UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NESTLÉ USA, INC.,

Petitioner,

v.

STEUBEN FOODS, INCORPORATED,

Patent Owner

_____

Case IPR2015-00249

Patent 6,481,468

_____

PATENT OWNER'S NOTICE OF APPEAL

via PTAB E2E
Patent Trial and Appeal Board

via Hand delivery
Director of the United States Patent and Trademark Office
Office of the General Counsel
Madison Building East, Room 10B20
600 Dulany Street
Alexandria, VA 22314

via CM/ECF
United States Court of Appeals for the Federal Circuit

Patent Owner Steuben Foods, Inc. hereby gives notice to the Director of the Patent and Trademark Office, pursuant to 35 U.S.C. §§ 141 and 142 and 37 C.F.R. §§ 90.2 and 90.3, of its appeal to the United States Court of Appeals for the Federal Circuit from the Final Written Decision on Remand by the Patent Trial and Appeal Board ("the Board") entered on August 16, 2019 (Paper 169), the Board's Decision Denying Patent Owner's Request for Rehearing on the Motion to Terminate entered on August 16, 2019 (Paper 168)[1], and from all orders, decisions, rulings, findings, and opinions relating to or underlying those decisions, including without limitation the decision that the petition was not time-barred under 35 U.S.C. § 315(b).

For the limited purpose of providing the Director with the information requested in 37 C.F.R. § 90.2(a)(3)(ii), Patent Owner anticipates that the issues on its appeal include, but are not limited to: whether the Board erred when it ruled that Petitioner had met its burden in proving by a preponderance of the evidence that claims 9 and 21 are unpatentable over either (1) Biewendt, Takei, and ZFL, or (2) ZFL, Takei, and BevTech; claims 20 and 23 are unpatentable over either (1) Biewendt and Takei, and ZFL, or (2) ZFL, Takei, and BevTech; claim 22 is

[1] Patent Owner has attached Paper 169 and Paper 171, as the public version of Paper 168.

unpatentable over either (1) Biewendt, Takei, and Chambers, (2) Biewendt, Takei, Campden, and Rose, or (3) ZFL, Takei, and BevTech; whether the Board erred when it ruled that the Petition was not time barred under § 315(b) based on Petitioner's relationship with GEA; any finding or determination supporting or relating to the foregoing issues; and any other issues decided adversely to Patent Owner in any orders, decisions, rulings, or opinions in the above-captioned *inter partes* review proceeding.

Pursuant to 37 C.F.R. § 90.3 and Rule 4(a)(3) of the Federal Rules of Appellate Procedure, this Notice of Appeal is timely, having been filed within 63 days after the date of the Final Written Decision and the Decision Denying Request for Rehearing.

Copies of Patent Owner's Notice of Appeal are being filed simultaneously today with the Director, the Patent Trial and Appeal Board, and the Clerk of the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

GARDELLA GRACE P.A.

Dated: October 18, 2019

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 18th day of October, 2019, a true and correct copy of the foregoing Patent Owner's Notice of Appeal was served on counsel of record for Petitioner by filing this document through the PTAB E2E System as well as delivering a copy to the following address(es):

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I hereby certify that on this 18th day of October, 2019, in addition to being filed electronically through the PTAB E2E System, a true and correct copy of the foregoing Patent Owner's Notice of Appeal was served by hand with the Director of the United States Patent and Trademark Office, at the following address:

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Madison Building East, 10B20
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I hereby certify that on this 18th day of October, 2019, a true and correct copy of the foregoing Patent Owner's Notice of Appeal was filed electronically along with the associated filing fee with the Clerk's Office of the United States Court of Appeals for the Federal Circuit via CM/ECF.

Dated: October 18, 2019

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Paper 169

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Paper 169
Entered: August 16, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NESTLÉ HEALTHCARE NUTRITION, INC.,
Petitioner,

v.

STEUBEN FOODS, INC.,
Patent Owner.

Case IPR2015-00249
Patent 6,481,468 B1

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

KAUFFMAN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION ON REMAND AND SUPPLEMENTAL FINAL WRITTEN DECISION

35 U.S.C. §§ 144 and 37 C.F.R. § 42.5(a)

I. INTRODUCTION

This Decision is issued pursuant to a remand from the United States Court of Appeals for the Federal Circuit ("the Federal Circuit") in *Nestlé USA, Inc. v. Steuben Foods, Inc.*, 884 F.3d 1350, 1352 (Fed. Cir. 2018) ("*Nestlé II*") as to claim 9.[1] This Decision is also a Supplemental Final Written Decision with regard to claims 20–23.

For the reasons given in this opinion, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 9 and 20–23 are unpatentable.

A. RELATED PROCEEDINGS

The instant proceeding, IPR2015-00249, involves U.S. Patent No. 6,481,468 B1 (Ex. 1001, "the '468 patent"), which is related to U.S. Patent 6,945,013 ("the '013 patent"), the subject of IPR2014-01235 ("the '1235 proceeding"). We have issued the Final Written Decision on Remand for IPR2014-01235 in response to *Nestlé USA, Inc. v. Steuben Foods, Inc.*, 686 F. App'x 917 (Fed. Cir. 2017) (non-precedential) ("*Nestlé I*"). IPR2014-01235, Paper 111 ("the '1235 Final Decision on Remand").

The '468 patent is also the subject of Appeal 2017-010674 (reexamination control 95/000,686).

B. PROCEDURE

Petitioner, Nestlé Healthcare Nutrition, Inc., filed a Petition (Paper 2, "Pet.") to institute an *inter partes* review of claims 1–3, 7, 9, and 20–23

[1] A copy of the Federal Circuit's opinion is found at Exhibit 3004.

("the challenged claims") of U.S. Patent No. 6,481,468 B1 (Ex. 1001, "the '468 patent"). We instituted trial only as to claims 1–3, 7, and 9[2], but not claims 20–23. Paper 25. Following trial, in our Final Written Decision, we determined that Petitioner had shown by a preponderance of the evidence that claims 1–3 and 7 of the '468 patent are unpatentable, but had not made such a showing with regard to claim 9. Paper 76 ("Dec.").

Petitioner appealed as to claim 9, and Patent Owner cross-appealed. Papers 82 (appeal), 83 (cross appeal); 155, 8:1–16 (transcript summarizing procedural history); 98, 1. Our determinations with regard to claims 1–3 and 7 were not challenged, and, consequently, are final.

On appeal, the Federal Circuit vacated our Final Written Decision and remanded the case to the Board for consideration of the patentability of claim 9. *Nestlé II*; PO remand Resp. 1. The Federal Circuit directed that we construe "aseptic" as articulated in *Nestlé I*.[3] *Nestlé II*, 884 F.3d at 1352. Therefore, initially, the unpatentability of claim 9 based on two grounds was before us on remand.[4]

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[2] With respect to claim 9, we instituted trial based on two asserted grounds as articulated in Section III below.

[3] The Federal Circuit determined that collateral estoppel precluded Patent Owner from revisiting the same claim construction issue in this case. *Nestlé II,* 884 F.3d at 1352.

[4] Biewendt - Ex. 1006, H.-G. Biewendt et al., *Report on the Type Testing of the Aseptic Filling and Sealing Plant for Glass Bottles for UHT Milk* (1996); Takei - Ex. 1005, Japanese Pat. App. Publ. No. H4-154501 (with translation) (May 27, 1992); ZFL - Ex. 1012, N. Buchner, *Aseptic Filling of Glass and Plastic Containers*, ZFL Magazine, Vol. 41, No. 5, 295-300 (with translation); Bev Tech – Ex. 1007, Luigi Baiocchi, Latest Innovations in Aseptic Filling, Int'l Soc. Of Beverage Technologists, Prcdgs. Of 44th Ann.

While this case was pending on remand, the Supreme Court issued *SAS Inst., Inc. v. Iancu,* 138 S.Ct. 1348 (2018), in which the Court held that institution of an *inter partes* review requires review of every claim challenged in a petition.[5] Accordingly, we amended our institution decision to add the following two grounds of unpatentability presented in the Petition: (1) Claims 20–23 as unpatentable under 35 U.S.C. § 103(a) over Biewendt, Takei, Chambers, Campden, and Rose, and (2) Claims 20–23 under 35 U.S.C. § 103(a) over ZFL, Takei, Bev Tech, Chambers, and Campden.[6] Paper 86; *see also* Paper 97 (clarifying Paper 86). These two grounds are the same as those challenging claim 9.

Therefore, claim 9 is before us for a Final Written Decision on Remand, and claims 20–23 are before us for a Supplemental Final Written Decision.

Conf. "Bev Tech 97," Ft Lauderdale, FL, Apr. 28–30, 1997, 123–130. As detailed later in this opinion, these two grounds addressed claims 1–3, 7, 9, and 20–23.

[5] *See also* Guidance on the Impact of SAS on AIA Trial Proceedings, April 26, 2018, available on line at https://www.uspto.gov/.

[6] Chambers – Ex. 1009, Chambers, J. et al. eds., *Principles of Aseptic Processing and Packaging* (2d ed. 1993); Campden - Ex. 1010, Campden Food Preservation Research Association, Aseptic Packaging: *Proceedings of Seminat held on the 20th of April 1983*; E; and Rose – Ex. 1011, D. Rose, *Pt. 1: Principles of Design, Installation and Commissioning*, Good manufacturing Practice –Guidelines for Processing and Aseptic Packaging of Low-Acid Foods (1st ed. 1986).

Post remand, Patent Owner submitted a Response, Petitioner submitted a Reply, and Patent Owner submitted a Sur-Reply. Paper 98 ("PO Remand Resp."), Paper 120, "Pet. Remand Reply"), Paper 129 ("PO Remand Sur-Reply").

On January 30, 2019, we held oral argument. Paper 155 ("Tr.").

On February 11, 2019, Patent Owner submitted a request for Precedential Opinion Panel review of a briefing issue raised in the case. Ex. 3011; Paper 153 (notification of receipt). The Board denied that request. Paper 156, 2.

On May 14, 2019, we denied Patent Owner's Motion to Terminate this proceeding.[7] *See* Paper 157; *see also* Paper 89 (authorizing the Motion); Paper 90 (Patent Owner's Motion), 15; Paper 92 (Petitioner's Opposition); Paper 93 (Patent Owner's Reply). On May 28, 2019, Patent Owner submitted a request for rehearing of our Decision denying Patent Owner's Motion to Terminate this proceeding. Paper 159; *see also* Papers 161 (authorizing briefing by Petitioner); 165 (Petitioner's opposition); 167 (Patent Owner's sur-reply). We denied that request. Paper 168.

II. CLAIMED SUBJECT MATTER

A. INTRODUCTION[8]

As background, the '468 patent explains that sterilized packaging systems in which a sterile food product is placed and sealed in a container to preserve the product for later use were "well known in the art." Ex. 1001,

[7] The same motion was also submitted in the '1235 proceeding.

[8] For context, we repeat this information from our Final Written Decision. *See* Dec. 27–28.

1:21–23. Further, the specification asserts that it was also known how to: sterilize incoming containers, fill containers with pasteurized product, and seal the containers in an aseptic tunnel. *Id.* at 1:23–26.

According to the '468 patent, it was not known how to aseptically fill containers having small openings at high output processing speed, while successfully complying with FDA standards for labeling such packaged products as aseptic.[9] *Id.* at 2:22–29. Further, it was not known how to aseptically package a low acid product in plastic bottles or jars. *Id*.

To overcome these shortcomings, the '468 patent discloses a method for filling aseptic containers with an aseptic food product. *Id*. at 2:39-40; Figs. 3, 22. The aseptic product is delivered to the aseptic containers through a valve and nozzle mechanism which controls the volume of aseptic product flowing into the aseptic containers. *Id*. at 14:54-15:18; Figs. 28, 30. A sterile tunnel surrounds the valve and nozzle mechanism to prevent contaminants from being carried into the aseptic product as the product exits the nozzle and flows into the aseptic container. *Id*. at 2:13-21; 15:19-62.

B. CLAIMS

Claims 1 and 20 are independent. Claim 9 depends from claim 1 and claims 21–23 depend from claim 20. Claims 1, 9, and 20 follow.

1. A method comprising:

controlling the flow of an aseptic product using a valve;

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

[9] We use "FDA" to refer the United States Food and Drug Administration.

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

9. The method of claim 1, further comprising:

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

20. A method comprising:

> aseptically disinfecting a plurality of containers in a sterile tunnel;
>
> controlling the flow of an aseptic product into the plurality of containers using a valve;
>
> surrounding a region where the aseptic product exits the valve with a sterile region wherein the sterile region is the sterile tunnel; and
>
> controlling the opening or closing of the valve with a sealed actuator, wherein the sealed actuator is surrounded with the sterile region.

C. CLAIM CONSTRUCTION

Here, as in the '1235 Final Written Decision on Remand, we apply the Federal Circuit's construction of "aseptic" as directed. The Federal Circuit construed "aseptic" as the "FDA level of aseptic," which is confined to "FDA regulations related to aseptic packaging." *Nestlé I*, 686 Fed. App'x at 919. The Federal Circuit also stated that

> [t]hough the FDA does not define "aseptic" outright, at the time of the application, it defined "aseptic processing and packaging" as "the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms." 21 C.F.R. § 113.3(a) (1999). And

> "commercial sterility" was defined as "free of viable microorganisms having public health significance, as well as microorganisms of nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution." *Id*. § 113.3(e) (1999).

Id. Moreover, the Federal Circuit expressly determined that the FDA level of aseptic does not include satisfaction of the regulatory requirement of 21 C.F.R. § 178.1005(d) that the final product have a hydrogen peroxide residue of less than 0.5 ppm.[10] *Id*.

III. CLAIM 9

A. ANALYSIS APPLICABLE TO BOTH GROUNDS

1. Introduction

Before addressing each ground of unpatentability separately challenging claim 9, we provide analysis that is applicable to both grounds.

In our Final Written Decision, we concluded that Petitioner had not demonstrated by a preponderance of the evidence that claim 9 was unpatentable over either of the asserted grounds. Dec. 56, 59. Those determinations were the result of requiring the asserted ground of unpatentability to comply with the residual hydrogen peroxide regulation. Dec. 55–56, 59. As detailed above, on appeal, the Federal Circuit held that our claim interpretation was incorrect, vacated our decision, and mandated that we reconsider with the proscribed claim construction.

[10] "ppm" means parts per million.

Claim 9 depends from claim 1 and recites, "aseptically disinfecting a plurality of bottles to a level producing at least about a 6 log reduction in spore organisms."[11] Ex. 1001, 26:19–22.

In light of the interpretation of "aseptic" provided by the Federal Circuit (*see* Section II.C.), the method of claim 9 requires aseptically disinfecting a plurality of bottles to produce at least a 6 log reduction in spore organisms. Claim 9 does not require: the use of a particular sterilant (*e.g.*, hydrogen peroxide), FDA approval, compliance with the residual hydrogen peroxide regulation, or reduction of a particular spore organism. *See* Section II.C. above; Pet. Reply 1, 3–5; *contra* PO Resp. 3–9; *see also* the '1235 Final Decision on remand, 29–33 (analyzing a similar limitation in claim 19 of the '013 patent).

2. Level of Ordinary Skill in the Art

Petitioner contends that the prior art relied upon in the grounds of unpatentability reflects the level of skill in the art. Pet. 11. Petitioner adds that a person of ordinary skill in the art would have: "an undergraduate scientific or engineering degree in a relevant field (such as microbiology or mechanical, packaging, process, or food engineering), at least five years of experience in an aseptic packaging or processing field (or a graduate degree conferring similar expertise), and an understanding of the relevant principles of microbiology and food science and technology." *Id.* (citing Ex. 1004 ¶ 37)

Patent Owner does not address the level of skill in the art.

[11] Claim 19 of the '1235 proceeding contains a similar limitation.

We agree with, and adopt, Petitioner's proposed level of skill. The level of skill in the art asserted by Petitioner is similar to the level we adopted in the '1235 Final Decision on remand. *See* the '1235 Final Decision on remand, 13.

B. OBVIOUSNESS OVER BIEWENDT, TAKEI, AND ZFL

1. Introduction

In the Petition, Petitioner identified this ground of unpatentability against claims 1–3, 7, 9, and 20–23 over Biewendt, Takei, Bev Tech, David, ZFL, Chambers, Campden, and Rose. Pet. 12, 27. For claim 1, Petitioner relied on only Biewendt and Takei. Pet. 27–32. For claim 9, Petitioner relies on Biewendt, Takei, and ZFL. Pet. 38–42. In our Final Written Decision, we held that Petitioner had shown by a preponderance of the evidence that claim 1 was obvious over Biewendt and Takei. Dec. 44–54. Our decision regarding claim 1 was not challenged and is now final. Because claim 9 depends from independent claim 1, the analysis below regarding claim 9 presumes that claim 1 is obvious over Biewendt and Takei.

2. Prior Art References[12]

In the late 1980s and early 1990s, Robert Bosch GmbH manufactured high speed aseptic bottling plants, and the ZFL and Biewendt references are

[12] We do not provide an overview of Takei because of the finality of our determination regarding claim 1, and because Patent Owner does not raise any issues with regard to Takei.

descriptions of Bosch plants. Pet. 14, 17; *see also* the '1235 proceeding, Paper 7, 10.

a) ZFL

ZFL describes Bosch plants, including a system having an upstream rinser.[13] Pet. 14, 38; Ex. 1012, 2, 4, Fig. 1. ZFL describes sterilizing bottles using a vaporized hydrogen peroxide sterilant applied onto all inner and outer surfaces of the containers (Ex. 1012, 2) before filling with Ultra High Temperature (UHT) treated foodstuffs.[14] Pet. 14–15; Ex. 1012, 1, 2. ZFL states that the bottles have residual hydrogen peroxide levels of less than 0.5 ppm. Ex. 1012, 3. ZFL further discloses that the described Bosch plant achieves, for glass bottles, a greater than an 8 log reduction in the spore organism *bacillus cereus*. Pet. 38–39; Ex. 1012, Table 1.

b) Biewendt

Seven years after the ZFL article, Bosch asked the German Institute for Process Technology to conduct a study of the Bosch aseptic filling and sealing plant for glass bottles for UHT milk. Pet. 17; Ex. 1006, 1.

Biewendt describes that study, and in particular, describes a sterilization machine that simultaneously treats 9 pre-cleaned bottles by spraying with a hydrogen peroxide and warm air mix which flows around the entire surface area of the bottles. Ex. 1006, 3–5. Biewendt also describes: preheating bottles to "approx. 45 to 55°C warm" (*id.* at 3–4);

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[13] ZFL describes a "rinser with vapor treatment" that is "arranged upstream." Ex. 1013, 3. The parties refer to this device using a variety of terms. *See* Pet. 38, "upstream rinser"; PO Resp. 1, "pre-rinser", PO Resp. 2, "steam prerinser." We use the term "upstream rinser" for consistency.

[14] "UHT" treatment is an Ultra High Temperature pasteurization process. Ex. 1001, 2:17–20; Pet. 20.

sterilant concentration of "minimum 33% H_2O_2" (*id.* at 11); bottle sterilization with a "sterilizing H_2O_2 warm air mixture [that] flows around the entire surface area of the bottles" (*id.* at 4–5); bottle drying induced by "at least 80 °C hot air" (*id.* at 18); and bottle filling and sealing wherein "2 x 5 = 10 bottles [are transported] to the lifting table in 6-second cycles, where they are lifted in cycles by the filling table, with the outlet pipe connections of the filling valves being lowered into the bottles" (*id.* at 6).

Biewendt discloses that "[t]he standard plant" "is designed to process 6,000 bottles per hour" (100 bottles per minute). Ex. 1006, 2.

3. Analysis

a) Asserted Ground

As described above, claim 9 requires aseptically disinfecting a plurality of bottles to produce at least a 6 log reduction in spore organisms.[15]

Petitioner asserts that Biewendt discloses disinfecting a plurality of bottles to achieve sterility. Pet. 38. Indeed, Biewendt discloses a UHT milk plant that aseptically fills and seals bottles, and further discloses that bottles disinfected with Biewendt's process showed "zero" germs after 15 days of storage, and milk packaged according to Biewendt's process "[did] not have any negative changes after 15 days of storage at 30 °C and less than 10 germs per 0.1 cm^3." Ex. 1006, 23–24; Pet. 38. Petitioner acknowledges that Biewendt does not disclose an explicit level of reduction in spore organisms, and relies on ZFL as disclosing at least about a 6 log reduction in spore

[15] Claim 19 of the '1235 proceeding similarly requires aseptically disinfecting bottles "to a level producing at least a 6 log reduction in spore organisms." The '1235 proceeding, Ex. 1001, 16:42–52.

organisms. Indeed, ZFL discloses a greater than 8 log reduction in the spore organism *bacillus cereus*[16] using a system that includes an upstream rinser and a hydrogen peroxide sterilizer. Ex. 1012, 3, table 1; Pet. 38–39. As an alternative to ZFL's disclosure of an 8 log reduction in *bacillus cereus*, Petitioner asserts that a 6 log reduction of other spore organisms would have been obvious in view of ZFL's disclosure to reach the desired disinfection level by adjusting the usage of sterilant. Pet. 38–42; Ex. 1012, 1–2; Ex. 1004 ¶ 80.

Petitioner reasons that it would have been obvious to modify Biewendt to achieve at least a 6 log reduction in spore organisms as taught by ZFL because of the similarities between the references. Pet. 42; *see also* 41 (asserting the references have "strikingly similar subject matter"). According to Petitioner, a person of ordinary skill would have been motivated to implement the details of the Bosch method found in ZFL that were not disclosed in Biewendt. Pet. 42.

b) Patent Owner Arguments

(1) Arguments that are Not Commensurate in Scope

Patent Owner makes three arguments that are not persuasive because they are not commensurate in scope with claim 9.

First, Patent Owner argues that ZFL does not achieve a 6 log reduction of the spore organism most resistant to a given sterilant (*bacillus subtilis* for use of hydrogen peroxide as a sterilant). PO Resp. 23–29. This

[16] Petitioner refers to this spore organism as "*B. Cereus*." *See, e.g.*, Pet. 39.

argument is not commensurate in scope with claim 9.[17] Patent Owner does not identify any FDA regulation on aseptic packaging to support that interpretation. Claim 9 broadly recites reduction of "spore organisms" and is not limited to a specific spore organism. Further, claim 9 does not require use of a particular sterilant, such as hydrogen peroxide.

Second, Patent Owner argues that when evaluating the reduction of spore organisms, the FDA would not consider the impact of an upstream rinser, such as the one utilized in ZFL. PO Resp. 29–33. This argument is premised on FDA validation as a requirement of claim 9, but claim 9 contains no such requirement. *See* Pet. Reply 10–11, 14 (explaining that claim 9 does not require FDA compliance). As in the previous argument, Patent Owner does not identify any FDA regulation on aseptic packaging to support that interpretation.

Third, Patent Owner argues that there would not be a reasonable expectation of success in the proposed combination because of the difficulty of complying with the residual hydrogen peroxide requirement. PO Resp. at 33–35. As detailed above, the Federal Circuit explicitly held that "aseptic" as claimed does not include compliance with the residual hydrogen peroxide requirement found at 21 C.F.R. § 178.1005(d). *See* Pet. Reply 14.[18]

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[17] As we stated in the Final Written Decision on Remand in the '1235 case, Patent Owner conflates "FDA level of aseptic" with "FDA approval or validation." '1235 Final Written Decision on Remand, 32.

[18] These first three arguments have no meaningful distinction from the arguments made by Patent Owner against ZFL and Biewendt regarding the ground of unpatentability asserted against claim 19 in the '1235 proceeding. *Compare* PO Resp. 23–46 *to* the '1235 proceeding, Paper 31, 30–60. Given that claim 19 contains a limitation similar to that of claim 9, our analysis

(2) Arguments Regarding Rationale and Reasonable Expectation of Success

Patent Owner argues that a person of ordinary skill would not be motivated to combine the Takei valve with the Biewendt and ZFL system. PO Resp. 35–39. This argument has three underlying contentions: (a) the Biewendt and ZFL combination already achieves aseptic filling, (b) the Biewendt and ZFL system already uses steam for sterilization so that the purported advantage provided by Takei is already present, and (c) there is no disclosure in Biewendt that there is a risk of contaminants entering the sterile region of Biewendt. PO Resp. 35–37.

In our Final Written Decision, we analyzed this argument with respect to the combination of Takei and Biewendt asserted against independent claim 1, and determined that it was not persuasive. *See* Dec. 50–54. Patent Owner's argument regarding claim 9 adds nothing with regard to ZFL that impacts our analysis. Consequently, this argument remains unpersuasive for the same reasons. Dec. 50–54.

Second, Patent Owner argues that a person of ordinary skill would not have a reasonable expectation of success in achieving the combined system.[19] PO Resp. 33–35, 39–46. This argument is premised on the characterizations that: (a) ZFL and Biewendt lack sufficient detail, (b) compliance with the residual hydrogen peroxide requirement created a narrow path between using enough sterilant to sufficiently reducing spore

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rejecting the same arguments in the '1235 Final Decision on remand is equally applicable here. *See* the '1235 Final Decision on Remand, 27–35.

[19] Here we presume that Patent Owner means a system that is capable of the claimed method.

organisms without using so much that the residual hydrogen peroxide requirement was not met, and (c) the "tailing effect" made increasing the application of sterilant not a viable option. *Id*.

Regarding the alleged lack of specificity in Biewendt, we addressed that argument, with regard to claim 1, in our Final Written Decision. *See* Dec. 47–50. There, we stated,

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

Dec. 49–50.

The additional limitation added by claim 9 does not affect our analysis. That analysis is applicable here.

Regarding the alleged lack of specificity in ZFL, Patent Owner's argument here is similar to that asserted in IPR2014-01235, and we incorporate that analysis here. *See* the '1235 Final Decision on Remand, 40–42. We agree with Petitioner that whether ZFL can be "replicated," as

Patent Owner argues (PO Resp. 41, 45), is not the salient point with regard to whether claim 9 would have been obvious. Pet. Reply 17. The proper inquiry is whether ZFL enables the portion of that reference relied upon. *Id.* at 17–18. We also agree with Petitioner that the '468 patent admits that aseptic bottling systems were known (Ex. 1001, 1:21–26). *Id.* at 18.

Regarding compliance with the residual hydrogen peroxide requirement, claim 9 does not include that limitation. For that reason, compliance with that requirement would not have prevented a reasonable expectation of success.

Patent Owner contends that the "tailing effect" would preclude Petitioner's proposed approach of achieving the claimed spore reduction by application of more sterilant. PO Resp. 34–35. In Patent Owner's words, the "tailing effect" means that after a given treatment, the treatment is ineffective on the more resistant microorganisms. PO Resp. 34. Patent Owner relies on Exhibit 2058, and a summary of the relevant portions of that document follows.

Sterilization cycles in the food industry designed to destroy microorganisms may be presented on a semi-log graph as a straight line where the abscissa is time and the ordinate is log spore concentration. Ex. 2058 ("Cerf"), 1–2, Fig. 1. When such a line has upward concavity, it is referred to as a "tail" or "tailing effect." Ex. 2058, Fig. 1 (line F). At the time of the '468 patent, while there was some consensus about representing such sterilization cycles as straight lines, the tail or tailing off of biphasic curves and the upward concavity had "not gained any consensus." Ex. 2058, 3.

As an initial matter, Patent Owner's assertions based on the "tailing effect" carry little weight because the very reference Patent Owner cites describes that the "tailing effect" had not gained consensus. Ex. 2058, 3. That is, at that time, the "tailing effect" was not a well understood and accepted effect.

Further, we agree with, and adopt, Petitioner's explanation of why Patent Owner's argument is not persuasive. *See* Pet. Reply 14–15. In particular, Patent Owner's expert acknowledges that the "tailing effect" is something that should be considered and accounted for in a sterilization system. Pet. Reply 14; Ex. 1021, 132:24–135:20. "Tailing" does not occur with all forms of sterilization, rather it occurs under certain conditions; a process may or may not be subject to a "tailing effect." Pet. Reply 15. For example, Cerf observed that a "tailing effect" may occur with a hydrogen peroxide concentration of 23% at 26º C with 7.7 pH, but conditions in ZFL/Bosch were different (hydrogen peroxide concentration of 33% at 50–70º C). Pet. Reply 15; Ex. 1013 ¶ 3.1.1. Ex. 2059, 23–24, Table 4. In sum, it was known there could be some loss in sterilization effectiveness over time under some conditions (tailing effect). This knowledge would help rather than preclude a person of ordinary skill from making the modification proposed by Petitioner.

4. Conclusion

As explained above, Patent Owner does not contest that Biewendt discloses a method of disinfecting a plurality of bottles that achieves sterility, and Patent Owner does not contest that ZFL discloses at least a 6 log reduction in the spore organism *bacillus cereus*. *See* Pet. Reply 10. Patent Owner's arguments regarding Petitioner's alternative assertion that

ZFL renders obvious varying use of sterilant to reach the required reduction in spore organisms are not persuasive. Consequently, we determine that Petitioner has demonstrated by a preponderance of the evidence that claim 9 would have been obvious over Biewendt, Takei, and ZFL.

C. OBVIOUSNESS OVER TAKEI, BEV TECH, AND ZFL[20]

In the Petition, Petitioner asserted that claims 1–3, 7, 9, and 20–23 would have been obvious over ZFL, Takei, Bev Tech, Chambers, and Campden. Pet. 12, 44. For claim 1, Petitioner relied on only Takei, ZFL, and Bev Tech, and in our Final Written Decision we held that Petitioner had shown by a preponderance of the evidence that claim 1 was obvious over that combination of prior art. Pet. 44–48; Dec. 57–59. Our decision regarding claim 1 was not challenged and is now final. For claim 9, Petitioner relies on ZFL in the same manner as for the ground against claim 1. Pet. 52 (relying on Pet. 38–42); Ex. 1011, 26:19–22. Therefore, here, as with the previous ground of unpatentability, we begin with a combination that rendered claim 1 obvious and consider whether Petitioner's proposed modification of that combination in view of ZFL would have rendered claim 9 obvious.

Patent Owner asserts the same three arguments against the ground of unpatentability at hand and the prior ground (Section III.B. above). *See* PO Resp. 23–46. As explained above, these three arguments are not commensurate in scope with claim 9. Additionally, our analysis regarding

[20] Bev Tech was relied upon for claim 1, but not for the additional limitation of claim 9. We do not provide a summary of Bev Tech because our determination with regard to claim 1 is final.

Patent Owner's contention that the combination would not have a reasonable expectation of success due to the lack of detail in ZFL is equally applicable here.

1. Analysis

Patent Owner's argument regarding rationale to combine the asserted references warrants additional analysis. PO Resp. 35–37. Patent Owner argues that a person of ordinary skill in the art would not combine Takei with ZFL based on three underlying contentions. Only the first contention, namely, that there is no reason to combine Takei and ZFL to achieve aseptic filling because ZFL already achieves aseptic filling, is supported by a citation to evidence that pertains to ZFL.[21] *See* PO Resp. 36; Ex. 2057, 132:3–7. The only supported contention relates to the reason for combining ZFL and Takei with regard to a limitation of claim 1, and not with regard to the added limitation of claim 9. Consequently, Patent Owner does not make any persuasive argument against Petitioner's reasoning for further modifying the asserted combination to include a greater than 6 log reduction in spore organisms, as required by claim 9 and as taught by ZFL.

2. Conclusion

Consequently, we determine that Petitioner has demonstrated by a preponderance of the evidence that claim 9 would have been obvious over Takei, ZFL, and Bev Tech.

[21] The second and third contentions are supported by citations to evidence relating to Biewendt, and this ground of unpatentability does not involve Biewendt. Therefore, those contentions are inapposite.

IV. CLAIMS 20–23

A. ANALYSIS APPLICABLE TO BOTH GROUNDS[22]

Before separately addressing each ground of unpatentability challenging claims 20–23, we provide analysis that is applicable to both grounds.

In our original Institution Decision, we did not institute on either of the two grounds asserted against claims 20–23 based on the interpretation that the prior art must comply with the regulatory requirement of 21 C.F.R. § 178.1005(d) that the final product have a hydrogen peroxide residue of less than 0.5 ppm.[23] *See* Paper 25, 28–29, 31. As explained above, the Federal Circuit held that "aseptic" as claimed does not include compliance with 21 C.F.R. § 178.1005(d).

Patent Owner argues that we should reach the same conclusion regarding claims 20–23 as we did with regard to claim 9 in our Final Written Decision because, according to Patent Owner, claims 20–23, like claim 9, require compliance with 21 C.F.R. § 178.1005(d). PO Remand Resp. 33. As just mentioned above, the Federal Circuit expressly held that "aseptic" as claimed does not include compliance with 21 C.F.R. § 178.1005(d).

Similarly, Patent Owner argues that even if the Board does not think that compliance with 21 C.F.R. § 178.1005(d) is required by claims 20–23, it would still be improper to ignore that requirement because the machines must achieve the residual limitation to produce aseptic products for human

[22] We apply the level of skill in the art detailed in Section III.A.2 above.

[23] Claims 21–23 depend from independent claim 20.

consumption. PO Remand Resp. 56; PO Remand Sur-Reply 18–19. We disagree for the following reasons.

First, we find this argument unpersuasive because it is circular in that Patent Owner argues that even if it is not a claim requirement, it is a claim requirement. Second, Patent Owner's assertion is not well supported. *See* PO Remand Resp. 56 (citing Ex. 2098 ¶ 66); PO Remand Sur-Reply 1, 18–19 (citing again to Ex. 2098 ¶ 66). Patent Owner's expert Dr. Sharon opines that if tasked with designing the machine disclosed in the ZFL/Biewendt system, he would account for compliance with the residual hydrogen peroxide requirement of 21 C.F.R. § 178.1005(d). Ex. 2098 ¶ 66. At most, Dr. Sharon's testimony establishes a design consideration for the ZFL/Biewendt system, and that is a different question from what is required by the claims at issue. Third, Patent Owner's argument is nothing more than an attempt to circumvent the claim construction mandated by the Federal Circuit.

Independent claim 20 is quite similar to claim 1, except that claim 20 includes an additional step, namely, aseptically disinfecting a plurality of containers in a sterile tunnel. Ex. 1001, 25:60–67, 27:50–61. For each of the two grounds of unpatentability advanced against claim 20, Petitioner presents the ground of unpatentability against claim 20 together with that for claim 1. Pet. 27–32 (Biewendt and Takei), 45–48 (ZFL, Takei, Bev Tech). Our decision regarding claim 1 was not challenged on appeal, and our analysis regarding claim 1 applies to the limitations that are common to claims 1 and 20. Consequently, our analysis with regard to claim 20 focuses on the Federal Circuit's interpretation of "aseptic" as it applies to the limitation that is additional to claim 1. *See* Pet. Remand Reply 6–7; *see also*

Pet. Remand Reply 6–7 (arguing that the limitations that overlap with claim 1 have been shown to be obvious).

B. Obviousness Over Biewendt, Takei, Chambers, Campden, and Rose

1. Introduction

In the Petition, Petitioner identified this ground of unpatentability against claims 1–3, 7, 9, and 20–23 over Biewendt, Takei, Bev Tech, David, ZFL, Chambers, Campden, and Rose. Pet. 12, 27–32. Petitioner applied Biewendt, Takei, Chambers, Campden, and Rose to claims 20–23, as detailed below.

2. Claim 20

a) Introduction

Petitioner contends that claim 20 would have been obvious over Biewendt and Takei. Pet. 27–32. As explained above, our determination that claim 1 would have been obvious over Biewendt and Takei is final, and thus, we analyze the additional limitation of claim 20.

b) Asserted Ground

Petitioner contends that Biewendt's system includes a bottle sterilizing machine that utilizes hydrogen peroxide and hot air within a sterile tunnel to disinfect a plurality of containers. Pet. 27–28. Indeed, Biewendt contains such a disclosure. *See* Ex. 1006, 4–5, 18, Fig. 1 (describing the bottle sterilization machine as processing groups of 9 bottles simultaneously); *see also* Ex. 1006, 1–2, Pet. 17–18 (describing Biewendt's plant as a tested aseptic filling and sealing plant for processing UHT milk filled under aseptic conditions).

c) Patent Owner Arguments

According to Patent Owner, Petitioner's ground of unpatentability is built on the incorrect interpretation that "aseptic" means "free of pathogenic microorganisms," when the proper interpretation is that "aseptic" addresses both pathogenic and nonpathogenic organisms. PO Remand Resp. 49–50 (citing Pet. 11; 21 C.F.R. § 113.3).

The Federal Circuit determined that although "aseptic" was not expressly defined by FDA regulations, "aseptic processing and packaging" is "the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms." *Nestlé I*, 686 Fed. App'x at 919 (citing 21 C.F.R. § 113.3(a) (1999)). We agree with Patent Owner that "commercial sterility" is defined as free of both microorganisms having health significance and microorganisms of non-health significance capable of reproducing in the food under normal non-refrigerated conditions. *Id.* (citing 21 C.F.R. § 113.3(e) (1999)). Further, we agree that in the Petition, Petitioner asserted that "aseptic" as claimed means "free of microorganisms." *See* Pet. 11.

Even accepting Patent Owner's contention, we do not agree that the Petition is defective as Patent Owner asserts. It is uncontested that elimination of pathogenic microorganisms will of necessity also eliminate microorganisms of non-health significance. *See* Pet. Remand Reply 8; Ex. 2019, 48:20–50:19 (Dr. Heldman explaining that elimination of pathogenic microorganisms eliminates other microorganisms); PO Remand Sur-reply, *passim* (making no assertion to the contrary). Therefore, we determine that the ground of unpatentability asserted by Petitioner meets the "aspetic"

requirement of claim 20 in that the process eliminates both pathogenic microorganisms and microorganisms of non-health significance capable of reproducing in the food under normal non-refrigerated conditions.

d) Conclusion

We determine that a preponderance of the evidence supports Petitioner's assertion that claim 20 would have been unpatentable as obvious in view of Biewendt and Takei.

3. Claim 21

a) Introduction,

Claim 21 depends from independent claim 20 and recites, "wherein the aseptically disinfecting is to a level producing as least a 6 log reduction in spore organisms." This limitation is similar to the limitation added by claim 9.[24]

b) Asserted Ground

Petitioner presents the ground of unpatentability for claim 21 together with that for claim 9, asserting that the claims would have been obvious over Biewendt, Takei, and ZFL. *See* Pet. 38–42; *see also* Section III.B.3.a above (summarizing the ground).

c) Patent Owner Arguments[25]

Before addressing Patent Owner's arguments individually, we note that the arguments regarding claim 21 in Patent Owner's Response on Remand are very similar to those for claim 9 in the Patent Owner's

[24] Claim 19 of the '1235 case includes a similar limitation.

[25] We recognize that Patent Owner's arguments here regarding a 6 log reduction in spore organisms and commercial sterility are not dependent on reading 21 C.F.R. § 178.1005(d) into claim 21. *See* PO Remand Sur-Reply 18.

Response. Our analysis of those arguments above (Section III.B.3.b.) is applicable here.

Patent Owner argues that under the *Phillips* claim construction standard, Petitioner has not met its burden to demonstrate that ZFL discloses a 6 log reduction as claimed. PO Remand Resp. 34–37; PO Remand Sur-Reply 19. We need not analyze this argument because we are applying a broadest reasonable claim construction.

Patent Owner also argues that ZFL discloses only a 5.1 log reduction in *bacillus cereus* because the FDA would not consider the results of the upstream rinser. PO Remand Resp. 37–42. Just as in the argument for claim 9 analyzed above, this argument is unpersuasive because it is premised on the interpretation that FDA validation is a claim requirement, when the Federal Circuit confirms that it is not.

Regarding Petitioner's alternative assertion that it would have been obvious to achieve a 6 log reduction in view of ZFL's disclosure to reach the desired disinfection level by adjusting the usage of sterilant, Patent Owner argues that this would not have been possible due to the residual hydrogen peroxide requirement. PO Remand Resp. 47; PO Remand Sur-Reply 23. That argument is not persuasive because, as we explained above, claim 20 does not call for compliance with the residual hydrogen peroxide requirement.

In addition, in the Sur-Reply, Patent Owner adds that in ZFL, the upstream rinser cannot contribute to reaching a 6 log reduction in spore organisms as claimed because the bottles are exposed to plant atmosphere after they leave the steam rinser and travel to the bottle sterilization machine. PO Remand Sur-Reply 20–21.

This ground of unpatentability incorporates ZFL's upstream rinser into the combined system of Biewendt and Takei. *See* Pet. 27–32, 38–42. In other words, Petitioner proposes that ZFL's upstream rinser would have been positioned within the *combined* Biewendt and Takei system, not positioned in ZFL's system. Patent Owner's argument is unpersuasive because it is inapposite and argues against the references individually. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (explaining that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references).

Patent Owner further argues that ZFL's disclosure of achieving a maximum insterility rate of 1:10,000 does not amount to the claimed 6 log reduction.[26] PO Remand Resp. 42–45; *see also* PO Remand Sur-Reply 22–23 (repeating this argument and stating that Petitioner has not met their burden). This argument is unpersuasive because it does not address the ground of unpatentability as articulated by Petitioner. Specifically, even if ZFL's disclosure of a maximum sterility rate of 1:10,000 does not amount to the claimed 6 log reduction, the ground of unpatentability asserts that it would have been obvious to modify sterilant application to reach the required sterility rate. Patent Owner does not address Petitioner's argument

[26] This argument only applies to Petitioner's alternative assertion that it would have been obvious in view of ZFL to reach the desired disinfection level by modifying the usage of sterilant. *See* Pet. 38–42; Ex. 1012, 1–2; Ex. 1004 ¶ 80. This argument does not apply to Petitioner's assertion that ZFL discloses a greater than 6 log reduction in spore organisms by disclosing a greater than 8 log reduction in the spore organism *bacillus cereus*.

that the asserted references render this limitation obvious, even if not expressly disclosed.

Similarly, Patent Owner argues that Petitioner has not met its burden to explain that ZFL meets the 6 log reduction requirement. PO Remand Sur-Reply 23. Simply arguing that Petitioner has not met its burden is not persuasive without an explanation of why that is the case.

d) Conclusion

Claim 21 is similar to claim 9 and our analysis of claim 9 is applicable here. Patent Owner's arguments are either not commensurate in scope with claim 21, or not responsive to the ground as articulated by Petitioner. See Pet. 38–42. We, thus, determine that a preponderance of the evidence supports Petitioner's assertion that claim 21 would have been unpatentable as obvious in view of Biewendt, Takei, and ZFL.

4. Claim 22

a) Introduction

Claim 22 depends from independent claim 20 and recites, "wherein the aseptic product has been sterilized to a level producing at least about a 12 log reduction in *Clostridium botulinum*."[27] Notably, claim 22 specifies a reduction of spore organisms in the aseptic product, while claims 9 and 21 specify a reduction of spore organisms for disinfection of bottles.

[27] In the 1235 proceedings, claim 18 includes a similar limitation. *Clostridium botulinum is also referred to as C. botulinum.*

b) Prior Art References

(1) Chambers[28]

Chambers is the second edition of *Principles of Aseptic Processing and Packaging*, from the Food Processors Institute. Ex. 1009, 1–5. Chambers describes aseptic processing and packaging as: commercial sterilization of foods (closed system) cooled to ambient temperature, sterilization of container, packaged in sterile environment at ambient temperature, and having extended shelf life without the need of refrigeration. Ex. 1009, 11.

Chambers describes that processes for commercial sterility of UHT milk use a "botulinal" cook to reduce the level of *Clostridium Botulinum* spores by 12 log. Ex. 1009, 48; Pet. 21, 42; Ex. 1004 ¶ 85.

(2) Campden[29]

Campden is the proceedings of a seminar regarding aseptic foodstuffs. Ex. 1010, 2. Campden describes aseptic packing as

> the packaging of sterilized pack contents in sterilized packs in sterile surroundings using sterile machinery, where after packaging neither the product nor the packaging material nor the internal atmosphere has any further sterilizing action and the product is not subjected to unpermissible growth of microorganisms.

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[28] *Principles of Aseptic Processing and Packaging* (James V. Chambers & Philip E. Nelson eds., 2d ed.) (1993) (Ex. 1009, "Chambers"). We refer to the page numbers added by Petitioner and not the native page numbers.

[29] Ex. 1010, Campden Food Preservation Research Association, *Aseptic Packaging: Proceedings of Seminar held on 20th April 1983* (Apr. 1983). We refer to the page numbers added by Petitioner and not the native page numbers.

Ex. 1010, 3.

Campden discloses that aseptic packaging requires a 12 log reduction of *Clostridium Botulinum* spores. Ex. 1010, 5; Pet. 21

(3) Rose[30]

Rose is directed to good manufacturing guidelines for processing and aseptic packaging of low-acid foods. Ex. 1011, 1.

Rose discloses that the minimum botulinum heat process must reduce the spore *Clostridium Botulinum* to not more than a negative 12 log. Ex. 1011 ¶ 2.20; Pet. 21, 43; Ex. 1004 ¶ 13.

c) Asserted Ground

Petitioner contends that Biewendt discloses an aseptic process of filling containers with UHT milk, and processing of UHT milk necessarily includes a 12 log reduction of spores, as disclosed by Chambers. Pet. 42; Ex. 1004 ¶ 85. Petitioner's contention is supported by the references. Specifically, Biewendt discloses filling and sealing bottles of UHT milk, and Chambers discloses that processing of UHT milk includes a 12 log reduction of *Clostridium botulinum* spores. Ex. 1006 ¶ 1; Ex. 1009, 48.

Alternatively, Petitioner contends that if Biewendt does not disclose the claimed 12 log reduction, it would have been obvious in view of Campden and Rose. Pet. 43–44. Specifically, Petitioner contends that each additional reference discloses that a 12 log reduction in *Clostridium botulinum* was a requirement for aseptic packaging. Pet. 43. We agree that each reference discloses that requirement. Ex. 1010, 5; Ex. 1011 § 2.2.

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[30] Ex. 1011, D. Rose, *Pt. 1: Principles of Design, Installation and Commissioning, Good Manufacturing Practice – Guidelines for the Processing and Aseptic Packaging of Low-Acid Foods* (1st ed. 1986).

d) Patent Owner Arguments

Patent Owner's arguments for claim 20 are unpersuasive, as explained above, and Patent Owner makes no additional arguments for claim 22.

e) Conclusion

We determine that a preponderance of the evidence supports Petitioner's assertion that claim 22 would have been unpatentable as obvious over (1) Biewendt, Takei, and Chambers, and (2) over Biewendt, Takei, Campden and Rose.

5. Claim 23

a) Introduction

Claim 23 depends from independent claim 20 and recites, "wherein the plurality of containers are filled at least about 100 containers per minute."[31]

We initially emphasize two aspects of claim 23. First, claim 23 does not require filling greater than 100 bottles per minute; rather, it requires filling the plurality of containers "at least about" 100 containers per minute. *See* Pet. Remand Reply 19. Second, claim 23 is not limited to bottles; rather, it more broadly recites "containers."

b) Asserted Grounds

Petitioner builds upon the contention that claim 20 would have been obvious over Biewendt and Takei by adding that Biewendt's system processes 100 containers per minute as required by claim 23. Pet. 44. Indeed, Biewendt states that its standard plant is designed to process 6,000 bottles per hour. Ex. 1006, 2.

[31] In the 1235 proceeding, claim 18 includes a similar limitation.

c) Patent Owner Arguments

Patent Owner argues that Petitioner has not shown that a person of ordinary skill in the art would have had a reasonable expectation of success "in achieving *bottling* speeds of *greater* than 100 bottles per minute."[32] PO Remand Resp. 51–56 (emphasis added).

This argument is not commensurate in scope with claim 23 in two respects. As explained above, claim 23 calls for a filling speed of *at least about* 100 containers per minute, and does not require filling speeds *greater* than 100 bottles per minute. Further claim 23 is not limited to *bottles*, it more broadly recites "*containers*." Beyond the fact that Patent Owner's overall argument is not commensurate in scope with claim 23, as explained below, Patent Owner's underlying contentions are also unpersuasive.[33]

First, Patent Owner suggests our determination here should follow some of the obviousness determinations in our initial Final Written Decision in IPR2014-01235. PO Remand Resp. 52–53 (citing Ex. 2081 (Final Written Decision in IPR2014-01235), 28–29). Patent Owner acknowledges that the Federal Circuit disagreed with our claim construction in our initial Final Written Decision, but asserts that "the Board's findings as to patentability were not disturbed." *See* PO Remand Resp. 53. We disagree. The Federal Circuit vacated the initial Final Written Decision in IPR2014-

[32] We note that arguments related to ZFL pertain to the next ground of unpatentability but not this one. Patent Owner acknowledges this by referring to Biewendt as newly instituted ground 1 and ZFL as newly instituted ground 2. PO Remand Resp. 51.

[33] Petitioner's observation that in the reexamination proceeding Patent Owner abandoned the filling speed limitation of claim 23 is also worth noting. *See* Pet. Remand Reply 20.

01235, which includes our patentability determinations as to all challenged claims in that proceeding. *See Nestlé II,* 884 F.3d 1350, 1352 (Fed. Cir. 2018); *see also* Pet. Remand Reply 21 (arguing that Patent Owner is incorrect based on the Federal Circuit's holding).

Second, Patent Owner contends that the complexity of navigating the tension between the FDA's commercial sterility requirement and the residual hydrogen peroxide requirement would prohibit reaching the claimed rate of greater than 100 bottles per minute. PO Remand Resp. 53. Again, claim 23 does not require a filling speed greater than 100 bottles per minute, and claim 23 does not require compliance with the residual hydrogen peroxide requirement. *See* Pet. Remand Reply 21.

Third, Patent Owner argues that Biewendt is mostly silent regarding how the sterilization process is achieved and does not disclose sufficient detail to reproduce the process. PO Remand Resp. 54–56; Ex. 2032 ¶¶ 34, 35, 37, 39. We agree with Petitioner that Patent Owner incorrectly focuses on whether Biewendt's system as a whole could be reproduced rather than on the proper question of whether a person of ordinary skill could have reproduced the portion of the prior art relied upon. Pet. Remand Reply 21– 22; Pet. 27–32.

d) Conclusion

Claim 23 calls for filling a plurality of containers at a rate of least about 100 containers per minute, and Biewendt expressly describes that capability. Patent Owner's argument that Petitioner has not shown a reasonable expectation of success is not commensurate in scope with claim 23. We determine that a preponderance of the evidence supports Petitioner's

assertion that claim 23 would have been unpatentable as obvious over Biewendt and Takei.

C. OBVIOUSNESS OVER ZFL, TAKEI, BEV TECH, CHAMBERS, AND CAMPDEN

1. Introduction

In the Petition, Petitioner asserted that claims 1–3, 7, 9, and 20–23 over ZFL, Takei, Bev Tech, Chambers, and Campden. Pet. 44. Petitioner applied ZFL, Takei, Bev Tech, and Campden to claims 20–23, as detailed below.

2. Claim 20

Our analysis here parallels our analysis with regard to claim 20 of the previous ground (Section Iv.B.).

Claim 20 is similar to claim 1, except that claim 20 includes an additional step. Petitioner presents the ground of unpatentability against claim 20 together with that for claim 1, contending that these claims would have been obvious over ZFL, Takei, and Bev Tech. Pet. 44–48. Our determination that claim 1 would have been obvious over ZFL, Takei, and Bev Tech is final.[34] Consequently, our analysis with regard to claim 20 focuses on the limitation that is additional to claim 1, namely, aseptically disinfecting a plurality of containers in a sterile tunnel. Here, as with the prior ground based on Biewendt and Takei, Petitioner relies on ZFL for the additional limitation of claim 20. For that reason, our analysis regarding claim 20 based on Biewendt and Takei is applicable here. We determine that

[34] Given that this determination is final, we need not include a summary of Bev Tech.

a preponderance of the evidence supports Petitioner's assertion that claim 20 would have been unpatentable as obvious in view of ZFL, Takei, and Bev Tech.

3. Claim 21

Claim 21 depends from independent claim 20 and recites, "wherein the aseptically disinfecting is to a level producing at least a 6 log reduction in spore organisms." This limitation is similar to the limitation added by claim 9. Petitioner relies on ZFL for the additional limitation in the same manner as for the prior ground based on Biewendt, Takei, and ZFL. *See* Pet. 52; *see also* Section III.B.3.a above (summarizing the ground).

This ground of unpatentability differs from the previous ground in a manner that necessitates further analysis. In the prior ground, the portion of the system from the upstream rinser to the bottle sterilization machine is that of the Biewendt and Takei combination, but here, Petitioner relies on ZFL for that portion. *See* Pet. 45–48. For that reason, Patent Owner's argument that in ZFL, the bottles are exposed to plant atmosphere after they leave the upstream rinser and travel to the bottle sterilization machine (PO Remand Sur-Reply 20–21), relates to this ground of unpatentability as articulated by Petitioner.

Despite relating to the ground as articulated by Petitioner, Patent Owner is unpersuasive for the following reasons. In the ground of unpatentability for claim 1 based on ZFL, Takei, and Bev Tech, Petitioner asserted that ZFL discloses a "fully enclosed system, which is ventilated by sterile air at a slight overpressure [and] is free of unsterile transport media." Pet. 45; Ex. 1004 ¶ 51. We determined with regard to claim 1 that in the

asserted ground, Takei's valve would be disposed in ZFL's sterile region. *See* Dec. 57–59. That analysis is applicable here.

Even considering Patent Owner's argument, it is not persuasive. As explained above with regard to the similar limitation of claim 9, Patent Owner conflates "FDA level of aseptic" with "FDA approval or validation." Claim 21 does not require FDA approval and therefore the impact of the upstream rinser is not precluded. Further, even if Patent Owner is correct that bottles exiting ZFL's upstream rinser are exposed to plant atmosphere, ZFL expressly discloses that those bottles are sterilized to achieve at least a 6 log reduction of spore organisms by the bottle sterilization area of the machine. *See* Pet. 38–39; Ex. 1012, Table 1. Consequently, that exposure to plant atmosphere, even if true, does not preclude sterilization to the claimed level.

We determine that a preponderance of the evidence supports Petitioner's assertion that claim 21 would have been unpatentable as obvious in view of ZFL, Takei, and Bev Tech.

4. Claim 22

Claim 22 depends from independent claim 20 and recites "wherein the aseptic product has been sterilized to a level producing at least about a 12 log reduction in *Clostridium botulinum.*"

Petitioner contends that ZFL describes aseptic filling of UHT milk, and that such process includes a 12 log reduction in *Clostridium botulinum.* Pet. 52 (referencing Section IV.B.2. found at Pet. 42–44). We agree that ZFL discloses aseptic filling of UHT milk. Ex. 1012, 1.

Patent Owner's arguments for claim 20 are unpersuasive, as explained above, and Patent Owner makes no additional arguments for claim 22.

We determine that a preponderance of the evidence supports Petitioner's assertion that claim 22 would have been unpatentable as obvious in view of ZFL, Takei, and Bev Tech.

5. Claim 23

Claim 23 depends from independent claim 20 and recites, "wherein the plurality of containers are filled at least about 100 containers per minute."

Petitioner builds upon the contention that claim 20 would have been obvious over ZFL, Takei and Bev Tech, by adding that ZFL is designed to process 100 containers per minute. Pet. 53. Indeed, ZFL expressly discloses a system having a fill rate of 100 bottles per minute. Ex. 1012, 4.

Patent Owner makes the same arguments against ZFL as were made with regard to claim 23 in the prior ground based on Biewendt and Takei. *See* PO Remand Resp. 51–56. These arguments are not commensurate in scope with claim 23, and our analysis there (Section IV.C.5.) is applicable here.

We determine that a preponderance of the evidence supports Petitioner's assertion that claim 23 would have been unpatentable as obvious over ZFL, Takei, and Bev Tech.

V. OTHER MATTERS

A. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner submitted a Motion to Exclude Exhibit 1046, an exhibited submitted by Petitioner in support of Petitioner's Motion to Disqualify Mr. Mark Mansour. Papers 111, 125. As background for our

ruling on Patent Owner's Motion to Exclude, we summarize Petitioner's Motion to Strike and Petitioner's Motion to Disqualify Mr. Mansour.

We granted Petitioner's Motion to Strike (Paper 110) the following information: (1) portions of Patent Owner's Response (Paper 98), (2) the entirety of Exhibit 2097 (Decl. Mark Mansour), and (3) portions of Patent Owner's Sur-Reply. *See* Paper 127 (Decision on Motion to Strike); Paper 130 (modifying Paper 127); Paper 134 (addressing Sur-Reply and providing direction on request for reheating); Paper 157 (denying Patent Owner's request for rehearing). We did not consider the stricken information when making this decision.

We clarify one point with regard to page 33 of Patent Owner's Response (Paper 98). Petitioner requested that we strike Section "IV.A (pages 3–32)" of Patent Owner's Response, but Section IV.A includes page 33. *See* Paper 110, 1, *see also* 10 (asking to strike Section "IV.A" without page numbers); Paper 127, 3 (specifying pages 3–32). Neither party raised this issue. Although page 33 is part of Section IV.A and includes content similar to the rest of that Section (*i.e.*, pages 3–32), Patent Owner did not have notice or opportunity to address striking that page, and consequently we considered that page in making this decision.

We denied Petitioner's Motion to Disqualify Mr. Mansour (Paper 111) as moot because we struck Mr. Mansour's Declaration (Ex. 2097). Paper 127 (granting Petitioner's Motion to Strike the Mansour Declaration), Paper 128 (denying Petitioner's Motion to Disqualify as moot); *see also* Paper 157 (denying Patent Owner's request for rehearing of the decision granting Petitioner's Motion to Strike).

Consequently, we need not consider Exhibit 1046, filed in support of the disqualification motion. Accordingly, we deny Patent Owner's Motion to Exclude Exhibit 1046 as moot.

B. PETITIONER'S MOTION TO EXCLUDE

Petitioner submitted a Motion to Exclude the following exhibits: the Nelson Declaration (Ex. 2092), the Sastry Declarations (Ex. 2085, 2093, 2100, and 2101), and the Mansour Declaration (Ex. 2097). Paper 122. Patent Owner submitted an Opposition. Paper 133. Petitioner submitted a Reply. Paper 135.

For the reasons that follow, we deny Petitioner's Motion as to all exhibits as moot.

1. Nelson Declaration (Ex. 2092)

Patent Owner cites Exhibit 2092 in support of the assertion that in the ZFL system, after the bottles leave the upstream rinser, the bottles are transported to the separate downstream bottle sterilization machine in ambient plant atmosphere. *See* PO Remand Resp. 38; *see also* PO Remand Resp. 41 (citing Exhibit 2092 in support of the assertion that a figure in ZFL reveals that the enclosed tunnel downstream of the bottle sterilization machine includes circles representing intervention points where the operator can reach into the sterile tunnel with gloves to handle bottles without risking contamination).

As detailed above, we determined with regard to claim 1 that ZFL discloses a closed system, and that determination is final. For that reason, we did not consider the Nelson Declaration. Consequently, Petitioner's motion is moot with regard to this exhibit.

2. Sastry Declarations (Ex. 2085, 2093, 2100, and 2101)

Petitioner contends that each of the Sastry Declarations is inadmissible hearsay. Paper 122, 5–7. Petitioner sought to cross-examine Dr. Sastry. Petitioner contends that the Sastry Declarations are cumulative of Dr. Sharon's testimony (Ex. 2098 ¶¶ 35, 47, 66). Paper 122, 7–8. Petitioner contends that Exhibit 2085 should also be excluded under Federal Rules of Evidence 401, 402, and 403. Paper 122, 8–9.

a) Exhibit 2085

Patent Owner only cited to Exhibit 2085 in a portion of Patent Owner's Response that was stricken. *See* PO Remand Resp. 23. We did not consider Exhibit 2085 in making this decision, and for that reason Petitioner's Motion is moot with regard to this Exhibit.

b) Exhibit 2093 and 2101

Patent Owner cites Exhibits 2093 and 2101 in support of the assertion that in the ZFL system, after the bottles leave the upstream rinser, the bottles are transported to the separate downstream bottle sterilization machine in ambient plant atmosphere. PO Remand Resp. 38. Just as with Exhibit 2092 above, our determination that ZFL discloses a closed system is final, and we did not consider the evidence associated with that argument. Consequently, Petitioner's motion is moot with regard to Exhibits 2093 and 2101.

c) Exhibit 2100

Patent Owner only cited to Exhibit 2100 in support of the argument that under a *Phillips* claim construction Petitioner has not met their burden. PO Remand Resp. 37. As explained above, we are not applying a *Phillips* claim construction, and for that reason, that argument is irrelevant, and we

did not consider Exhibit 2100. Consequently, Petitioner's motion is moot with regard to this exhibit.

3. Mansour Declaration (Ex. 2097)

Given that we struck the Mansour Declaration, as detailed above, the motion to exclude is moot with regard to this Exhibit.

C. PETITIONER'S ALLEGEDLY NEW ARGUMENTS

Patent Owner contends that Petitioner makes two arguments on pages 12–14 of Petitioner's Reply on Remand that are new arguments necessary to make a *prima facie* case of obviousness, and, as such, these arguments were required to be in the Petition. PO Remand Sur-Reply 20–22. Those arguments alleged to be new are that ZFL's system is fully enclosed and that it would have been obvious to make it enclosed. PO Remand Resp. 20–22.

Contrary to Patent Owner's contentions, and as discussed above (Section IV.C.3.), Petitioner asserted in the Petition that ZFL discloses a "fully enclosed system." Pet. 45. For that reason, Petitioner's arguments are not new and Patent Owner's contention is unpersuasive.

D. MOTIONS TO SEAL

The record will remain undisturbed as ordered below.

E. ADMINISTRATIVE PROCEDURE ACT

Patent Owner contends that the Board's actions on remand violated the Administrative Procedure Act (APA) in three ways.

1. Additional Briefing

Patent Owner contends that our decision to preclude additional briefing on the grounds of unpatentability against claim 9 (Paper 86)

violated the APA in that Patent Owner did not have a fair opportunity to address the grounds under the Federal Circuit's claim construction.[35] PO Remand Resp. 58–59. Patent Owner's contention is unpersuasive for two reasons.

First, Patent Owner had opportunity to argue claim construction in *Nestlé II*. *See* Pet. Remand Reply 24. Second, Patent Owner did not request claim construction with regard to claim 9 in this proceeding. In our first order after remand, we noted that we had denied Patent Owner's request for additional claim construction briefing in related case IPR2014-01235, and further noted that *Patent Owner had not requested claim construction briefing in the proceeding at hand*. Paper 86, 2–3.[36] Patent Owner did not request reconsideration of our decision in Paper 86.

Second, Patent Owner does not identify, nor are we aware, of any APA case holding that due process requires permitting a party additional briefing on remand where that case was remanded based on a change in claim construction provided by the Federal Circuit.

2. Fair Notice

Patent Owner contends that our supplemental institution decision instituting on two grounds against claims 20–23 (Paper 86) violated the APA in that it did not give fair notice to Patent Owner because the Board did not provide reasoning to explain how the Petitioner demonstrates a reasonable

[35] We note this argument is limited to claim 9 and does not apply to claims 20–23.

[36] Paper 97 clarifies Paper 86 on an issue that is not relevant to our analysis here.

likelihood that those grounds would render claims 20–23 unpatentable. PO Remand Resp. 59.

Our Institution Decision (Paper 35) explained how Petitioner had shown a reasonable expectation of success with regard to at least one claim, and that explanation is sufficient under the APA. *See generally* 35 U.S.C. § 314(a); 37 C.F.R. § 42.108; *SAS Inst. V. Iancu*, 138 S.Ct. 1348 (2018).

3. Phillips Claim Construction

Patent Owner contends that their rights were violated by the Board denying the opportunity to provide briefing on a *Phillips* type claim construction. PO Remand Resp. 59–60. Patent Owner elaborates that in this proceeding, and IPR2014-01235, Patent Owner "disclaimed any claim construction that would not require compliance with the FDA's residual hydrogen peroxide requirement set forth in 21 C.F.R. § 178.1005." PO Remand Resp. 60.

Here, we apply a broadest reasonable claim interpretation as our rules required at the time, and not a *Phillips* type interpretation. Consequently, briefing on a Phillips type construction is not needed.

Even considering Patent Owner's contention, it is not persuasive. The actions that Patent Owner alleges amount to disclaimer (arguing in both this proceeding and the '1235 proceeding that the claims only applied to processes that meet the residual hydrogen peroxide requirement), occurred prior to *Nestle I* and *Nestle II*, and yet the Federal Circuit did not limit the claims as Patent Owner asserts. *See* Pet. Remand Reply 24–25. If we were to find Patent Owner's actions to be disclaimer, such finding would render the Federal Circuit's claim construction meaningless. That we will not do.

VI. CONCLUSION

We conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 9 and 20–23 are unpatentable.

VII. ORDER

For the reasons given, it is:

ORDERED that claim 9 has been shown by a preponderance of the evidence to be unpatentable over either (1) Biewendt, Takei, and ZFL, or (2) ZFL, Takei, and Bev Tech;

ORDERED that claim 20 has been shown by a preponderance of the evidence to be unpatentable over either (1) Biewendt and Takei, or (2) ZFL, Takei, and Bev Tech;

ORDERED that claim 21 has been shown by a preponderance of the evidence to be unpatentable over either (1) Biewendt and Takei, and ZFL, or (2) ZFL, Takei, and Bev Tech;

ORDERED that claim 22 has been shown by a preponderance of the evidence to be unpatentable over either (1) Biewendt, Takei, and Chambers, (2) Biewendt, Takei, Campden, and Rose, or (3) ZFL, Takei, and Bev Tech

ORDERED that claim 23 has been shown by a preponderance of the evidence to be unpatentable over either (1) Biewendt and Takei, or (2) ZFL, Takei, and Bev Tech;

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

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

FURTHER ORDERED that the record shall remain undisturbed until no later than thirty days after the resolution of any appeals or the expiration of time for filing such appeals, at such time the expectation is that the information filed under seal will be made public in due course; and

FURTHER ORDERED that any motion to expunge confidential information is due no later than thirty days after the resolution of any appeals or the expiration of time for filing such appeals.

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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Paper 171
(public version of Paper 168)

Paper No. ____
Filed: August 22, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NESTLÉ USA, INC.,
Petitioner,
v.

STEUBEN FOODS, INC.,
Patent Owner

Case 2015-00249
Patent No. 6,481,468

REDACTED DECISION DENYING PATENT OWNER'S REQUEST FOR REHEARING

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Paper 168
Entered: August 16, 2019

[redacted]

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NESTLÉ HEALTHCARE NUTRITION, INC.,
Petitioner,

v.

STEUBEN FOODS, INC.,
Patent Owner.

Cases
IPR2014-01235 (Patent 6,945,013 B2)
IPR2015-00249 (Patent 6,481,468 B1)

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

KAUFFMAN, *Administrative Patent Judge.*

DECISION
Denying Patent Owner's Request for Rehearing on the Motion to Terminate
37 C.F.R. §42.71

[redacted]

I. Overview

Patent Owner asks that we modify our Decision (Paper 158, "Decision" or "Dec.") denying Patent Owner's Motion to Terminate (Paper 90, "Motion," or "Mot."). Paper 159 ("Request" or "Req. Reh'g"); Paper 167 ("PO Reply").[1] Petitioner opposes. 37 C.F.R. § 42.71(d) (standard); Paper 165 (Petitioner's "Opposition" or "Opp.").

For the reasons that follow, we deny Patent Owner's Request.

II. Analysis

A. Ventex

Patent Owner contends that we misapprehended or overlooked three issues[2] related to *Ventex*.[3] Req. Reh'g 1–8. In short, Patent Owner contends that when the record is properly evaluated under *Ventex*, Petitioner and GEA are privies. *Id.*

Patent Owner argues that our privity analysis was "infected" by our reference to *Ventex* as a routine, non-precedential case, when in fact, by the

[1] Where the privity issue is the same in both proceedings, we reference only IPR2015-00249. Where the cases differ, we reference each case individually.

[2] We refer to the Request, Sections I-III.

[3] *Ventex Co., Ltd. v. Columbia Sportswear N. Am., Inc.*, Case No. IPR2017-00651 (PTAB Feb. 19, 2019) (precedential).

[redacted]

time our Decision issued, *Ventex* had been designated precedential.[4] Req. Reh'g. 1. We disagree. Petitioner correctly points out that "the precedential nature of *Ventex* has no substantive impact on the Decision." Opp. 9.

Ventex is distinguishable from the cases at hand. First, in *Ventex*, the petitioner and Seirus had a supplier agreement that required *Ventex* to

> indemnify, defend and hold harmless Seirus . . . from and against any and all claims, demand, damages, liabilities, losses, costs and expenses, (including without limitation, attorney's fees and costs), of any nature whatsoever, which arise from [Ventex's] failure to perform its obligations.

Ventex, slip op. 7.

In contrast, in the cases at hand involve significantly less control. *See generally* Opp. 10–11. The Line 8 Agreement does not require Petitioner to indemnify GEA for "any and all claims," nor does it require Petitioner to defend GEA. Paper 25, 11–19; Paper 76, 6 (incorporating the analysis of Paper 25). Rather, the Line 8 Agreement provides: [redacted]. Paper 25, 11–19;

[4] *See* Dec. 25. *Ventex* was designated precedential on April 16, 2019, and our Decision was entered on May 14, 2019. After briefing for the Motion to Terminate was complete, but before the Decision was issued, the parties identified, by email to the Board, five cases (including *Ventex*) as relevant to our Decision. *See* Dec. 24–25; Exs. 3008, 3009, 3012. The parties did not submit briefing on those cases.

[redacted]

Paper 76, 6 (incorporating the analysis of Paper 25). Further, Patent Owner has admitted that Petitioner and GEA do not control each other under their Joint Defense Agreement. Dec. 23. Patent Owner's Request does not contest that admission.

Second, in *Ventex*, petitioner and Seirus entered into an Exclusive Manufacturing Agreement that dictated petitioner only manufacture Heatwave fabric for Seirus, for which Seirus paid an exclusivity fee. *Ventex*, slip op. 7. In contrast, in the cases at hand, Petitioner and GEA were not in an exclusive manufacturing agreement.[5]

Third, *Ventex* involved evidence suggesting that the Exclusive Manufacturing Agreement may have been a cover for Seirus to fund the *inter partes* reviews. *Ventex*, slip op. 13. The cases at hand do not include evidence of such a funding scheme. *See* Opp. 10–11.

Ventex is distinguishable from the cases at hand, and for that reason alone, consideration of *Ventex* does not show that we should modify our Decision.[6] *Contra* Req. Reh'g 5–9.

Furthermore, in the section alleging that under *Ventex*, Petitioner and GEA are privies, Patent Owner does not assert that our Decision overlooked

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[5] We previously analyzed Patent Owner's assertion that GEA built Lines 1–6 and 7 to Petitioner's Specifications, and we determined that assertion was not supported by the evidence of record. Paper 42, 47–58. Patent Owner repeats that unsupported assertion here without citation to any evidence. Req. Reh'g 5.

[6] In distinguishing *Ventex*, we do not rely on when the Line 8 agreement was executed relative to the timing of service of the complaint. *See* Req. Reh'g 3–5.

[redacted]

or misapprehended anything; rather, Patent Owner simply repeats old assertions. *See* Req. Reh'g 5–8. We agree with Petitioner that this line of argument is premised on a mischaracterization of *Ventex*, and it does not demonstrate that our Decision should be modified. *See* Opp. 11–13.

Patent Owner implies that our analysis improperly ignores Judge Reyna's concurrence in *RPX*[7] as applied via *Ventex*. Req. Reh'g 1–2. *Ventex* cites to Judge Reyna's concurrence in *RPX* for two legal propositions.[8] The first proposition was that the six factors in *Taylor v. Sturgell*, 553 U.S. 880 (2008) apply to both real party in interest and privity.[9] Our Decision applies the six factors enumerated in *Taylor*. Dec. 20; *see also* Paper 25 (following these six factors); Paper 76, 5–6 (adopting the analysis of Paper 25).

The second proposition is that alignment of interest and lack of conflict are both indicators of privity. We considered Patent Owner's argument regarding commonality of interest (Dec. 17–18), and the record does not include lack of conflict as a factor for our consideration. Consequently, our analysis is consistent with the portions of Judge Reyna's concurrence cited in *Ventex*. Additionally, Patent Owner ignores that our Decision goes on to analyze expressly each of Patent Owner's arguments to show that our privity analysis is consistent with the guidance in *RPX*. *See*

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[7] We use "*RPX*" *to* refer to *Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336 (Fed. Cir. 2018) because that is the term the parties use.

[8] We agree with Petitioner's identification of these two propositions by the three citations in *Ventex*. *See* Opp. 10.

[9] This proposition is found in footnote 8 at pages 10–11 and on page 12.

[redacted]

Dec. 13–22. Patent Owner's Request does not identify any analysis in our Decision that is inconstant with *RPX*. *See generally* Req. Reh'g.

Patent Owner argued throughout these proceedings that Petitioner and GEA are privies and Patent Owner did not argue that Petitioner and GEA are real parties in interest. Yet, Patent Owner relies heavily on *RPX* in both this Request and in the Motion. *See e.g.*, Mot. 2, 3, 5 (citing repeatedly to *RPX*). *Ventex* analyzed both whether the petitioner and Seirus were real parties in interest and whether they were privies. *Ventex*, slip op. 5. For the real party in interest inquiry, *Ventex* looked primarily to *RPX* for guidance, and for the privity inquiry, *Ventex* looked primarily to *WesternGeco LLC v. ION Geophysical Corp.*, 889 F.3d 1308, 1317 (Fed. Cir. 2018). *Ventex*, slip op. 6–15. Our Decision makes this same distinction and explains that the Federal Circuit acknowledged that distinction in *RPX*. Dec. 14. Certainly the privity and real party in interest inquiries overlap, but the fact that Patent Owner cites mostly to case law that primarily relates to real party in interest, and largely does not rely on case law dealing with privity, is somewhat revealing.

Patent Owner does not apprise us of anything we misapprehended regarding the applicability of *Ventex*.

B. Allocation of Burden

Patent Owner acknowledges that our Decision correctly states that Petitioner has the burden of persuasion to demonstrate compliance with 35 U.S.C. § 315(b), but argues that our Decision improperly allocated the burden because Petitioner: (1) relied primarily on attorney argument, and (2)

[redacted]

did not produce the entire Joint Defense Agreement (JDA). Req. Reh'g 8–9. We disagree.

Patent Owner's argument regarding Petitioner's reliance on attorney argument is premised on the proposition that Petitioner has a burden of production with regard to 35 U.S.C. § 315(b). Req. Reh'g 8 (citing *Worlds Inc. v. Bungie, Inc.*, 903 F.3d 1237, 1244 (Fed. Cir. 2018) for the proposition that the Federal Circuit views with skepticism the practice of a petitioner relying almost entirely on attorney argument). Our reading of *Worlds Inc.* is that Petitioner bears the burden of persuasion, and that *Worlds Inc.* says nothing about a burden of production for a petitioner. *See Worlds*, 903 F.3d at 1243 (indicating that in an *inter partes* review, petitioner's initial identification of the real parties in interest should be accepted unless and until disputed by a patent owner.) Patent Owner's argument is unpersuasive because it is not supported in the law. As we determined in our Decision, Petitioner's arguments are supported by the evidence of record.

Regarding the JDA, Patent Owner cites *RPX* in support of the assertion that we should have reviewed the entire JDA. Req. Reh'g 8 (citing RPX, 897 F.3d at 1352); PO Reply 5. *RPX* held that a real party in interest inquiry demands a flexible approach that takes into account equitable and practical considerations regarding the evidence of record. *RPX*, 897 F.3d at 1351–52. *RPX* did not hold, nor even state as *dicta*, that the Board must or should review the entire JDA when such an agreement is at issue. Our Decision explains that we need not review the entire agreement because we rely upon the District Court's determination that only paragraph five of the JDA (which was produced and is in the record) relates to Patent Owner's

[redacted]

privity argument. Dec. 22–24. Nothing in Patent Owner's Request causes us to question that reliance.

For these reason, we agree with Petitioner that our Decision properly allocated the burden of proof. Opp. 14–15.

C. Mandate Rule[10]

Patent Owner argues that we misapprehended application of the mandate rule because Patent Owner did not have a reasonable opportunity to appeal the privity issue. Req. Reh'g 9–11, 13–14. We disagree.

1. IPR2014-01235

Regarding IPR2014-01235, Patent Owner emphasizes that when the Federal Circuit mandate issued, privity decisions were not appealable. Req. Reh'g 9, 13–14.

Indeed, our Decision expressly acknowledges that at the time the mandate issued in IPR2014-01235, privity decisions were not appealable. Dec. 3–6, 12. Patent Owner, however, does not address the numerous other factors that led us to conclude Patent Owner had a reasonable opportunity to appeal. *See* Opp. 2–3. For example, we explained that more than four months prior to the issuance of the mandate in the appeal of the '1235 proceeding, the Federal Circuit granted *en banc* review of *Wi-Fi One*, and the Court announced that it would address whether *Achates* should be overruled.[11] Dec. 3–6, 12. We explained that other patent owners's sought

[10] Here we address Sections V. and VIII. Of the Request.

[11] *Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364 (Fed. Cir. 2018).

[redacted]

appeal of a 35 U.S.C. § 315(b) issue prior to issuance of *Wi-Fi One*. Dec. 12. Perhaps most importantly, we explained that Patent Owner gave notice of appeal in IPR2015-00249 that included the issue of privity *prior to issuance of the mandate in IPR2014-01235*. Dec. 3–6, 12. This demonstrates that Patent Owner believed privity to be an appealable issue when there was still an opportunity to pursue that issue.

Patent Owner points to one fact (issuance of the mandate prior to issuance of *Wi-Fi One*), and ignores the remainder of our analysis. Patent Owner does not cite to any legal authority for the proposition that we improperly applied the mandate rule. The fact that the Office argued in *Wi-Fi One* that the Board's interpretation of 35 U.S.C. § 315(b) is final and nonappealable is of little or no significance to our determination here. *See* Req. Reh'g 10. Patent Owner disagrees with our determination in the Decision without pointing out anything we misapprehended.

2. IPR2015-00249

Regarding IPR2015-00249, Patent Owner argues that *Wi-Fi One* issued only two days before argument at the Federal Circuit and argues that any finding in IPR2014-01235 would necessarily apply to IPR2015-00249 because "privity is not specific to a proceeding." Req. Reh'g 10.

Our Decision expressly acknowledges that *Wi-Fi One* issued two days prior to argument at the Federal Circuit for IPR2015-00249. Dec. 3–6, 9. Here, just as in the argument above, Patent Owner points to one fact while ignoring the remainder of our analysis, and Patent Owner does not cite any legal authority in support of the assertion that we misapplied the mandate rule. For example, Patent Owner does not address that the mandate in

[redacted]

IPR2015-00249 issued more than two months after *Wi-Fi One* issued, and does not address that Patent Owner actually appealed the privity issue. Dec. 9. Patent Owner's disagreement with our determination in the Decision does not mean we misapprehended anything.

3. Both Proceedings

With regard to both proceedings, Patent Owner argues that we overlooked the impact a waiver finding would have on appellate policy. Req. Reh'g 10–11. Patent Owner's characterization that our Decision "would require every party to appeal every issue no matter how clear the law is that the issue is not appealable" is an overstatement. *Id*. at 10. Rather, our Decision determined that in the limited circumstances of this case, where Patent Owner actually appealed the issue of privity to the Federal Circuit, and then chose not to pursue that issue, further pursuit of the privity issue was waived by the mandate rule.[12] Further, we agree with, and adopt, Petitioner's response that the mandate rule is Federal Circuit law and not Board policy, and further, it is a rule of law that promotes judicial efficiency. *See* Opp. 3.

Patent Owner's argument is not persuasive for either proceeding.

[12] *See* Dec. 9 (noting that Patent Owner chose to abandon appeal of the privity issue).

[redacted]

D. Whether Patent Owner waived arguments as to 35 USC 315(b)

Patent Owner argues that we misapprehended that § 315(b) is jurisdictional and cannot be waived. Req. Reh'g 11–12 (citing *Wi-Fi One* and *Click-to-Call Technologies, LP v. Ingenio, Inc.*, 899 F.3d 1321, 1330 (Fed. Cir. 2018)). We disagree.

Wi-Fi One held that "time-bar determinations [in *inter partes* reviews] under § 315(b) are reviewable by this court." *Wi-Fi One, 878 F.3d at 1374. Click-to-Call* dealt primarily with the issue of whether the bar of § 315(b) is triggered by a voluntary dismissal without prejudice of the civil action in which the complaint was served. *Click-to-Call*, 899 F.3d at 1328. Consequently, *Wi-Fi One* and *Click-to-Call*[13] are not directly on point because neither case dealt with the mandate rule or held that a Patent Owner could not waive a § 315(b) challenge. *See* Opp. 5.

Patent Owner contends that our reliance on *Hamilton Beach Brands, Inc. v. F'Real Foods, LLC*, 908 F.3d 1328, 1336–1337 (Fed. Cir. 2018) (cited in our Decision at 7) is misplaced because that case did not address whether § 315(b) is jurisdictional. *Id.* at 12.

Although *Hamilton* does not expressly state that § 315(b) can be waived or is not jurisdictional, Patent Owner does not direct us to anything in *Hamilton* that supports Patent Owner's position in the Request.

Patent Owner asserts that the Board has acknowledged that § 315(b) is jurisdictional. *Id.* at 12 (citing *Ruiz Foods Products, Inc. v. Macropoint*

[13] Certiorari granted in part by *Dex Media, Inc. v. Click-to-Call Tech., LP*, 2018 W.L. 234884 (June 24, 2019).

[redacted]

LLC, Case IPR2017-0216 (PTAB Feb. 14, 2019)). *Ruiz* held that failure to raise a § 315(b) argument in a preliminary response did not preclude making such an argument in the patent owner's response. *Ruiz,* slip op. 2–15. *Ruiz* did not deal with the significantly different circumstances of application of the mandate rule.

Patent Owner's argument does not persuade us that we misapprehended § 315(b), and does not demonstrate that our Decision should be modified.

4. SAS

Patent Owner argues that we misapprehended or overlooked the impact of *SAS*[14] on our finding that Patent Owner had waived the privity argument. Reh'g 12–13. We disagree.

Patent Owner does not identify any evidence or rule of law that we overlooked or misapprehended. Rather, Patent Owner simply repeats the argument that because when making our supplemental institution decision (Paper 86) we did not consider Petitioner's argument with respect to the non-instituted grounds waived, we likewise should not consider Patent Owner's argument with respect to privity waived. *Compare* Reh'g 12–13 to Paper 93, 11. We stated in our Decision

> Patent Owner's contention is not persuasive because the situations are not analogous. We did not consider an argument by Petitioner that we should have treated as waived. Rather, we instituted on all grounds because of the Supreme Court's holding in *SAS Inst., Inc. v. Iancu,* 138 S.Ct. 1348 (2018). T20; *see also* Guidance on the Impact of SAS on AIA Trial

[14] *SAS Inst., Inc. v. Iancu,* 138 S. Ct. 1348, 1359–60 (2018).

[redacted]

Proceedings, April 26, 2018, available on line at https://www.uspto.gov/.

Dec. 11. Nothing in Patent Owner's argument undermines our analysis.

Patent Owner's argument does not demonstrate that we should modify our Decision.

E. Decision on Motion Prior to Final Written Decision on Remand in IPR2014-01235

Patent Owner argues that our Final Written Decision on Remand for IPR2014-01235 was required to resolve all necessary issues, including privity, and for that reason, it was improper to resolve privity later in our Decision on the Motion to Terminate. Req. Reh'g 14–15.

We agree with Petitioner that Patent Owner's request with regard to the Final Written Decision on Remand in IPR2014-01235 was previously addressed, and this is not a proper request for this Request for Rehearing of the Motion to Terminate. *See* Opp. 8–9; IPR2014-01235, Paper 114 (decision on Patent Owner's request to issue a Final Written Decision on Remand).

III. Conclusion

Patent Owner has not persuaded us that we should modify our decision.

IV. Order

We deny Patent Owner's request for rehearing.

[redacted]

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing **REDACTED DECISION DENYING PATENT OWNER'S REQUEST FOR REHEARING** was served on August 22, 2019, via email directed to counsel of record for the Patent Owner at the following:

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Dated: August 22, 2019

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