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Paper 69
December 21, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NESTLÉ USA, INC.,
Petitioner,

v.

STEUBEN FOODS, INC.
Patent Owner.

Case IPR2014-01235
Patent 6,945,013

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

ELLURU, *Administrative Patent Judge*.

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

I. INTRODUCTION

Nestlé USA, Inc. ("Petitioner") filed a corrected Petition requesting an *inter partes* review of claims 18–20 of U.S. Patent No. 6,945,013 (Ex. 1001, "the '013 patent"). Paper 7 ("Pet."). Steuben Foods, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 9 ("Prelim. Resp."). On December 22, 2014, we instituted an *inter partes* review of claims 18–20. Paper 12 ("Dec."), 21. Patent Owner timely filed a Response to the Petition. Paper 36 ("PO Resp.")[1]. Petitioner subsequently timely filed a Reply to Patent Owner's Response. Paper 54 ("Pet. Reply")[2].

An oral hearing for this proceeding was held on August 4, 2015, a transcript of which has been entered in the record. Paper 61 ("Tr.")

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

For the reasons that follow, we determine that Petitioner has not shown by a preponderance of the evidence that claims 18–20 of the '013 patent are unpatentable.

A. Related Proceedings

Petitioner indicates that the '013 patent is being asserted in several district court cases. Pet. 54–55. The '013 patent is the subject

[1] We refer to the public version of Paent Onwer's response.
[2] We refer to the public version of Petioner's Reply.

of Case IPR2014-00041, *GEA Process Engineering, Inc. v. Steuben Foods, Inc.*, slip. op. at 27 (PTAB Feb. 3, 2015) (Paper 140), which has been terminated. Petitioner also indicates that the '013 patent is the subject of other Office proceedings. Pet. 55. In addition, the '013 patent is related to other United States patents, which are or were the subject of Office proceedings. *Id*.

B. The '013 Patent (Ex. 1001)

The '013 patent is directed to a method and aseptic packaging system for the aseptic packaging of food products in containers, such as bottles. Ex. 1001, 1:10–14. The '013 patent specification discloses the steps of: "providing a plurality of bottles; aseptically disinfecting the plurality of bottles; aseptically filling the aseptically disinfected plurality of bottles with the aseptically sterilized foodstuffs; and filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute." *Id.* at 3:9–18. Additionally, the method provides for the step of aseptically disinfecting the plurality of bottles at a rate greater than 100 bottles per minute. *Id*. at 3:23–24.

C. Instituted Claims

We instituted a review of claims 18–20, which are reproduced below.

> 18. A method for automatically aseptically bottling aseptically sterilized foodstuffs comprising the steps of:
>
> providing a plurality of bottles;
>
> aseptically disinfecting the bottles at a rate greater than 100 bottles per minute; and
>
> aseptically filling the bottles with aseptically sterilized foodstuffs, wherein the aseptically sterilized

> foodstuffs are sterilized to a level producing at least a 12 log reduction in *Clostridium botulinum.*
>
> 19. A method for automatically aseptically bottling aseptically sterilized foodstuffs comprising the steps of:
>
> providing a plurality of bottles;
>
> aseptically disinfecting the bottles at a rate greater than 100 bottles per minute, wherein the aseptically disinfected plurality of bottles are sterilized to a level producing at least a 6 log reduction in spore organisms; and
>
> aseptically filling the bottles with aseptically sterilized foodstuffs.[3]
>
> 20. A method for automatically aseptically bottling aseptically sterilized foodstuffs comprising the steps of:
>
> providing a plurality of bottles;
>
> aseptically disinfecting the bottles at a rate greater than 100 bottles per minute, wherein the disinfecting the bottles is with hot hydrogen peroxide spray, wherein a residual level of hydrogen peroxide is less than 0.5 PPM; and
>
> aseptically filling the bottles with aseptically sterilized foodstuffs.

D. Ground of Unpatentability Instituted for Trial

We instituted trial based on the following ground of unpatentability: Claims 18–20 as unpatentable under 35 U.S.C. § 103 over Biewendt, Bosch, Buchner, ZFL, and Chambers. Dec. 21.

[3] *See* Certificate of Correction deleting at column 16, line 46 "organism" and inserting "organisms".

Reference	Patents/Printed Publication	Date	Exhibit
Buchner	N. Buchner, *Aseptic Glass in the Food Sector*, Pharma Technologie J., at 25 (with translation).	1988	Ex. 1006
ZFL	N. Buchner, *Aseptic Filling of Glass and Plastic Containers*, 41 ZFL 295 (with translation).	1990	Ex. 1007
Biewendt	H.-G. Biewendt et al., *Report on the Type Testing of the Aseptic Filling and Sealing Plant for Glass Bottles for UHT Milk*, 48 Kiel Dairy Research Reports 321 (with translation).	1996	Ex. 1019
Bosch	Robert Bosch GmbH, *Aseptically Operating Filling and Closing Lines for Bottles, Jars and Wide-Mouth Containers of Glass.*	May 1990	Ex. 1009
Chambers	Principles of Aseptic Processing and Packaging (James V. Chambers & Philip E. Nelson eds., 2d ed.).	1993	Ex. 1010

Petitioner provides the declaration of Dennis R. Heldman, Ph.D. ("Heldman Declaration") in support of its petition. Ex. 1005.

II. ANALYSIS

A. Privity and 35 U.S.C. § 315(b)

Patent Owner reasserts its argument that Petitioner's Petition is time barred pursuant to 35 U.S.C. § 315(b) because Petitioner is a privy of GEA Process Engineering, Inc. ("GEA"), the petitioner in IPR2014-00041, and because GEA was served with a complaint

alleging infringement of the ’013 patent more than a year before the instant petition was filed. PO Resp. 1–16. We addressed, albeit preliminarily, Patent Owner’s privy argument in our Decision. Dec. 7–11. We incorporate that analysis here.

The privity requirement “seeks to protect patent owners from harassment via successive petitions by the same or related parties, to prevent parties from having a ‘second bite at the apple,’ and to protect the integrity of both the USPTO and Federal Courts by assuring that all issues are promptly raised and vetted.” Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012) (“Trial Practice Guide”). The notion of “privity” is more expansive and encompasses parties that do not necessarily need to be identified in the Petition as a real party-in-interest. 77 Fed. Reg. at 48,759. Privity is a “flexible and equitable” doctrine rooted in common law. *Id*. The privity inquiry seeks to determine whether the relationship between the purported “privy” and the relevant party is “sufficiently close such that both should be bound by the trial outcome and related estoppels.” *Id*.; *See* 154 Cong. Rec. S9987 (daily ed. Sept. 27, 2008) (statement of Sen. Kyl) (“The concept refers to a relationship between the party to be estopped and the unsuccessful party in the prior litigation which is sufficiently close so as to justify application of the doctrine of collateral estoppel.”) (citations omitted).

Since our Decision, the only new evidence that Patent Owner has provided in support of its 315(b) bar argument, based on an alleged privity relationship between Petitioner and GEA, is the “Line

8" indemnity agreement. Tr. 77:5–79:25; Ex. 2054[4]. The Line 8 agreement was executed after GEA was served with a complaint alleging infringement. *See* PO Resp. 12; Pet. Reply 3. Given this timing, Patent Owner asserts that "it would be nonsensical to apply a rigid requirement that the privity analysis must be conducted at the snapshot in time when the earlier complaint was served." PO Resp. 8–9. In addition, according to Patent Owner, the Line 8 agreement "directly contradicts" Petitioner's position that "neither [Petitioner] nor GEA has any control, or opportunity for control, over the other." *Id*. at 10. This evidence does not alter our preliminary determination.

Based on certain provisions in the Line 8 agreement, Patent Owner makes two primary arguments. First, Patent Owner contends that Petitioner, as purchaser, will be liable for a significant percent of the damages in the event the district court awards damages, based on a royalty per bottle, for products sold by GEA. PO Resp. 11–12; Tr. 73:8–25. According to Patent Owner, the Line 8 indemnity provision applies to all the products sold by GEA to Petitioner, and the indemnity provision was triggered upon the filing of the complaints in district court cases. *Id*. at 10–11. Petitioner responds that Patent Owner had already sued GEA before the execution of the Line 8 agreement, that pursuant to the agreement the parties [redacted] and the agreement [redacted]

[4] The "Line 8" agreement has been filed under seal. Paper 48.

Pet. Reply 4. Patent Owner also argues that pursuant to the agreement, the parties are to [redacted] and that Petitioner has [redacted] Tr. 74:19–24, 75:2; PO Resp. 12–13[5]. In response, Petitioner contends that [redacted] Pet. Reply 5 (citing Ex. 2054 ¶ 3(e)). Petitioner further avers that [redacted] is not 'control' of GEA's defense to create privity because it does not give Petitioner a 'full and fair opportunity' to litigate the liability claim" and that [redacted] Pet. Reply 5. Based primarily on the indemnity agreement, Patent Owner argues that:

> privity should be applied in PTAB proceedings to avoid the anomalous result than an indemnitor who is cooperating closely with a petitioner-indemnitee can make the deliberate decision not to join the earlier review

[5] The Line 8 agreement provides that [redacted] Ex.2054 ¶ 2. The agreement also provides tha [redacted] *Id*. ¶ 3.

> proceeding and instead attempt to have a "second bite at the apple" in the event that indemnitee's petition proves unsuccessful.

PO Resp. 8 (citing 77 Fed. Reg. 48,759).

We need not decide whether the Line 8 agreement covers all products sold by GEA to Petitioner, or when in time we should analyze Petitioner's relationship with GEA, because we are not persuaded by Patent Owner's arguments regarding the Lini 8 agreement itself.

We disagree with Patent Owner's contention that the Line 8 agreement shows Petitioner and GEA had control over each other. *See* PO Resp. 10. For example, pursuant to the Line 8 agreement, [redacted] Under the provisions of the Line 8 agreement, [redacted] Ex. 2054 ¶ 4. [redacted] *Id*. Indeed, the Line 8 agreement [redacted] *Id*. Cost sharing is also reflected in the sharing of legal costs. Pursuant to the agreement, [redacted] *Id.* ¶ 3b. Moreover, we find that neither the settlement nor appeal provision in the Line 8 agreement provides Petitioner with the type of control over GEA's litigation that rises to a level sufficient to establish privity. The Line 8 agreement specifically contemplates that [redacted] Ex. 2054 ¶ 3(e). Under such circumstances, Petitioner is

[redacted] *Id*. Furthermore, the agreement does not mandate that Petitioner has authority to direct GEA with respect to any appeal; rather, the agreement gives [redacted] *Id*. at ¶ 7. Thus, Patent Owner has not demonstrated, based on the Line 8 agreement, that Petitioner had the right or opportunity to control GEA's participation in any litigation, including GEA's participation in IPR2014-00041.

Accordingly, Patent Owner has not provided a sufficient factual basis upon which to conclude that Petitioner and GEA are privies. We, therefore, conclude that the Petition is not time barred under § 315(b) based on Petitioner's relationship with GEA.

B. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. *See In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015); 37 C.F.R. § 42.100(b). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

For purposes of this Decision, we construe the claim term "aseptic," which is recited in each challenged claim.

"aseptic"

Patent Owner argues that "aseptic" should be interpreted to "require the [Federal Drug Administration ("FDA")] level of aseptic, which in turn require[s] no more than a 0.5 ppm of residual hydrogen peroxide." PO Resp. 33.

Petitioner disagrees with Patent Owner's proposed construction, contending that the FDA regulations do not define a "'level'" of "'aseptic.'" Pet. Reply 8. Petitioner further contends that (1) Patent Owner attempts to limit "aseptic" beyond what is required by the FDA regulations; (2) the proposed construction invalidates claim 17 for failing to further limit claim 1, which recites "aseptically" in a similar manner to challenged claims 18–20, because claim 17 recites "[t]he method of claim 1, wherein aseptically denotes meeting the United States FDA level of aseptic;" and (3) the proposed construction incorporates all the differentiating limitations of claims 18–20, leaving all three claims with exactly the same meaning and scope. *Id*. at 8–9. According to Petitioner, the term "aseptic" "means the same in the claims as in the prior art, i.e., free from pathogenic microorganisms." *Id.* at 9.

We disagree with both Patent Owner's and Petitioner's interpretations. The ordinary meaning of "aseptic" is "free or freed from pathogenic microorganisms." *See* Ex. 3001. However, the specification explicitly states that "aseptic" means "to the FDA level

of aseptic." Specifically, the '013 patent specification expressly states that "[i]n the following description of the present invention, the term 'aseptic' denotes the United States FDA level of aseptic." Ex. 1001, 1:67–2:2. The specification further states:

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

Id. at 4:23–28 (emphasis added). In addition, the specification makes clear that the requirements that satisfy "the FDA level of aseptic" depend on the context of "aseptic"—e.g.,the process, apparatus, or foodstuff involved. For example, an aseptic filler packaging aseptic food products must use an FDA approved sterilant. *Id*. at 1:48–52. Neither Patent Owner's nor Petitioner's arguments dissuade us from the express construction of "aseptic" provided by the specification.

Initially, we agree with Petitioner that Patent Owner's proposed construction of "aseptic" would impose particular restrictions (e.g., FDA level of aseptic requires a hydrogen peroxide (H_2O_2) sterilant, a 6-log reduction in *Bacillus subtilis* ("*B. subtilis*") spores, etc. Pet. Reply at 7–8; *see* PO Resp. 30–33, 34, 40–46. Patent Owner has not persuaded us that either the '013 patent specification or the FDA regulations supports such a narrow construction.

We, however, are not persuaded by Petitioner's claim differentiation argument, which is based on recitations in claims 1 and 17. The claim differentiation doctrine is not a hard and fast rule, but

instead "a rule of thumb that does not trump the clear import of the specification." *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1332 (Fed. Cir. 2009); *see also Netcraft Corp. v. eBay, Inc.*, 549 F.3d 1394, 1400 n. 1 (Fed. Cir. 2008) ("While claim differentiation may be helpful in some cases, it is just one of many tools used by courts in the analysis of claim terms."); *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1366–67 (Fed. Cir. 2000) (there is a rebuttable presumption that different claims are of different scope); *Seachange Int'l, Inc. v. C–COR, Inc.*, 413 F.3d 1361, 1369, 1370–72 (Fed. Cir. 2005) (holding that the presumption established by claim differentiation was rebutted because the written description "consistently" referred to the claim term in a specific manner and arguments made during prosecution amounted to a clear and unambiguous disclaimer of claim scope). Here, the specification explicitly states that "aseptic" refers to the FDA level of aseptic.

Further, when properly construed, the scope of claims 18–20 varies. For example, claims 18 and 19 require "aseptically disinfecting," but are not limited to use of a particular sterilant, such as hydrogen perioxide (H_2O_2), to aseptically disinfect the bottles. Claim 20, however, recites "aseptically disinfecting" "wherein [ ] disinfecting the bottles is with hot hydrogen peroxide spray." Indeed, claim 20 is even more limited because it not only specifies a sterilant, but it also specifies that the sterilant must be in the form of a hot spray. Furthermore, claim 18 also requires "aseptically filling the bottles with aseptically sterilized foodstuffs," "wherein the aseptically

sterilized foodstuffs are sterilized to a level producing a 12 log reduction in *Clostridium botulinum*." Claim 19 does not include this limitation. Rather, claim 19 requires that the bottles are sterilized to a specified level (a 6 log reduction in spore organisms). Thus, claims 18–20 do not have the same claim scope.

Accordingly, based on the express disclosure of the '013 patent specification, based on the present record, we construe "aseptic" as "aseptic to any applicable United States FDA standard, and in the absence of any such standard, aseptic assumes its ordinary meaning of free or freed from pathogenic microorganisms."

C. Prior Art References[6]

Four of the five asserted references—Biewendt, Bosch, Buchner, and ZFL—all describe the same "Bosch" aseptic bottling technology manufactured by Robert Bosch GmbH. Pet. 10–14, 32. While all four references describe Bosch bottling technology, the systems and methods disclosed in each of the references are not

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

identical. Moreover, the references do not disclose information about the same parameters of the bottling technology (e.g., sterilant temperature and application time), as discussed below.

1. Buchner (1988)

In 1988, a Bosch employee, Dr. Norbert Buchner, published the Buchner article. Pet. 10. Buchner describes a Bosch pilot plant (Ex. 1005, 2–5), wherein preheated bottles are sprayed "with hydrogen peroxide at effective temperatures between 50 and 70° C." *Id*. at 2. The "bottles are sprayed on either side with hydrogen peroxide at 3 stations for approximately 15 sec." and subsequently, the bottles are "washed out externally at 1 station and internally at 3 station with sterile water and blown out again with sterile air at a further station." *Id*. at 3. Buchner states that "*[d]epending on the mode of operation of the plant and the bottle size,* residual peroxide values are achieved that are below 0.5 or considerably less than 1 ppm." *Id*. at 4 (emphasis added). According to Buchner, the disclosed method achieved *B. subtilis* bacterial count reduction "of more than 5 or more than 5.5 orders of magnitude," which Petitioner contends also meant a greater than 12-log reduction in *C. botulinum* spores. *Id*. at 4; Pet. 11. With regard to output rate, the Bosch pilot plant utilized a 6-line bottle sterilizer (6-bottle-wide) and achieved output rates of "between 3,000 bottles per hour for the larger containers and 4,200 per hour for smaller" bottles, i.e., 50–70 bottles per minute. *Id*. at 2–3. Based on the experience with the Bosch pilot plant, Buchner concluded that it was *possible* to increase output "to 6,000 per hour [100 bottles per

minute] with a maximum filling volume of 1 litre, a 9-line sterilizer machine being used," and that "[f]urther planning *anticipates* an increase to 12,000 per hour [200 bottles per minute]." *Id*. at 5 (emphasis added).

2. ZFL (1989)

In 1989, Dr. Buchner wrote an article describing Bosch plants that had been built. Ex. 1007, 4. The described system includes a "precleaner machine (special rinser)," not disclosed in Buchner. *Id*. at 2, Figure 1; *see* Tr. 40:7–10 (Patent Owner argues that Bosch modified the technology in Buchner by adding the steam cleaner in ZFL to "get[] the biggest pieces of junk out of the system"). The bottles are sterilized using a vaporized hydrogen peroxide sterilant applied onto all inner and outer surfaces of the containers (*id*. at 2) before filling with UHT-treated foodstuffs (*id*. at 1). But, as Petitioner acknowledges (Pet. 12), ZFL omits certain details provided in Buchner, such as sterilant temperature and application time. ZFL explains that the applied hydrogen peroxide is "dried off after a certain exposure time [of hydrogen peroxide] using sterile hot air" (Ex. 1007, 2), unlike Buchner, which used a sterile water rinse that in turn was blown off by sterile air (Ex. 1006, 3). ZFL discloses that the bottles have residual hydrogen peroxide levels less than 0.5 ppm. Ex. 1007, 3. ZFL further discloses that the described Bosch plant achieves ">8D" reduction in *Bacillus cereus*, a spore organism, for glass bottles. *Id*. at 3, Table 1. In addition, the Bosch plant described in ZFL had "an output of 100 [bottles]/min." *Id*. at 4. ZFL further

states that "[p]lants in dual-line design for an output of 200/min are in development." *Id*.

3. Bosch Brochure (1990)

The Bosch Brochure was published in 1990. Ex. 1009. The Bosch Brochure describes an aseptic filling plant and method for "low-acid" products by "applying heated hydrogen peroxide" and explains the "[r]esidual sterilizing media is removed by drying with sterile air." *Id*. at 1. Petitioner acknowledges that the Bosch Brochure "omits many of the specific parameters of the Bosch method (e.g., sterile temperature, application time, and sterilization rates)." Pet. 13. The Bosch Brochure states that "[o]ur program comprises sterilization machines with 6 to 30 lines for outputs ranging from 6000 to 12000 bottles/hr [100 to 200 bottles per minute], depending on the filling volume." Ex. 1009, 2. The Bosch Brochure further states: "Nominal throughput: up to 200 containers/min, depending on product, fill volume and neck diameter." *Id*. at 4. Petitioner submits that this statement "confirms that the 200-bottle-per-minute rate design disclosed in *ZFL* and *Buchner was* achieved." Pet. 13, 35. Patent Owner disagrees that Bosch achieved an aseptic filling plant with an output of 200 bottles per minute. Tr. 40:15–16 ("Here in 1990 they say we are hoping to get to 200.").

4. Biewendt (1996)

In 1996, Robert Bosch GmBh asked the German Institute for Process Technology to conduct a study of the Bosch aseptic filling and sealing plant for glass bottles for Ultra High Temperature

("UHT") milk. Pet. 13 (citing Ex. 1008, 1)[7]. Biewendt describes a 9-line sterilizer wherein pre-cleaned bottles are sprayed with hydrogen peroxide warm air which flows around the entire surface area of the bottles, which are subsequently blow-dried with filtered, clean air on the inside and outside. Ex. 1019, 3–5. Petitioner acknowledges that "*Biewendt* omits some of the details about sterilant application time and temperature," but contends that the reference provides additional parameters not disclosed in earlier publications—the sterilant is maintained at a concentration of a "minimum 33% H_2O_2" and is removed by drying with "at least 80° C hot air." Pet. 14 (citing Ex. 1008, 11, 18). Biewendt states that "[t]he standard plant" "is designed to process 6,000 bottles per hour [100 bottles per minute]." Ex. 1019, 2. Patent Owner submits that "[t]his reference makes no mention of 200 bottles per minute" and that "[i]f they had accomplished 200 in 1996, one surmises that they would have said so." Tr. 40:22–41:8.

D. State of the Art

As Patent Owner notes (PO Resp. 16–17), the '013 patent specification is directed to methods and apparatus for low acid aseptic sterilization and filling ("LAASF"). PO Resp. 16–17. The '013 specification states, for example, "[i]n order to overcome the above deficiencies, the present invention provides a method and apparatus for providing aseptically processed low acid products in a container

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

having a small opening, such as a glass or plastic bottle or jar, at a high output processing speed." Ex. 1001, 2:5–9.

Although the challenged claims are not limited to processes involving low acid foodstuffs, Petitioner's asserted ground of unpatentability is based upon references that include processing of low acid foodstuffs. *See* Ex. 1006, 5 (Buchner stating the "[t]he following products, inter alia, are of interest for aseptic packing in the pH range above 5.5; milk products . . ."); Ex. 1007, 1 (ZFL stating that "[t]here is a whole array of filling goods in the neutral or low-acid pH-range, such as UHT milk and UHT milk drink"); Ex. 1009, 1 (Bosch Brochure stating that "[f]or low-acid and neutral products (pH>4.5), a special process is used, applying heated hydrogen peroxide."); Ex. 1019, 1 (Biewendt discloses aseptic filling and sealing plant for bottles for UHT milk). *See* Tr. 23:10–12 (Petitioner agrees that the Bosch references are about low acid foodstuffs).

Patent Owner argues that the engineering underlying LAASF is unpredictable. PO Resp. 16–17. In support, Patent Owner refers to the declaration of its witness, Andre Sharon, Ph.D. *Id*. at 17 (citing Ex. 2025). Dr. Sharon states that "[t]he narrow path between using enough sterilant to sterilize the bottles on the one hand while being able to remove the sterilant sufficiently such that the residual requirement for the FDA is met on the other, largely drives the design process of a low acid sterilization and filling machine that will meet FDA levels of aseptic." Ex. 2025 ¶ 26. "The narrow path," explains Dr. Sharon, "makes the design of low acid sterilization and filling

systems for FDA approval particularly difficult and complex." *Id*. ¶ 24. Dr. Sharon further states that "[o]ther considerations include sterilant temperature, temperature of the rinsing fluid, concentration of the sterilant, any heat limitations on packaging material, the temperature of the bottle when the sterilant is applied to it, the temperature of the bottle when the rinsing fluid is applied to it, and the required microbial kill, among other factors." *Id*. ¶ 26. Dr. Sharon explains that the "[v]arious parameters of an aseptic filling machine are interdependent on one another and can affect the sterilization of the bottle." *Id*. ¶ 40. "For example, the bottle temperature, sterilant concentration, sterilant application time, drying time, flow rates, etc. will impact the efficacy of sterilization." *Id*.; *see* Tr. 24:3–23 (Petitioner acknowledges that "it is well recognized within the field that it is easier to do aseptic processing for high acid foods than low acid foods"). While the challenged claims are not limited to filling with low acid foodstuffs, the evidence of interdependence between parameters is nevertheless instructive.

Patent Owner also contends that the failures of others, after the filing date of the '013 patent, in their attempts to design aseptic bottling machines that met FDA requirements, demonstrate the unpredictability of the art. PO Resp. 17–20. For example, Patent Owner presents evidence that an aseptic equipment manufacturer that in 2009 was forced to abandon a five-year long effort to install a functioning aseptic sterilization and filling machine. PO Resp. 19 (citing Ex. 2019 ¶¶ 11, 41). The customer filed suit against the

manufacturer alleging, for example, that "after years of modifications and tests, the bottling system still [did] not work" and could not consistently or reliably sterilize bottles or produce products that could meet FDA requirements, specifically excessive peroxide residual levels exceeded the FDA requirement to be saleable. Ex. 2019 ¶¶ 2, 41. We acknowledge, as Petitioner argues (Tr. 18:13– 22), thatPatent Owner's evidence of these failures is not specific as to whether these failures were due to the fact that the parties could not practice the claimed limitations or for other reasons. Despite this shortcoming, howver, these failures are some evidence of the unpredictability of the art.

It is against this background that we review Petitioner's challenge to claims 18–20 of the '013 patent.

E. Principles of Law

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

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007).

"[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently,

known in the prior art." *KSR*, 550 U.S. at 418. "[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine elements in the way the claimed new invention does." *Id.* Moreover, in order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or method." *Beckman Instruments, Inc. v. LKB Produkter, AB*, 892 F.2d 1547, 1551 (Fed. Cir. 2010) (citing *In re Payne*, 606 F.2d 303, 314 (CCPA 1979)). In addition, a person of ordinary skill in the art must have had a reasonable expectation of success of doing so. *PAR Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1193 (Fed. Cir. 2014).

The prior art does not demonstrate a reasonable expectation of success where a skilled artisan would have had to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result because the prior art did not reveal which of the many possible choices was to be successful. *In re Kubin*, 561 F.3d 1351, 1360–61(Fed. Cir. 2009). Similarly, if the prior art merely encourages exploration of a general approach without giving specific guidance as to how to achieve the claimed invention there is no reasonable expectation of success. *Id.*

The ground of unpatentability before us is based on obviousness rather than anticipation. For that reason, we are not concerned with whether individual references are enabled standing alone. *Cf. Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003) (anticipatory prior art

must be enabled); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003) (in obviousness analysis a reference need not be enabled, rather it qualifies as prior art for what is disclosed therein). Consequently, our inquiry is whether the prior art asserted by Petitioner, as a whole, enables the claimed methods so that a skilled artisan would have had a reasonable expectation of success in practicing the methods.

F. Claims

As explained above, while claim 20 is limited to use of a particular sterilant (hydrogen peroxide), claims 18 and 19 do not contain such a limitation. Petitioner, however, asserts references disclosing sterilization apparatus and methods that utilize hydrogen peroxide as the sterilant. Pet. 41–50. We agree with Patent Owner that because Petitioner is relying on sterilization apparatus and methods that use hydrogen peroxide to read on the challenged claims, including claims 18 and 19, Petitioner must show that "aseptically disinfecting" and "aseptically filling," as taught by the asserted references, is "aseptic to any applicable United States FDA standard" in the context of using hydrogen peroxide as the sterilant. *See* Tr. 33:1–35:20. In effect, through its choice of prior art, Petitioner has imposed the limitations expressly recited in claim 20 into claims 18 and 19 as well.

At the time of the invention, in order for a sterilization process that used hydrogen peroxide to satisfy an FDA level of aseptic, it had to have no greater than 0.5 ppm hydrogen peroxide residue in the

packaging. Specifically, FDA regulation, 21 C.F.R. § 178.1005(d) (as implemented at 49 Fed. Reg. 32,345 (Aug. 14, 1984)) (Ex. 1011), mandates the following:

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

Petitioner disagrees that this regulation describes a FDA level of aseptic, arguing that the regulation is "in part of the statute that is talking about food additives." Tr. 89:3–15. We are not persuaded by this argument. The language of the regulation makes clear that it is relevant to the sterilization of food packaging material. Moreover, referring to 21 C.F.R. § 178.1005, Petitioner's own witness, Dr. Heldman, acknowledges that the "FDA require[s] no greater than 0.5 ppm H_2O_2 residue in the sterilized bottle." Ex. 1005 ¶ 22. Therefore, in order for the combination of asserted prior art references to teach or suggest the claimed methods, the combination had to enable a skilled artisan to practice a hydrogen peroxide sterilization method that resulted in no greater than no greater than 0.5 ppm H_2O_2 residue in the sterilized bottle with a reasonable expectation of success. *See Beckman Instruments, Inc.*, 892 F.2d at 1551; *PAR Pharm., Inc.*, 773 F.3d at 1193; *see also* Tr. 90:10–12 (Petitioner recognizes "that the prior art has to put the method in the hands of the public, so the public has to be able to practice the method").

The question before us is whether the asserted prior art, as a whole, was enabling such that a skilled artisan would have had a reasonable expectation of success in building a machine to practice the claimed method that would meet the relevant FDA standard level of aseptic, including the 0.5 ppm residual hydrogen peroxide requirement. Tr. 47:1–4. We determine that Petitioner has not sufficiently persuaded us, by a preponderance of the evidence, that a skilled artisan would have had a reasonable expectation of successfully practicing the claimed methods.

We are cognizant, as Patent Owner argues (PO Resp. 16–17), that the parameters of sterilization technology are interdependent, and specifically that sufficient sterilant must be applied to sterilize the bottles, while being able to remove the sterilant sufficiently to satisfy the FDA requirement. *See* Ex. 2025 ¶¶ 26, 40. In other words, there is a "sweet spot"—sufficient sterilant to sterilize, but only so much that it can be removed sufficiently to meet the FDA requirement. *See* Tr. 47:18–21 (Patent Owner arguing that "[b]ecause if you hit the right time and temperature you don't have to use as much sterilant. If you don't use as much sterilant, you can evacuate it much more easily and you can process it much more quicky."). Petitioner disagrees that this tension applies, arguing that "any such problems presuppose that the claims require both a minimum disinfection level and a maximum 0.5 ppm residue," and "they do not," "[w]hereas claim 19 recites 6-log disinfection levels." Pet. Reply 22. We are not persuaded by Petitioner's argument.

The parties dispute the level of sterilization required by the challenged claims, but both agree that some degree of sterilization is required. Patent Owner argues that the "FDA level of aseptic" required "demonstrating that a 6 log reduction of spore organisms was achieved on the packing material," and that "the target organism was *bacillus subtilis*" when hydrogen peroxide was the sterilant. PO Resp. 41, 44–46. Petitoner argues that although "[t]he FDA regulations [] do not define a 'level' of 'aseptic,'" the regulations do state that "'aseptic processing and packaging' is the filling of containers 'in *an atmosphere free of microorganisms* . . . having public health significance.'" Pet. Reply 8 (citing 21 C.F.R. § 113) (emphasis added); Tr. 12:17–20, 13:22–24. We need not decide what level of sterilization is required by the challeneged claims, as it is not disputed that some level is required. Thus, we disagree with Petitioner's contention that "any difficulty" with using enough sterilant to sterilize and not too much to meet the 0.5 ppm residual level is "immaterial." Thus, we agree with Patent Owner that interdependence between using a sufficient sterilant amount and being able to remove it to a sufficient level is relevant in practicing the claimed methods.

As noted above, claim 20 is limited to hydrogen peroxide as the sterilant. Specifically, claim 20 recites "aseptically disinfecting the bottles . . . wherein the disinfecting the bottles is with hot hydrogen peroxide spray, wherein a residual level of hydrogen peroxide is less than 0.5 PPM." Petiotner's argument that claim 20 would have been obvious relies on Biewendt's disclosure of a "'sterilizing H_2O_2 warm

air mixture flow[ing] around the entire surface area of the bottles' before being dried off with 'at least 80 °C hot air'" as teaching the recited "'hot hydrogen peroxide spray.'" Pet. 49 (citing Ex. 1008, 5, 18); Pet. 49 (Petitioner also refers to the teachings of Buchner and ZFL for this limitation). With respect to the recitation "wherein a residual level of hydrogen peroxide is less than 0.5 PPM," Petitioner admits that Biewendt "does not, however, specify that residual H_2O_2 is 'less than 0.5 PPM,' as claimed." Pet. 49. For this limitation, Petitioner refers to Buchner and ZFL, each of which discloses a residual hydrogen peroxide level of not greater than 0.5 PPM. Pet. 49–50 (citing Ex. 1006, 4; Ex. 1007, 3).

Petitioner has not persuaded us that the prior art taught a skilled artisan how to reach the sweet spot identified above (the balance between enough sterilant to aseptically disinfect without exceeding the specified residual level) with a reasonable expectation of success. For example, although Buchner teaches sterilant temperature and application time, and that the FDA required residual hydrogen peroxide level is met, Petitioner refers to a disclosure of sterilant concentration in Biewendt and does not identify such a disclosure in Buchner that teaches sterilant concentration. *See* Pet. 49 (citing Ex. 1006, 4 (no disclosure of concentration)); Pet. Reply 12 (citing Biwendt, 18). Moreover, Buchner teaches washing out the bottles with sterile water to remove the sterilant. Ex. 1006, 3. Petitioner relies on Buchner as disclosing rinsing time (with sterile water) of "5s out, 15s in." Pet. Reply 12 (citing Ex. 1006, 3); *see also* Pet. 10–12,

49–50 (no citation regarding sterile water rinsing time). Buchner discloses spraying with hydrogen peroxide for approximately 15 seconds, but does not disclose the amount of time that bottles are rinsed with sterile water. *See* Ex. 1006, 3.

Even accepting Petitioner's assertions about Buchner, Petitioner does not provide persuasive argument or evidence that Buchner's sterile water-rinse to remove the sterilant can be incorporated into Biewendt, which teaches removing the sterilant by drying the bottles with hot air (Ex. 1019, 18), to achieve the FDA required residual hydrogen peroxide level. *See* Pet. 49–50; Pet. Reply 9. For example, Petitioner does not sufficiently persuade us that a skilled artisan could modify the Biewendt apparatus—by substituting in a water-rinse, with the associated parameters taught by Buchner, for drying the bottles with hot air at 80 °C—without changing any other parameters disclosed in Biewendt, and still achieve the FDA required residual level of hydrogen peroxide at an output rate of more than 100 bottles per minute. Petitioner's assertion that a water-rinse is more effective than drying with hot air does not change our determination. *See* Pet. Reply 22–23. Petitioner also does not persuade us that a skilled artisan would have known how to modify the sterilant parameters taught by Biewendt to include the Buchner water-rinse, and still achieve the FDA required residual level of hydrogen peroxide and an output rate of more than 100 bottles per minute.

Regarding ZFL, we agree that ZFL discloses residual sterilant levels of less than 0.5 PPM. Ex. 1007, 3. However, ZFL does not

provide sterilant temperature and sterilant application time, even though it states that the disclosed apparatus achieved the FDA required residual level of hydrogen peroxide. *See* Pet. 12, 49–50; Ex. 1007, 3; *see also* Pet. Reply 12 (relying on Buchner regarding residual sterilant, and not addressing ZFL).

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

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

> ensure that the actual bottle in a machine is exposed to these same theoretical conditions.

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

Petitioner also contends that the prior art enables the claimed methods because the "Bosch references" disclose "at least as much information as the '013 patent" and "actually provide more information than the '013 patent about parameters." Pet. Reply 12. Specifically, Petitioner argues that the combination of Biewendt and Buchner teaches a greater rate of sterilization than the process described by the '013 patent because the combination teaches the application of the sterilant, hydrogen peroxide, at a greater temperature and for an increased time than that disclosed in the '013 patent. Pet 47–48; Ex. 1005 ¶¶ 66–67. Whether the '013 patent is enabled is not the issue. The issue is whether Petitioner has shown that the cited references would have led a person of ordinary skill in the art to the methods of the challenged claims. Furthermore, Petitioner cites to two Federal Circuit decisions (Pet. 13–14), neither

of which is instructive to our analysis. *Sri Int'l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008), relates to the enablement standard for prior art under 35 U.S.C. § 102(b), not at issue here. In *Motorola, Inc. v. Interdigital Technology Corp.*, 121 F.3d 1461, 1471 (Fed. Cir. 1997), the Federal Circuit reviewed the district court's denial of JMOL and stated that "the record was sufficient to entitle the jury to conclude that the reference was enabling," facts that are not relevant to our analysis.

Moreover, we do not find Petitioner's comparison of the disclosures in the combined Bosch disclosures to the disclosure in the '013 patent to be sufficiently persuasive with respect to enablement such that a skilled artisan would have had a reasonable expectation of success. For example, Petitioner avers that Biewendt teaches "Bottle Preheat" at "45-55°C [113-131°F]." Pet. Reply 12 (citing Ex. 1019, 4). As Patent Owner argues (PO Resp. 36; Tr. 42:1–20), this disclosure, however, relates to the temperature of bottles *before they enter the* "bottle sterilization machine." Ex. 1019, 3–4. As Patent Owner argues, Biewendt does not disclose the "temperatures of the bottles when they enter the sterilization machine, their temperature during sterilization contact, air flow rates, the manner in which the sterilant is atomized or vaporized, or the amount of sterilant used." PO Resp. 35–36; Ex. 1019, 4–5; Tr: 42:21–43:20. Petitioner further avers "Sterilant Applicant Concentration" is "33% min." Pet. Reply 12 (citing Ex. 1019, 18). As Patent Owner argues (Tr. 43:21–22), however, this is the temperature of the hydrogen peroxide in the

"storage tank," *before sterilization*. Ex. 1019, 11. Petitioner's witness, Dr. Heldman, testified, however, that what's relevant to sterilization is the sterilant concentration and temperature *when it hits the bottle, because that is where the spore organisms are likely to be*. Ex. 2024, 274:14–278:19. The remaining disclosures that Petitioner compares to the '013 patent are from Buchner, not the identical process as disclosed in Biewendt, as discussed above, and they also do not disclose sterilant composition and temperature during sterilization. *See* Pet. Reply 12. Therefore, even assuming these disclosures disclose as much as the '013 patent, Petitioner has not persuaded us, with a preponderance of the evidence, that these disclosures enable a skilled artisan to practice the challenged claims with a reasonable expectation of success.

III. CONCLUSION

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

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 18–20 have not been shown to be unpatentable; and

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

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