low as 30 ppm. *Id.* In the cited testimony, however, Dr. Heldman was only responding based on the assumptions proposed by counsel, which he did not necessarily agree were "reasonable." *See* Ex. 2055, 90:12–93:21 (answering, in response to

counsel's questions about the reasonableness of assuming a 100-fold difference that "I believe it's possible that it could be that amount"). Patent Owner has not pointed to any testimony from Dr. Sharon or other evidence as to the basis for the assumptions that Dr. Heldman was asked to make during his deposition. Moreover, in contrast to the 30 ppm airborne sterilant concentration calculated based on counsel's assumptions, Petitioner calculates an airborne concentration of 297,000 ppm based on the testimony of Patent Owner's expert in another related IPR. Pet. Reply 13 (citing Ex. 2061, ¶¶ 14, 18).

Additionally, Patent Owner argues that the FDA Regulations do not apply to the Scholle system because they only focus on the sterilant concentration on the interior of the package as opposed to in the air, and there is no risk in Scholle of H_2O_2 ever coming into contact with the interior of the container into which the liquid will be filled. PO Resp. 21–22. Patent Owner relies upon a) the fact that the bags used for Scholle's apparatus are "presterilized," and b) the fact that Scholle's filling process involves the formation of an "overlay arrangement with the inner end of the spout to seal of the spout and exclude entry of air and other foreign matter." *Id.* at 21 (citing Ex. 2056, ¶¶ 35–36, 41; Ex. 2049, 2:15–24). Patent Owner asserts that the airborne sterilant concentration in the fill zone could be as high as approximately 500 ppm while still meeting the FDA residual peroxide test. *Id.* at 16–17, 27 (citing Ex. 2056, ¶¶ 22–24).

Although Scholle does not specify the sterilant concentration in the filling compartment, Petitioner counters that "[b]ecause the *Scholle* system uses a H_2O_2 solution to sterilize food packaging material, this regulation expressly applies to *Scholle*." Pet. Reply 11. Petitioner contends that the

skilled artisan would have found it obvious to minimize the residual sterilant concentration in the filling compartment as much as possible in view of the FDA Regulations, which specify that the residual concentration should be less than 0.5 ppm. *Id.* at 11–15.

We are not persuaded by Patent Owner's arguments because, as discussed above, regardless of whether the presterilized bags are filled in the manner asserted by Patent Owner, it is undisputed that Scholle's apparatus is designed such that the H_2O_2 concentration in the filling compartment will be lower than the concentration in the spraying compartment. Tr. 122:12–14. Moreover, the evidence of record establishes that other prior art aseptic bottling systems recognized the importance of limiting the concentration of H_2O_2 in the filling zone in order to comply with regulatory limits. For example, ZFL teaches with respect to the Bosch system that: "As for the admissible residual peroxide in the containers, there is a limit of up to 0.5 ppm only in the U.S. The maximum allowable concentration in the workplace of 1 ppm for H_2O_2, in contrast, is an international limit. *The plants are adjusted so as to fall below both thresholds*." Ex. 1010, 297 (emphasis added). Elliot teaches that a "window of operation" for sterilization can be created by "varying the peroxide dosage/container and the heated air temperature" in order "to give the maximum allowable peroxide residual of 0.5 ppm/container." Ex. 1015, 118. Thus, contrary to Patent Owner's arguments with respect to airborne sterilant concentrations, the prior art recognizes that maintaining a low sterilant concentration in the filling zone compared to the sterilization zone (i.e., the ratio of sterilant concentration levels between the two zones) was "result effective." *See* PO Resp. 12 (citing *In re Antonie*, 559 F.2d 618, 620 (CCPA 1977)).

Furthermore, even assuming *arguendo* Patent Owner's assertion that the concentration in the filling zone could be as high as 500 ppm and satisfy the FDA test, we note that the at least about 5 to 1 ratio requirement will still be satisfied when that concentration is compared to the approximately 300,000 ppm concentration that has been shown to exist in the sterilization zone.

"The outcome of optimizing a result-effective variable may still be patentable if the claimed ranges are 'critical' and 'produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art.'" *In re Applied Materials, Inc.*, 692 F.3d 1289, 1297 (Fed. Cir. 2012) (citing *Aller*, 220 F.2d at 456; *Antonie*, 559 F.2d at 620)). Here, Patent Owner has not offered any credible evidence of criticality or unexpected results associated with the claimed ratio. The '435 patent itself does not mention anything about maintaining a particular ratio of sterilant concentration levels other than in the claims. Accordingly, "[n]othing [of record] indicates that the optimization of the variables [i.e., the sterilant concentration levels] was anything other than the exercise of ordinary skill in the art." *Id.*

In addition to the 5 to 1 sterilant concentration ratio requirement, Petitioner has met its burden of showing that each of the other recited claim elements are taught or suggested by the prior art references relied upon for this challenge, and that there would have been a reason for the skilled artisan to combine the references to arrive at the claimed invention as a whole. *See* Pet. 19–38. We, therefore, determine that a preponderance of the evidence establishes the obviousness of independent claims 1, 4, 17, and 33 based on the teachings of Scholle in view of Chambers, the FDA Regulations, Biewendt, Kelbrick, Elliott, Akai, and Kodera. Additionally, we have

considered the evidence and arguments presented by Petitioner with respect to dependent claims 2, 3, 5–10, 14, 16, 18–21, 25, 27, 29, 32, and 34–36, and determine that Petitioner has also proven the obviousness of those claims by a preponderance of the evidence based on the same combination of references. *See* Pet. 23–28, 32–35, and 38. As noted above, Patent Owner has not separately argued these dependent claims.

2. Biewendt in view of the FDA Regulations, Buchner, ZFL, Scholle, Kelbrick, Akai, Kodera, and Elliott

For the second obviousness challenge instituted in this proceeding, Petitioner relies upon the Bosch system described in the Biewendt reference (Ex. 1024), as well as in Buchner (Ex. 1011) and ZFL (Ex. 1010), in combination with other references considered in the first challenge. Petitioner asserts that the apparatus described in Biewendt includes a "bottle sterilization machine," an "aseptic filling machine," and an "aseptic sealing machine," which define a "plurality of zones" as required by the claims. Pet. 40 (citing Ex. 1024, Fig. 1). Moreover, to the extent partitions are required in order to create the claimed "zones," Petitioner argues that it would have been obvious to provide the apparatus described in Biewendt with the partitions of Scholle's apparatus in order to provide the advantages of (1) reducing or eliminating the transfer of H_2O_2 from a sterilization zone to a filling zone, and/or (2) preventing contamination in the various sterilization zones. *Id.* at 40, 45 (citing Ex. 1005, 6:25–43).

Petitioner asserts that the 5 to 1 sterilant ratio requirement is satisfied based on Beiwendt's teaching that bottles "are sprayed with hydrogen peroxide (H_2O_2)," which is stored at a "minimum 33% H_2O_2" concentration, and that "[t]esting with Merckoquant 10 001 testing strips did

not show any proof of contamination with H_2O_2 residue in filled UHT milk bottles." Pet. 41 (citing Ex. 1024, 5, 11, 18). Petitioner asserts that using a "minimum 33% H_2O_2" solution would result in a concentration of 330,000 ppm being maintained. *Id.* (citing Ex. 1004, ¶ 100). Based on the accuracy of Merckoquant test strips at the time of Biewendt, Petitioner asserts that the skilled artisan would have understood Biewendt to disclose that H_2O_2 residue on the filled bottles was observed to be 1 ppm or less. *Id.* at 41–42 (citing Ex. 1004, ¶ 101; Ex. 1012, 4:43–43). Petitioner also asserts that "[e]ven without *Biewendt's* disclosure regarding sterilant concentrations, a concentration ratio of at least about 5 to 1 between the applied and residual sterilant levels would have been obvious in view of *Chambers* and/or the *FDA Regulations*." *Id.* at 42.

Patent Owner contends that because the system of Biewendt is not maintained at a pressure above atmospheric, Biewendt does not disclose a "sterilization tunnel for surrounding a plurality of containers with pressurized gas," as required by each of the challenged independent claims. PO Resp. 28–34 (citing Ex. 2056 at ¶¶ 14, 20, 51, 55–56; Ex. 2055 at 146–148). In particular, Patent Owner asserts that the aseptic tunnel of Biewendt is kept at a pressure 20 Pa above atmospheric while the bottle sterilization machine appears to be kept at ambient or at a slightly negative pressure. *Id.* at 30 (citing Ex. 2056, ¶ 55; Ex. 1024 at 18). Patent Owner draws this conclusion based on Biewendt's description of the bottle sterilization machine as being a "clean room" that is isolated from the aseptic tunnel through an aseptic lock, and that the mixture of H_2O_2 and warm air is "suctioned off through the cover plate openings and separated again in catalysts located outside the clean room." *Id.* at 31–32 (citing Ex. 1024, 5).

We are unpersuaded by this argument. As an initial matter, Patent Owner does not dispute that at least the aseptic tunnel portion of Biewendt's apparatus (considered part of the claimed sterilization tunnel) is kept pressurized. The claims, on their face, do not require the entirety of the sterilization tunnel be kept above atmospheric pressure. Moreover, even if the claims were interpreted to require all "zones" in the sterilization tunnel be kept above atmospheric pressure, Biewendt's apparatus still satisfies that requirement based on the disclosure that hot sterile air is blown into the sterilizing machine to activate the H_2O_2 and dry the bottles, in a manner similar to disclosure in the '435 patent. *See* Pet. 16 (citing Ex. 1024, 17–18; Ex. 1035, 154:21–155:25; Ex. 1001, 10:3–5). Contrary to Patent Owner's arguments, we credit Dr. Heldman's testimony that a "clean room" would have been kept above atmospheric pressure. Ex. 2055, 148:9–14, 150:11–151:8. We further note that Buchner and ZFL, which also describe the Bosch system, both disclose that the entire plant (i.e., the fully enclosed system) is subject to a "slight overpressure." Ex. 1010, 298; Ex. 1011, 27. A preponderance of the evidence therefore supports the conclusion that the Bosch system, as described by Biewendt, Buchner, and ZFL, includes a "sterilization tunnel for surrounding a plurality of containers with pressurized gas."

We are also unpersuaded by Patent Owner's argument that, even assuming the sterilization machine in Biewendt is pressurized, "it would be apparent to a [person of ordinary skill in the art] that the concentration of airborne sterilant in the sterilization machine would fall by orders of magnitude as between the tank and the air of the sterilization zone of the Biewendt system." PO Resp. 35. For reasons similar to those discussed

above with respect to the Scholle apparatus, the evidence supports the finding that the 33% H_2O_2 solution utilized in Biewendt would result in a sterilant concentration close to 330,000 ppm in the liquid phase at least at some point after it is sprayed into the sterilization machine. *See* Ex. 1004, ¶ 99. Specifically, Biewendt discloses that "[t]he effectiveness of this sterilization method is on the one hand based on an optimally fine, *even dispersion of the H_2O_2 on the surface of the bottle*, but in particular on the drying effect of said H_2O_2 with at least 80 °C hot air." Ex. 1024, 18 (emphasis added). Furthermore, in order to comply with the FDA Regulations (Ex. 1013), the skilled artisan would have had an incentive to ensure that the residual sterilant concentration on the bottle surfaces in the fill zone after drying is minimized as much as possible so that the 5 to 1 ratio requirement is satisfied. This is also reflected in Biewendt's teaching that testing with the Merckoquant 10 001 testing strips (accurate to 1 ppm) did not show any contamination with H_2O_2 residue in the filled bottles. Ex. 1024, 18; Ex. 1012, 4:43–43.

Additionally, even if airborne concentrations were taken into account, we are not persuaded by Patent Owner's contention that the airborne sterilant concentration ratio would be on the order of 1 to 1. PO Resp. 36. Patent Owner bases this conclusion on the fact that a) "Dr. Heldman . . . ultimately agreed that the airborne sterilant concentration in the sterilization zone of Biewendt could be .0035 parts per hundred, or 35 parts per million," and b) Dr. Sharon's explanation concerning the potential for the airborne sterilant concentration in the fill zone being as high as 500 ppm. *Id.* at 35–36 (citing Ex. 2055, 91:24–92:15, 98:7–9). As discussed above, however, the cited testimony was only based on certain assumptions proposed by

counsel during questioning regarding the flow rate of sterile air in the sterilization chamber. Dr. Heldman did not necessarily agree that those assumptions were "reasonable," but rather only indicated it was "possible." *Id.* Moreover, contrary to Patent Owner's characterization, Dr. Heldman did not testify about the reasonableness of assuming an *additional* 100-fold decrease in sterilant concentration between the time it is taken from the tank and put through the atomizer. *Id.* Nor has Patent Owner offered any credible evidence supporting those assumptions.

Finally, we are unpersuaded by Patent Owner's argument that the skilled artisan would not have reasonably expected that Biewendt and Scholle could be combined because Biewendt does not disclose sufficient information "to construct the aseptic bottling apparatus disclosed therein" and meet FDA requirements. PO Resp. 38. Patent Owner also argues against a reasonable expectation of success because "many manufacturers failed in their attempts to develop FDA-compliant aseptic filling processes." *Id.* at 39. We agree with Petitioner that the claims do not require an "FDA-compliant aseptic filling process." Pet. Reply 19. *See Allergan, Inc. v. Sandoz, Inc.*, 726 F.3d 1286, 1292 (Fed. Cir. 2013) ("[T]he person of ordinary skilled need only have a reasonable expectation of success of developing the *claimed* invention."). Patent Owner has not offered any persuasive evidence that failure by others to develop an FDA-compliant process was solved by the 5 to 1 sterilant concentration ratio or any other feature recited in the claims of the '435 patent. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 305 n.42 (Fed. Cir. 1985) ("For secondary considerations to have probative value, the decision maker

must determine whether there is a nexus between the merits of the claimed invention and the secondary considerations.").

In addition to the pressurized sterilization tunnel and the 5 to 1 sterilant concentration ratio requirements, Petitioner has met its burden of showing that each of the other recited claim elements are taught or suggested by the prior art references relied upon for this challenge, and that there would have been a reason for the skilled artisan to combine the references to arrive at the claimed invention as a whole. *See* Pet. 39–58. We, therefore, determine that a preponderance of the evidence establishes the obviousness of independent claims 1, 4, 17, and 33 based on the teachings of Biewendt in view of Chambers, the FDA Regulations, Buchner, ZFL, Scholle, Kelbrick, Akai, Kodera, and Elliott. Additionally, we have considered the evidence and arguments presented by Petitioner with respect to dependent claims 2, 3, 5–10, 14, 16, 18–21, 25, 27, 29, 32, and 34–36, and determine that Petitioner has also proven the obviousness of those claims by a preponderance of the evidence based on the same combination of references. *See* Pet. 43–48, 53–56, and 58. As noted above, Patent Owner has not separately argued these dependent claims.

III. PETITIONER'S MOTION TO EXCLUDE EVIDENCE

Petitioner moves to exclude the following documents: Ex. 2036 (the Spinak Transcript, Ex. 2037 (the Oxford Declaration), Ex. 2038 (the Gehl Complaint), Exs. 2043, 2051 (the Buchner Declarations), and Exs. 2056, 2065 (the Sharon Declarations). Paper 75. Because we do not rely on Exhibits 2036, 2037, 2038, 2043, 2051, and 2065 in this Final Written Decision, we dismiss Petitioner's Motion to exclude those exhibits as moot.

Petitioner argues that the Sharon Declaration submitted in this proceeding (Ex. 2056) should be excluded because Dr. Sharon is not a qualified expert, and it fails to satisfy the requirements of FRE 703 and 37 C.F.R. § 42.65, requiring the disclosure of the bases for his opinions. Paper 75, 12–15. Specifically, Petitioner contends that "Dr. Sharon admits that he has no experience in microbiology, sterilization, food science, or machine design for aseptic food processing." *Id.* at 13. Petitioner also contends that "the foundations for Dr. Sharon's conclusions—specifically the tests used to reach such conclusions—are not disclosed, and Dr. Sharon . . . admits that he does not know how such tests would be conducted." *Id.* at 15. We determine that Petitioner's arguments more appropriately go to the weight Dr. Sharon's testimony should be given rather than the admissibility of his declaration. On that basis, we deny Petitioner's Motion to exclude Ex. 2056.

IV. PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE

Patent Owner moves to exclude Exhibits 1042–1044. Paper 73. Because we do not rely on those exhibits in this Final Written Decision, we dismiss Patent Owner's Motion to Exclude as moot.

V. PETITIONER'S MOTIONS TO SEAL

Petitioner has filed a motion to seal Exhibits 1033, 1042, 1043, and 1044, which Petitioner asserts "reveal confidential business information belonging to Petitioner, including information about the terms of Petitioner's relationship with its supplier, and about Petitioner's production facilities and capabilities." Paper 62, 1. Petitioner has also filed a motion to seal the

confidential version of Patent Owner's Response (Paper 57)[15] and Exhibit 2063 for similar reasons. Paper 65, 1. Patent Owner does not oppose either motion to seal.

The record for an *inter partes* review shall be made available to the public, except as otherwise ordered, and a document filed with a motion to seal shall be treated as sealed until the motion is decided. 35 U.S.C. § 316(a)(1); 37 C.F.R. § 42.14. The standard for granting a motion to seal is "good cause." 37 C.F.R. § 42.54. There is a strong public policy that favors making information filed in *inter partes* review proceedings open to the public. *See Garmin Int'l v. Cuozzo Speed Techs., LLC,* Case IPR2012-00001, slip op. at 1-2 (PTAB Mar. 14, 2013) (Paper 34) (discussing the standards applied to motions to seal). The moving party bears the burden of showing that the relief requested should be granted. 37 C.F.R. § 42.20(c). That includes showing that the information is truly confidential, and that such confidentiality outweighs the strong public interest in having an open record. *See Garmin*, slip op. at 3.

Having considered the documents at issue, we are persuaded that Petitioner has demonstrated "good cause" for keeping them under seal during the course of this proceeding, as they relate to confidential business information of Petitioner. We did not rely upon any of the confidential information in our Final Written Decision. We note, however, that confidential information subject to a protective order will ordinarily become public 45 days after this final judgment unless the parties file a motion to expunge the information prior to the information becoming public. *See*

[15] Patent Owner has filed a redacted version of its Patent Owner Response. Paper 66.

Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48760–61 (Aug. 14, 2012); 37 C.F.R. § 42.56. In accordance with prior practice, the parties may also seek to preserve the record and keep any confidential documents sealed until the outcome of any appeal of this decision. *See Nestlé USA, Inc. v. Steuben Foods, Inc.*, Case IPR2014-01235, Order Granting Request to Preserve Record Pending Appeal (Paper 68) (PTAB Feb. 9, 2016).

VI. CONCLUSION

We conclude that Petitioner has demonstrated by a preponderance of the evidence that claim 1–10, 14, 16–21, 25, 27, 29, and 32–36 are rendered obvious under 35 U.S.C. § 103 by a) Scholle in view of Chambers, the FDA Regulations, Biewendt, Kelbrick, Elliott, Akai, and Kodera; and b) Biewendt in view of Chambers, the FDA Regulations, Buchner, ZFL, Scholle, Kelbrick, Akai, Kodera, and Elliott.

VII. ORDER

Accordingly, it is

ORDERED that claims 1–10, 14, 16–21, 25, 27, 29, and 32–36 of U.S. Patent 6,475,435 B1are held to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude Evidence (Paper 75) is dismissed as moot with respect to Exhibits 2036, 2037, 2038, 2043, 2051, and 2065; and denied with respect to Exhibit 2056;

FURTHER ORDERED that Patent Owner's Motion to Exclude Evidence (Paper 73) is dismissed as moot;

FURTHER ORDERED that Petitioner's Motion to Seal Exhibits 1033, 1042, 1043, and 1044 (Paper 62), and Petitioner's Motion to Seal the confidential version of the Patent Owner Response and Exhibit 2063 (Paper 65) are granted;

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

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