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
U.S. Patent No. 6,945,013

PATENT OWNER'S RESPONSE

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I. INTRODUCTION

The evidence shows that the relationship between Nestlé and GEA is sufficiently close to justify preclusion given that Nestlé had more than ample opportunity to participate in, and control, the GEA IPRs. Nestlé is contractually obligated to [redacted] in the district court litigation, and Nestlé has [redacted] Ex. 2054 at ¶¶ 3(e), 4, 7. Consistent with the foregoing, Nestlé has been cooperating closely with GEA in both the IPRs and the district court litigation. Ex. 2055 at 12-13. Nestlé could have openly participated in the earlier-filed GEA IPRs, but chose not to do so either because Nestlé was comfortable letting GEA take the lead (while Nestlé provided input and strategic guidance behind the scenes), or because Nestlé wanted to attempt "a second bite at the apple" in the event the first round of IPRs were unsuccessful. Either way, this is precisely the type of conduct that the privity rules are designed to prevent.

Turning to the merits, the Petition is premised on the notion that the various Bosch machines described in various brochures and promotional literature are prior art. They are not. Only the brochures and promotional literature are prior art and they do not provide the technical detail required to allow competitors to replicate the system described in the brochures with any reasonable expectation of success. Bosch is in the business of selling industrial equipment – it has no interest in revealing the

key operational details of its equipment to its competitors. Indeed, Bosch was careful to "avoid[] publishing sufficient knowledge and details which could enable a competitor to successfully build a machine with the same or a higher output." Ex. 2017 at ¶ 17.

Bosch's decision to keep its technology as a trade secret paid off, as many competitors failed in their attempts to build aseptic bottling machines which could meet the FDA standards, as required by the claims. Ex. 1001, Col. 1, ll. 63-67 (defining "aseptic" as the FDA level of aseptic). More than a decade after the Bosch brochures were published, a European equipment manufacturer failed in its attempt to attain FDA validation of an aseptic sterilization and filling apparatus, even with the help of a former-FDA official working as a consultant. Ex. 2020 at pp. 11-14. GEA Procomac similarly abandoned a multi-year effort to develop a peroxide-based aseptic sterilization and filling machine (like the Bosch systems) and switched to a different sterilant and system design. Ex. 2020 at pp. 5, 6, and 11. Hamba Filltec GmbH & Co., a well-established manufacturer of aseptic cup filling equipment, was unable to deliver an aseptic bottling machine, which could meet FDA standards. Ex. 2022 at ¶¶ 20-25. As recently as 2009, another European aseptic equipment manufacturer abandoned a five-year long effort to install a functioning aseptic sterilization and filling machine. Ex. 2019 at ¶¶ 11; 41.

Even if one were to assume that an artisan of ordinary skill would have been able to replicate one of the Bosch systems – a fanciful notion in light of the history of

failures in the industry – there is no credible evidence that the Bosch system was able to come anywhere close to achieving FDA levels of aseptic by achieving a 6 log reduction as recited in claim 19. Petitioner's equipment supplier and indemnitee, GEA, concluded that such hydrogen peroxide systems could not achieve more than a 4-5 log reduction in the relevant spore organism, *bacillus subtilis*. Ex. 2021 at 5, 6, and 10. There is no evidence that any of the Bosch systems were able to achieve a 6 log reduction. Indeed, Dr. Buchner explains that in 1992 - after the publication of ZFL, Buchner, and Bosch - one of his graduate students could not achieve a 6 log reduction in spore organisms using hydrogen peroxide even in a lab setting. Ex. 1017 at ¶ 24-25. That is consistent with the fact that, to the best of Patent Owner's knowledge, Bosch had only one customer in the United States for its packaging equipment. Ex. 2053.

Petitioner's argument that any artisan of ordinary skill could readily improve upon the Bosch system so that it met FDA standards is, with respect, far-fetched. If ordinary artisans could achieve the alleged improvements, why did Bosch only have a single customer in the U.S.? Why did numerous competitors fail in their multi-year attempts to build aseptic bottling machines that met FDA standards? Petitioner's argument that any skilled artisan could replicate and readily improve upon the Bosch systems withers when exposed to the evidence of actual experiences in the industry.

II. NESTLÉ'S PETITION SHOULD BE DISMISSED AS TIME BARRED BECAUSE IT IS IN PRIVITY WITH GEA

A. THE GOVERNING STANDARD FOR PRIVITY

The privity inquiry is equitable and flexible in nature with the ultimate goal being to determine "whether the relationship between the purported 'privy' and the relevant other party is sufficiently close such that both should be bound by the trial outcome and related estoppels." 77 Fed. Reg. 48,756, 48,759. Such relationships are rooted in traditional common law preclusion principles. *Id.* at 48,760. The core function of the privity requirement is to ensure proper application of the statutory estoppel provisions, which are, in turn, intended "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 the USPTO and Federal Courts by assuring that all issues are promptly raised and vetted." *Id.* at 48,759.

The Board recently reiterated these principles in *Azure Gaming v. MGT Gaming*, IPR2014-01288 (Feb 20, 2015, Paper No. 13 at 12-16) where the Board explained that "the privity inquiry focuses on the relationship between the *parties* . . . " rather than the non-party's relationship to a specific proceeding. *Id.* at 13.

The Supreme Court in *Taylor v. Sturgell* laid out six categories of situations in which nonparty estoppel would apply, noting that the categories are "meant only to provide a framework for our consideration of [privity], not to establish a definitive

taxonomy." 553 U.S. 880, 893 (2008). One such category is "substantive legal relationships" sufficient to justify preclusion. *Id.* Another category looks to whether a "nonparty assumed control over litigation." *Id.* Yet another category looks to whether a "person agrees to be bound by determination of issues in action between others." *Id.*

It should be noted that "control" is its own stand-alone category under *Taylor v. Sturgell*. Thus, the other five categories delineated by the Supreme Court in *Taylor* do not require control. Accordingly, while establishing control is one way to justify preclusion, it is not the only way. Attempting to impart a rigid requirement that privity requires a finding of control would be inconsistent with the flexible and equitable nature of the privity doctrine and the Supreme Court's admonition that the list of substantive legal relationships justifying preclusion was not limiting. *Taylor*, 553 U.S. at 893. Indeed, in the recent *Azure* decision, the Board explained that assumed control is not a prerequisite for a finding of privity. *Azure*, Paper No. 13 at 14. Control very well might establish privity, but control is not required given the equitable and flexible nature of the privity inquiry. *Id.* at 15.

Instead, a variety of preexisting legal relationships have been viewed as appropriately establishing preclusion both before and after the Supreme Court's decision in *Taylor*. Indeed, the Federal Circuit has recognized that certain substantive legal relationships appropriately result in a finding of privity in the absence of control. *Underwood Livestock, Inc. v. U.S.*, 417 Fed. Appx. 934, 939 (Fed. Cir. Mar. 31, 2011)

(unpublished) (recognizing that preclusion is appropriate based on substantive legal relationships under *Taylor v. Sturgell*). One such preexisting legal relationship is indemnification. *Garver v. Brown & Co. Securities Corp.,* 1998 WL 54608, at *5 (S.D.N.Y. Feb. 10, 1998) ("courts applying … res judicata rules have found that 'privity' exists between parties in an indemnification relationship"); *Lanphere Enterprises, Inc. v. Doorknob Enterprises LLC*, 145 Fed. Appx. 589, 592 (9th Cir. 2005) (affirming trial court's conclusion that indemnity relationship established privity for preclusion purposes). As one district court aptly noted, **"[t]he fact that the Supreme Court in *Taylor* did not specifically mention [sic] include the indemnitor/indemnitee relationship does not mean that it does not suffice for a finding of a pre-existing substantive legal relationship.**" *Internal Marine, LLC v. FDT, LLC*, Case No. 10-0044, 2014 WL 7240143, at *6 (E.D. La. Dec. 19, 2014) (emphasis added).

Section 57 of the Restatement, cited by the Supreme Court in *Taylor v. Sturgell*, explains that at common law an indemnitor may be bound by a judgment rendered against its indemnitee where the indemnitor had the opportunity to participate in the action taken by the indemnitee and the indemnitee adequately represented the interests of the indemnitor. *Comment b* to Section 57 Restatement states:

> In defending the action by the injured party, the indemnitee ordinarily has incentive to litigate in order to minimize his own loss if the loss is later found to be outside the scope of the indemnity obligation. If the loss is later found to be within the indemnity obligation, in retrospect the indemnitee has performed a task of defense that the indemnitor should

> have performed, and thus acted for the latter…. [T]he nature of the contingency is such that the indemnitee's incentive to defend is greatest when it is most doubtful that the indemnitor should have assumed defense of the action, and is marginal only when it is clear that the indemnitor should have assumed the defense. **The indemnitor should not be allowed to relitigate an issue that he could have litigated merely because it was arguable that he had no duty to indemnify**. . . .

Id. (emphasis added). The Second Circuit has held that an indemnitor "is bound by the result only when its interests have been adequately represented in the original action by the indemnitee." *SCAC Transport (USA) Inc. v. S.S. Danaos,* 845 F.2d 1157, 1162 (2d Cir. 1988) (*citing* Restatement (Second) of Judgments § 57); *see also Universal American Barge Corp. v J-Chem, Inc.*, 946 F.2d 1131, 1136 (5th Cir. 1991) (an indemnitor may be subject to a prior determination in an action involving an indemnitee if the indemnitor did not appear and defend in the first action); *Step-Saver Data Sys., Inc. v. Wyse Tech.*, 912 F.2d 643, 650 (3d Cir. 1990) ("Because defendants chose not to defend the customer suits on their own, they will be held liable as long as the defect proven in the customer suits is attributable to them").

In determining whether the indemnitor is bound by the result of the action against the indemnitee, one consideration is whether the indemnitor had notice of the earlier action but made the deliberate decision not to participate in the first action. *Progressive Casualty Ins. Co. v. Morris,* 603 N.E.2d 1380, 1383 (Ind. Ct. App. 1992). Even if the indemnitor does not have an affirmative duty to defend the indemnitee, the

indemnitor must protect its interests by participating in the action against the indemnitee. *Id.* If an indemnitor opts not to participate in that first action, "it does so at its peril." *Id.* This is equitable because an alternative approach would produce anomalous results such as the indemnitor being relieved of liability where the indemnitee is held liable in the earlier action. *Id.*

Privity is applied flexibly so as to avoid such results. *Garver*, 1998 WL 54608 at *5. For instance, the concept of indemnitor/indemnitee privity is applied to prevent plaintiffs from bringing a first action against an indemnitor and then, if that first action is unsuccessful, bringing a second action against the indemnitee. *Id.* Likewise, privity should be applied in PTAB proceedings to avoid the anomalous result that an indemnitor who is cooperating closely with a petitioner-indemnitee can make the deliberate decision not to join the earlier review proceeding and instead attempt to have "a second bite at the apple" in the event the indemnitee's petition proves unsuccessful. 77 Fed. Reg. at 48,759.

For the foregoing reasons, privity includes certain indemnity relationships and does not require control. In the event the Board disagrees and deems privity to require some form of control, all that should be required is that the indemnitor or indemnitee have an opportunity to control the earlier action. *Zoll Lifecor Corp. v. Philips Elecs. N.A.*, IPR2013- 00609, 2014 WL 1253109, *6 (PTAB Mar. 20, 2014).

Especially given the equitable and flexible nature of privity, 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. See 35 U.S.C. § 315(b); *see also Synopsys, Inc. v. Mentor Graphics Corp.*, IPR2012-00042, 2014 WL 722009, at *7 (PTAB Feb. 19, 2014) ("[W]e also take into consideration the nature of the relationship between the parties at the time that the statutorily referenced complaint was served"). Doing so would plot a simple course for petitioners to circumvent the statutory estoppel provisions: start cooperating the week after the complaint is served. That would be an anomalous and unfair result – the type that the privity rules are intended to prevent. 77 Fed. Reg. at 48,759.

The Board recently acknowledged that the privity inquiry is by no means limited to the time the earlier complaint was served. In *VMware, Inc. v. Good Technology, Inc.*, IPR2014-01324, Paper No. 28 (Feb. 20, 2015) the Board noted:

> at least some of the factors analyzed in determining whether a party is a real party in interest or a privy of the petitioner involve actions or events that may occur after service of a complaint alleging infringement of the challenged patent. Petitioner cites to several non-precedential decisions of the Board in inter partes review proceedings, but does not identify any language in the statute or any other persuasive rationale to support the argument that privity under § 315(b) is determined only at the time of service of the complaint alleging infringement of the challenged patent.

VMware, Paper No. 28 at 3. Ultimately, the panel in *VMware* was correct to find that privity need not be measured at the time of service of the complaint. *Id.* at 3-4.

B. THE SALES AGREEMENT SHOWS THAT NESTLÉ BEARS [redacted] AND MADE THE DELIBERATE CHOICE TO LITIGATE THROUGH ITS PROXY, GEA

The sales agreement recently produced by Nestlé directly contradicts the representation that it has repeatedly made to Patent Owner and the Board to the effect that neither Nestlé nor GEA has any control, or opportunity for control, over the other. *See, e.g.*, Exhibit 1018 at 11, l. 20 – 12, l. 6. The agreement was drafted specifically to address [redacted] sales contract for the purchase of a machine worth [redacted] Ex. 2055 at 12. Pursuant to the agreement, "GPNA and Nestlé will [redacted] throughout the duration of any Steuben Claim (including appeal)." Ex. 2054 at ¶ 3(d).

The Steuben Claim has already been made according to the definition set forth in the sales agreement. Paragraph 3 includes the definition of a "Steuben Claim" and states:

[redacted]

[redacted]

Ex. 2054 at ¶ 3. In the complaints in both the GEA and Nestlé litigations, Patent Owner alleges infringement by GEA and Nestlé through the sale and/or use of Infringing Machines that "include the 'Unibloc' or ECOSpin' systems … including without limitation the 'Fillstar' bottle filling machine." Ex. 2056 at ¶ 27; Ex. 2057 at ¶ 27. GEA's packaging lines are known as ECOSpin systems with GEA's aseptic bottle filling component known as the Fillstar FX. Ex. 2058. Thus, a [redacted] claim was triggered upon the filing of the complaints in the district court cases.

Nestlé is obligated to [redacted], which means that Nestlé will be [redacted] in the event the district court awards a royalty of just 5 cents per bottle. Ex. 2054 at ¶ 4. Paragraph 4 of the agreement states that Nestlé and GEA will [redacted] *Id.* Thereafter, Nestlé "will [redacted]" *Id.* at ¶ 4. The total liability for infringement is far in excess of 100 million U.S. dollars. For example, Nestlé and GEA have been using the patented technology for at least about five years to bottle

approximately one billion bottles per year. Ex. 2059 (3-4 million bottles per day). Use of the infringing machines generates about $1,000,000,000 per year from infringing production (assuming Nestlé sells product at an average of $1.00 per bottle based on the retail price of $1.28 (Ex. 2060 at 1) with the retailer making a margin of between 20-30%). The net infringement liability for the span of, *e.g.*, 5 years is approximately $250,000,000 at a royalty rate of 5%, or 5 cents per bottle. Indeed, the royalty rate is likely higher than 5 cents a bottle making the $250,000,000 figure a conservative estimate. Thus, the [redacted] agreement makes Nestlé [redacted]

The sales agreement also gives Nestlé the right to [redacted]. The agreement states [redacted]" Ex. 2054 at ¶ 3(e). Thus, Nestlé cannot [redacted]. *Id.* Likewise, GEA could not have [redacted]. *Id.*

The sales agreement further provides that Nestlé and GEA [redacted]. Paragraph 7 states that [redacted]

[redacted]

[redacted]" Ex. 2054 at ¶ 7. The plain language of paragraph 7 makes clear that [redacted] The filing of an IPR petition in response to a charge of an infringement is an action that is taken in connection with a Steuben Claim. Thus, [redacted]

Agreements concerning terms of settlement are a touchstone of privity relationship. *Tilmon-Jones v. Bridgeport Music, Inc.*, Case No. 11-13002, 2012 WL 4470452, at *4 (E.D. Mich. Sep. 26, 2012). A party, [redacted], that has input into and agrees to be bound by settlement executed by another party is a privy for preclusion purposes. *Id.*

Further, the objective evidence indicates that Nestlé made the deliberate and purposeful decision to rely upon GEA to litigate as its proxy. Nestlé appears to have concluded that [redacted] would sufficiently incentivize GEA to vigorously defend against the Steuben claims. From the recent notices of appeal filed by GEA from the termination decision (which appear to lack statutory basis) (*See, e.g.*, Ex. 2060) and GEA's writ of mandamus seeking to overturn as capricious the Board's termination decision, it appears that Nestlé was correct in its assessment. Ex. 2062. Nestlé made a choice to participate

behind the scenes and let GEA take the lead in the district court litigation and the IPR proceedings and should be bound by that decision.

Moroever, Nestlé is a privy of GEA due to its own tactical choices as an actively engaged [redacted]. Based on the evidence presented above, there can be no real dispute that: (1) Nestlé is obligated to [redacted]; (2) Nestlé and GEA share [redacted]; (3) Nestlé was well aware that GEA was going to seek IPR of the Steuben patents; (4) Nestlé and GEA have been cooperating closely on legal strategy relative to the Steuben patents; (5) Nestlé had multiple opportunities to file petitions seeking inter partes review both before and after its one year bar date; and (6) Nestlé and GEA have nearly identical or identical interests in defending against the Steuben patents. It is also beyond reasonable dispute that such a [redacted] relationship is one of the types of relationships, which can justify application of preclusion principles under *Taylor v. Sturgell*.

Nestlé had a chance to file its petitions in parallel with GEA, in 2012 or 2013. Nestlé also could have filed in March 2014, after it had been served with a complaint in district court on November 12, 2013, a petition along with a motion to join GEA's inter partes review proceedings. Nestlé took neither step, instead choosing to sit back – for two years – and attempt "a second bite at the apple" in the event GEA's petition proved unsuccessful. Only once it appeared that the GEA IPRs were at risk of being terminated did Nestlé present itself from behind the curtain.

Steuben filed a complaint against GEA in September 2012 based primarily on GEA's sale of six aseptic bottle fillers to Nestlé and put Nestlé on notice of that action through service of a notice letter with a courtesy copy of the complaint. Ex. 2051 at 31; Ex. 2063. Nestlé acknowledged receipt of the letter and complaint on October 9, 2012. Ex. 2064. In that letter, Nestlé indicated that it was reserving all rights against Steuben and stated that it understood that it would be forced to defend itself. *Id.* Steuben served the complaint on GEA on October 10, 2012. Ex. 2065.

On September 3, 2013, Steuben filed a complaint in district court against Nestlé after settlement negotiations proved unfruitful and ultimately deferred service of the complaint. Ex. 2056. Steuben sent Nestlé a courtesy copy of that complaint indicating that it preferred to reach a settlement with Nestlé rather than serve the complaint. Ex. 2066. More than a month later, between October 9 and 10, 2013, GEA filed six petitions for *inter partes* review. In connection with those proceedings, Patent Owner offered detailed responses to the institution decisions, contingent motions to amend, and several expert declarations, while Nestlé sat back and watched Steuben's arguments unfold.

In August 2014, the Board granted Patent Owner authorization to seek termination of the GEA IPRs. It was at that point that Nestlé decided that its plan to allow GEA to fight its battle for it was in jeopardy – only then did Nestlé file its IPR petitions. Ex. 2067; Ex. 2068 at 9

Nestlé's conscious decision to sit back and let GEA fight on its behalf should preclude it from taking further action at the PTAB. Such a result is not only just, but supported by common law doctrines of preclusion. Indeed, Nestlé agreed to be bound by the results of the GEA IPRs in exchange for a stay in the district court, such that Nestlé cannot argue facing a preclusive effect as a result of the GEA IPRs is unfair. Ex. 2069. Nestlé should not get "a second bite at the apple" simply because the Board did not have jurisdiction to reach a final written decision in the GEA case. *See, e.g.*, IPR2014-00043, Paper Nos. 114, 120.

It would be inequitable to permit the company that is controlling the review proceedings and litigation (from behind the scenes) and that bears [redacted] to sit back for more than two years and wait to see if the supplier's efforts at the PTAB were successful. This is exactly the type of serial attack or "second bite at the apple" that the statutory estoppel provisions are designed to prevent. TPG, 77 Fed. Reg. at 48,759. Nestlé should thus be deemed a privy of GEA and the instant proceeding should be dismissed as time-barred under 35 U.S.C. §315(b).

III. THE ENGINEERING UNDERLYING LOW ACID ASEPTIC STERILIZATION AND FILLING IS HIGHLY UNPREDICTABLE

Each of the Bosch machines discussed in Exhibits 1006-1009 was used to process low acid foodstuffs. Ex. 1006 at 5; Ex. 1007 at 1, Ex. 1008 at 1; Ex. 1009 at 1. Petitioner's focus on low acid aseptic equipment is consistent with the specification of the '013 patent, which states that the "present invention provides a method and

apparatus for providing aseptically processed low acid products in a container having a small opening, such as a glass or plastic bottle or jar, at a high output processing speed." Ex. 1001, Col. 2, ll. 5-10.

The field low acid aseptic sterilization and filling ("LAASF"), is highly unpredictable. Ex. 2025 at ¶ 13; Ex. 2013. Development of LAASF processes usually requires half a decade or more of experimental trial and error due to the competing and conflicting design parameters and the inherent complexity of both the fluid dynamics in a bottling system and the related sterilization chemistry. Ex. 2025 ¶ 16; Ex. 2018 at 1. Of particular importance is the tension between using enough sterilant to kill the relevant microorganism of greatest concern on the one hand, while on the other the hand ensuring that less 0.5 parts per million residual peroxide remains on the interior of the package before it is filled (which is required by the FDA). Ex. 2017 at 47; Ex. 2025 at ¶ 26. This inherent tension makes the design of LAASF systems quite challenging and prompted companies like Bosch to closely guard their trade secret technologies.

A. MANY COMPANIES FAILED IN THEIR ATTEMPTS TO DESIGN ASEPTIC BOTTLING MACHINES THAT MET FDA REQUIREMENTS

In the years following the filing date, many manufacturers failed in their attempts to develop FDA-compliant aseptic sterilization and filling processes. There is every reason to believe that the manufacturers were fully aware of the Bosch machines, as those machines were being advertised by one of the leading companies

in the industry. Notwithstanding this, many failed in their attempts to develop a peroxide-based bottling systems (as in Bosch) which met FDA standards.

Around 2006, a European equipment manufacturer requested FDA validation of an aseptic sterilization and filling apparatus and that application was rejected. Ex. 2020 at pp. 11-14; Ex. 2025 at ¶ 28. The company hired an outside aseptic processing expert (who was a former-FDA official) but even with that help, the company was apparently unable to overcome the engineering hurdles and switched to an older, less efficient design. *Id.*

In that same year, GEA Procomac abandoned its multi-year effort to develop a peroxide-based aseptic sterilization and filling machine and switched to a different design. Ex. 2021 at pp. 5, 6, and 11; Ex. 2025 at ¶ 29, 57, 68.

> For cold filled PET bottles, which are lightweight and not heat-resistant, Procomac has determined that **vapor H2O2 cannot reach 5 log reduction on peroxide-resistant microorganisms**.

Ex. 2021 at 6 (emphasis in original); Ex. 2025 at ¶ 29, 57, 68. GEA concluded that hydrogen peroxide based systems like Bosch could simply not achieve more than even a 5 log reduction of spore organisms in any reasonable manner:

> **H_2O_2 sterilization processes cannot reach more than 4 to 5 log reductions** with lightweight bottles and reasonable bloc footprints.

Id. at 11 (emphasis in original); Ex. 2025 at ¶ 29.

Around 2008, Kan-Pak, LLC purchased a purportedly aseptic bottle filler from Hamba Filltec GmbH & Co., a well-established manufacturer of aseptic cup

equipment. Ex. 2022 at ¶¶ 20-25; Ex. 2025 at ¶ 28. Soon after the machine was delivered to Kan-Pak, Kan-Pak determined that it did not function properly and would not receive FDA validation absent significant modifications. *Id.* at ¶¶ 22-25; Ex. 2025 at ¶ 28. Notwithstanding Hamba's years of aseptic cup experience, it simply could not deliver FDA approvable low acid aseptic bottle filler.

In 2009, a European aseptic equipment manufacturer, KHS AG, was forced (by its customer) to abandon a five-year long effort to install a functioning aseptic sterilization and filling machine. Ex. 2019 at ¶¶ 11; 41; Ex. 2025 at ¶ 28. "[A]fter years of modifications and tests, the bottling system still [did] not work" and did not meet FDA standards." *Id.* at ¶ 2; Ex. 2025 at ¶ 28.

In all likelihood, many additional failures occurred but were not publicized. FDA applications are confidential and companies are, for obvious reasons, not inclined to publicize failures. Accordingly, it is reasonable to presume that the foregoing are merely representative examples of the broader experience in the industry.

That presumption would be consistent with the observation of numerous industry observers. Food Engineering published an article explaining that tireless research and development and many years of trial and error were necessary to develop FDA-compliant aseptic processes:

> Breakthrough products and packaging require **years of technological trial and error** before they burst on the scene. In the food industry . . .

> the **technology underlying the processing and packaging** changes that make them possible are usually the **result of decades of development**.

Ex. 2018 at 1 (emphasis added); Ex. 2025 at ¶ 21. The Handbook of Aseptic Processing and Packaging by David *et al.*, similarly explains that the competing concerns of effective disinfecting and low residual peroxide residue leave only a "narrow path" for successful aseptic processing designs. Ex. 2017 at 47; Ex. 2025 at ¶ 24.

Many in the industry found the path narrow, indeed. So narrow, in fact, that they either abandoned their efforts entirely or succeeded only after years of redesign.

B. THE FDA'S REQUIREMENT OF 0.5 PPM OR LESS RESIDUAL STERILANT IS THE STRICTEST IN THE WORLD AND MAKES THE DESIGN OF ASEPTIC PROCESSES EXTREMELY CHALLENGING

In contrast to the European Union – home to equipment manufacturers like Bosch – the FDA requires microbiological (challenge) and chemical tests to document whether an aseptic system provides an adequate margin of safety. Ex. 2017 at 148; Ex. 2025 at ¶ 25. Furthermore, the FDA sets the maximum sterilant residue levels at 0.5 ppm and:

> [a]s a consequence, U.S. processors must concern themselves with maximum hydrogen peroxide levels as well as minimum levels, to ensure proper sterilization. The resulting effect of these regulations is a **much lower peroxide level in the United States as compared to the rest of the world** and a **greater potential for the production of**

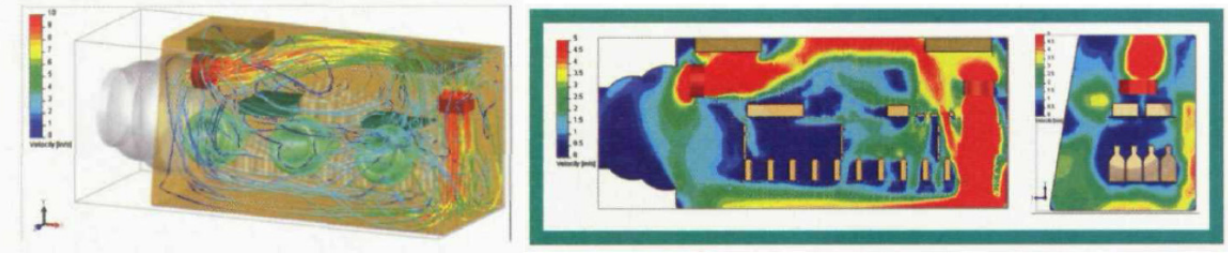
> **defective containers due to an insufficient amount of peroxide for proper sterilization** . . . .
>
> This leaves the operator with a **narrow path** between having enough peroxide to sterilize the container and not too much to meet the residual tolerances. It can be done, but requires extra controls and monitors not found on some models of Brik Pak or Combibloc fillers overseas.

Ex. 2017 at 43 (emphasis added); Ex. 2025 at ¶ 25.

The declarations of Professors Sharon and Buie further explain that the unpredictability in LAASF processes arises from the fact that the design of such processes requires delicate balancing of interdependent variables such as temperature of the sterilant, temperature of the rinsing fluid, concentration of sterilant, any structural limitations on the packaging material, the temperature of the bottle when the fluids (both sterilizing and rinsing) are applied to the bottle, airflow through the system, sterilant droplet size, and sterilant flow rates. *See, e.g.* Ex. 2025 ¶¶ 20, 30, 39-40, 45-47; Ex. 2026 ¶¶7-11. Each of these parameters is non-linear and oftentimes cannot be adjusted without having an adverse effect on another parameter. *Id*; *id.* For example, increasing the dose of sterilant can improve disinfection but may create exponential difficulties in removing the sterilant before filling. Ex. 2027 at 62; Ex. 2025 at ¶¶24, 26.

As a further example, the fluid dynamics associated with LAASF was still being actively studied and developed as of the mid-to-late 2000s, many years after the filing

date. *See* figures below, Exhibit 2028. In 2009, Radl noted that "there only a few practical guidelines for the proper design and development of hydrogen peroxide decontamination systems" and described new methods to accurately predict hydrogen peroxide condensation. Ex. 2029 at 52.



The 2009 study undertaken by Radl demonstrates specific airflows and temperatures throughout an enclosed pressurized environment through the use of numerical results relative to the airflow and temperature distribution as demonstrated in the figures below. (Ex. 2029 at 61).

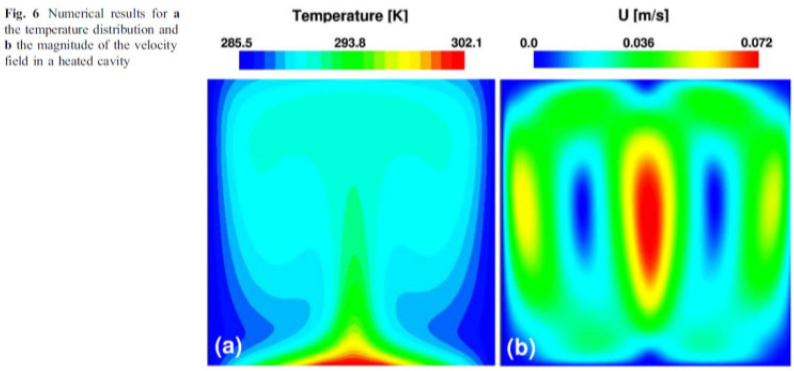


Fig. 6 Numerical results for **a** the temperature distribution and **b** the magnitude of the velocity field in a heated cavity

As can be seen from Fig. 6(a), the temperature tends to be at the highest in the center of the cavity with the temperature dropping toward the outer edges of the cavity. Ex. 2025 at ¶48. Fig. 6(b) shows airflow velocity throughout the cavity with air moving at its highest velocity in the center of the cavity with the velocity dropping

away from the center of the cavity only to increase again at the outer edges. *Id.* The particular airflow patterns disclosed by Radl, for the first time 10 years after the filing date, inject substantial complexity into the design of an LAASF system. Ex. 2025 at ¶¶47-49. For example, the reduction in temperature from the center toward the outer edges of the sterile tunnel will impact bottle temperature, which is a very important factor in the sterilization process. Ex. 2025 at ¶¶ 26, 48. The same is true of airflow patterns, which will vary across the tunnel unless properly accounted for during the design process. Airflow patterns through the tunnel have a direct impact on sterilant distribution as the sterilant is most often sprayed into the sterilization zone of an LAASF system.

Importantly, the various sections or zones of the sterile tunnel will have different temperatures depending on the function each zone is to achieve. Ex. 2025 at ¶ 26. For example, the sterilization zone will generally be at a higher temperature than the fill zone given the introduction of heated sterilant and air into that zone as opposed to the introduction of ambient product into the fill zone. *Id.* The varying temperatures as between or among zones, will impact bottle temperature. *Id.* There again, the varying temperatures between or among the zones inject substantial complexity into the bottling process as each zone will have an effect on bottle temperature. *Id.*

The temperature of the bottle is just one example of many that is affected by most any other variable in aseptic bottling. Such interdependent variables require

careful balancing, which needs to be undertaken in a realm of substantial scientific certainty. Ex. 2025 at ¶¶30, 40.

C. FDA VALIDATION REFLECTS THE COMPLEXITY AND UNPREDICTABILITY OF LAASF PROCESSING

It is precisely because of the unpredictability of the underlying science and engineering principles that the FDA requires microbiological and chemical tests to document whether an aseptic system provides an adequate margin of safety. Ex. 2025 at ¶ 25; Ex. 2017 at 148. The spoilage data used by European regulators is, in the view of the FDA, simply inadequate to predict the future performance of a LAASF process. Ex. 2025 at ¶ 25; Ex. 2017 at 148.

The FDA requires that a LAASF machine be capable of reducing a certain population of microorganisms by a certain amount on a logarithmic scale. In order to ensure that all viable microorganisms have been killed, the FDA requires that the chosen test organism be the organism of greatest concern for a given sterilant. In other words, the FDA requires that the test microorganism be the most resistant microorganism to a given sterilant. Various research papers available as of February 2, 1999, identify sterilant specific target organisms. In the case of hydrogen peroxide, that organism is *bacillus* subtilis. Ex. 2040 at 234-235; Ex. 2025 at ¶ 58. In the case of oxonia, that organism is *bacillus cereus*. Ex. 1012 at 264; Ex. 2025 at ¶ 58.

If any substantial change is made to a LAASF process then the process must be revalidated with the FDA. Ex. 2025 at ¶ 27; Ex. 2031 at 5. As an example, the

addition of a processing lane would necessitate that the entire process be revalidated. *Id.*; *id.* The validation process tests the lanes on an individual basis to ensure that process variations across the lanes such as temperature, air flow, and droplet size have not caused either inadequate sterilization or inadequate removal of sterilant. *Id.; id.*

For a typical LAASF apparatus, the initial validation process spans multiple years. Ex. 2020 at 394, l. 16 – l. 395, l. 11. During that process, it is common for the FDA to identify problems with the design and ask the applicant to revise the apparatus and method accordingly. *Id.* at 13, ll. 10-13. In many circumstances, the manufacturers are unable to overcome the problems and are forced to switch to older lower throughput technologies. *Id.* at 13, ll. 18-21.

IV. PERSON OF ORDINARY SKILL IN THE ART

Petitioner urges that a person of ordinary skill in the art would "have had an undergraduate scientific or engineering degree in a relevant field (such as microbiology or mechanical, packaging, process, or food engineering), at least 5 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." Ex. 1005 at ¶ 12.

Patent Owner disagrees with Petitioner's definition only in that it does not **require** a mechanical engineering degree. Ex. 2025 at ¶ 14. As conceded by GEA's expert in the related IPRs, LAASF processes are principally mechanical engineering innovations. Ex. 2020 at 111, ll. 2-4; Ex. 2025 at ¶¶ 14, 18.

V. THE TAGGART SPECIFICATION REPRESENTS A SIGNIFICANT ADVANCE OVER THE PRIOR ART

Professor Buie explains that the '013 patent contains various key design parameters not found in the cited prior art that "enable a person of ordinary skill in the art to reproduce the system, process, and results described in the '013 patent related to sterilant delivery and removal." Ex. 2026 at ¶ 43 Those features include venturi atomization of H_2O_2 into a second flow of sterile air, high flow rate of air in the bottle to avoid melting, using drying air at 230 ºF (or 110 ºC) that cools to 131 ºF in the bottle, application of the drying air for 24 seconds to achieve a constant temperature of 131 ºF for at least about 5 seconds, and forcing most of the sterile air exhaust upstream to help warm the bottles before they arrive at the sterilization station. Ex. 2026 at ¶¶ 23, 41.

A. CONSTANT AND UNIFORM VENTURI ATOMIZATION

The '013 patent describes a first sterile air supply that is used to atomize a sterilant (*e.g.*, hydrogen peroxide) via a venturi atomizing system. Ex. 2026 at ¶ 10. A second sterile air supply provides hot sterile air to the sterilant leaving the atomizing system, which carries it to the heat exchanger. Ex. 2026 at ¶ 10; '013 Patent Col. 6, ll. 10-17. The air stream that carries the atomized peroxide to the heat exchanger helps to prevent hydrogen peroxide from condensing on the conduit walls prior to injection into the container. Ex. 2026 at ¶10. This, in turn, prevents excessively large droplets

from forming in the container, which would cause residual sterilant to remain after the drying operation. Ex. 2026 at ¶ 10.

Based on the disclosure set forth in the Taggart Patents, Dr. Buie was able to model the atomization of hydrogen peroxide using a venturi. Ex. 2026 at ¶¶ 12-20. While his analysis does not define the exact operating conditions, he opines that a person of ordinary skill in the art would be able to construct and use the atomization system disclosed in the '013 patent as of February 2, 1999. Ex. 2026 at ¶ 12.

B. AIRFLOWS THAT PREHEAT THE BOTTLES AND ENSURE STERILITY OF THE ASEPTIC ENVIRONMENT

The '013 patent also discloses the use of different zones to ensure that the target hydrogen peroxide concentration of 0.5 parts per million is met. Ex. 2026 at ¶ 23. In connection with the creation of those zones, which are kept at different pressures while the entire system is kept sterile under an overpressure of sterile air, Taggart discloses a specific airflow regime. *Id.* The air flow regime is designed such that air flows away from the filling zone and out the bottle inlet and outlet sections. *Id.* This airflow prevents contaminants from entering the aseptic environment of the filler. *Id.* The airflow away from the filler toward the bottle inlet section also serves the **important purpose of preheating the bottles such that the 5 second dwell time at 131°F is possible while achieving the desired throughput**. *Id.*

The system disclosed in the '013 patent includes an exhaust fan 73 that functions to force air out of the system through exhaust conduit 70. Ex. 2026 at ¶ 25.

Air also exits the system disclosed in the '013 patent through opening 282 in the bottle outlet zone. Ex. 2026 at ¶ 25; '013 Patent, Col. 12, ll. 32-40, Fig. 14. The hot sterile air is also drawn out of the bottle interior sterilization zone through a bottom opening 62 in the infeed and sterilization apparatus. '013 Patent, Col. 7, ll. 48-51. The figure below demonstrates the airflow regime disclosed in the specification of the '013 patent.

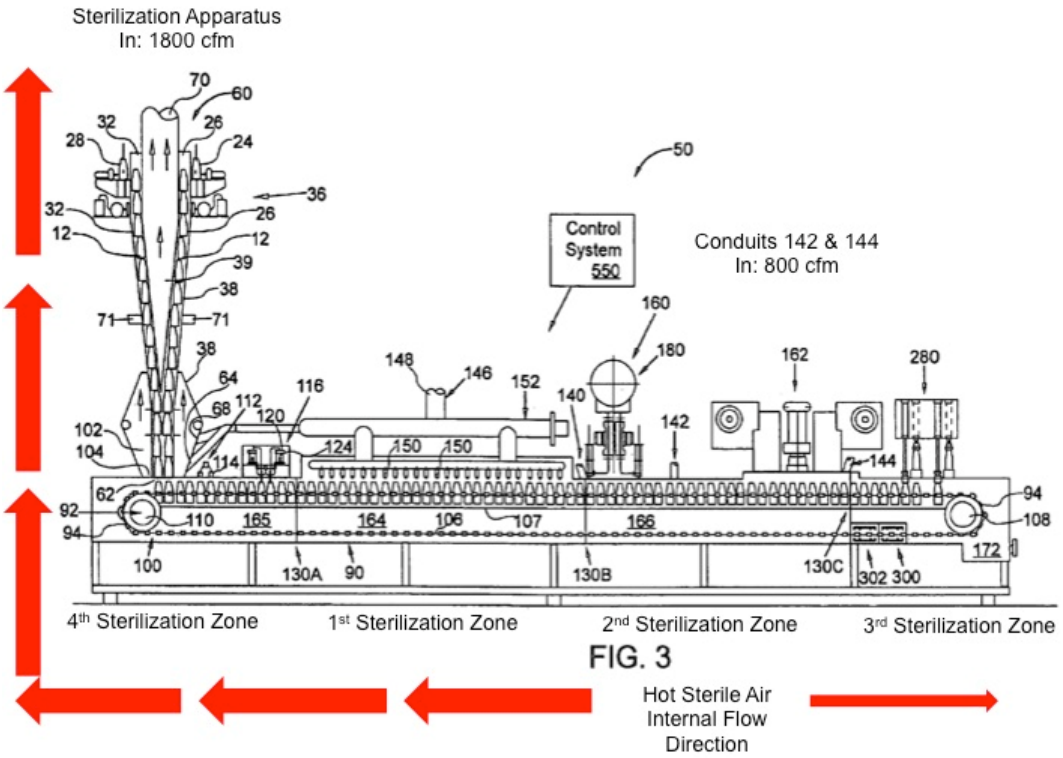


FIG. 3

After conducting a lengthy analysis, Dr. Buie concluded that a person of ordinary skill in the art could make and construct the system disclosed in the Taggart Patents such that the air would flow downstream and upstream of the filling zone while achieving the critical tasks of preventing contaminants from entering the sterile or aseptic zone while also ensuring pre-heating of the bottles. *Id.* at ¶¶ 25-35.

C. USE OF RELATIVELY HIGH FLOW RATES OF RELATIVELY COOL AIR TO AVOID MELTING THE BOTTLE WHILE ACHIEVING A SET TEMPERATURE FOR A SPECIFIED PERIOD OF TIME

Importantly, Taggart explains that the heat sensitive nature of PET and HDPE bottles must be accounted for in the aseptic bottling process. Ex. 1001, Col. 9, ll. 63-66. Taggart explains that in an aseptic processing system a low volume of air is typically used at high temperatures to rinse the sterilant from the package. Ex. 1001, Col. 9, ll. 66–10:1. However, this could result in deformation of heat sensitive packaging such as HDPE and PET bottles. Ex. 1001, Col. 10, ll. 2-3. Accordingly, to overcome this obstacle, Taggart discloses the use of high volumes of air at relatively low temperatures. Ex. 1001, Col. 10, ll. 4-6. Further, according to the '013 patent, the sterile air is applied to the bottles at a temperature of 55 ºC, which avoids softening of PET and HDPE bottles. Ex. 1001, Col. 10, ll. 21-25.

The '013 patent further explains that sterile air is directed into the bottle for a relatively long period of time, which is necessitated by both the heat sensitive nature of HDPE and PET and the geometry of the bottle. Ex. 1001, Col. 10, ll. 4-6. In that regard, Taggart discloses a method of directing hot sterile air into the bottles for approximately 24 seconds such that the air rinsing the hydrogen peroxide from the bottles does not soften the plastics bottles. Ex. 1001, Col. 10, ll. 12-16. The 24 seconds of air ensures sterility by achieving a bottle temperature of 55 ºC for at least about 5 seconds. Ex. 1001, Col. 10, ll. 16-18. Taggart explains that the hot sterile air used to rinse the bottles leaves the nozzle at a temperature of about 110 ºC. Ex. 1001,

Col. 10, ll. 21-22. The 24 seconds provides adequate time to allow the bottle to heat to 55 ºC. According to the '013 patent, this is sufficient for removing the sterilant such that less than 0.5 parts per million of residual sterilant remains on the bottle. Ex. 1001, Col. 10, ll. 24-30.

Based on another detailed analysis, Dr. Buie concluded that one of ordinary skill in the art would be able to construct and use the system disclosed in the specification to reach 131ºF for five seconds within the 24 seconds specified in the patent, which ensures the requisite 6 log reduction of spore organisms. Ex. 2026 at ¶¶ 35-41. Dr. Buie is "confident that the Taggart Patents enable a person of ordinary skill in the art to reproduce the system, process, and results described in the Taggart patents related to sterilant delivery and removal." Ex. 2026, ¶ 43.

VI. BROADEST REASONABLE INTERPRETATION OF THE TERM "ASEPTIC"

Patent Owner bases this response upon the broadest reasonable interpretation of the claim language. All claim terms not specifically addressed in this section have been accorded their broadest reasonable interpretation in light of the patent specification including their plain and ordinary meaning. Patent Owner's position regarding the scope of the claims under their broadest reasonable interpretation is not to be taken as stating any position regarding the appropriate scope to be given the claims in a court or other adjudicative body under the different claim interpretation standards that may apply to such proceedings. In particular, Patent Owner notes that the standard for claim construction used in district courts differs from the standard

applied before the USPTO. Any claim construction offered by Patent Owner in this response is directed to the USPTO standard, and Patent Owner does not acquiesce or admit to the constructions reflected herein for any purpose outside of this proceeding.

The term aseptic is specifically defined by the Taggart specification as "the FDA level of aseptic." The Background section states that "[i]n the following description of the present invention, the term 'aseptic' denotes the United States FDA level of aseptic." Ex. 1001 at col. 4, ll. 29-30. The Detailed Description of the Invention expands on this, stating as follows:

> The present invention provides an aseptic processing apparatus 10 that will meet the stringent FDA (Food and Drug Administration) requirements and 3A Sanitary Standards and Accepted Practices required to label a food product (foodstuffs) as "aseptic". **Hereafter, "aseptic" will refer to the FDA level of aseptic**. The present invention provides a method and apparatus for producing at least about a 12 log reduction of *Clostridium botulinum* in food products. In addition, the present invention produces packaging material with at least about a 6 log reduction of spores. Actual testing of the aseptic processing apparatus is accomplished with spore test organisms.

Ex. 1001 at col. 4, ll. 23-33.

Nestlé's expert Dr. Heldman acknowledges that the "FDA require[s] no greater than 0.5ppm H_2O_2 residue in the sterilized bottles." Ex. 1005 at ¶ 22. Indeed, 21 C.F.R. § 178.1005(d) states:

> 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 product conditions (assay to be performed immediately after packaging).

Ex. 1011; *see also* Ex. 1010 at 60 ("The FDA regulations place a limit of a final concentration of not more than 0.5 ppm after packaging (Code of Federal Regulations, 1990a"); Ex. 2017 at 136 ("As previously mentioned, the FDA now permits only a hydrogen peroxide residue of 0.5ppm in a container"). Accordingly, the FDA level of aseptic requires that the sterilant be removed from a package such that less than 0.5ppm remains on the package before it is filled.

Patent Owner notes that claim 20 recites "wherein a residual level of hydrogen peroxide is less than 0.5 PPM." The fact that certain claims in the patent specifically identify the FDA level of aseptic for peroxide residual does not mean such a limitation is not implicit in the claims through the use of the word aseptic. Indeed, "claim differentiation is a rule of thumb that does not trump the clear import of the specification." *Eon-Net LP v. Flagstar Bancorp*, 653 F.3d 1314, 1323 (Fed. Cir. 2011).

Here, the specification makes clear that the methods of the invention are FDA-compliant. The Background section explains that "[f]or the aseptic packaging of food products, an aseptic filler must, for example, use an FDA (Food and Drug Administration) approved sterilant, meet FDA quality control standards, use a sterile

tunnel or clean room, and must aseptically treat all packaging material." The specification explains the object of the invention as follows:

> Furthermore, the prior art has not been successful in providing a high output aseptic filler that complies with the stringent United States FDA standards for labeling a packaged product as "aseptic." **In the following description of the present invention, the term "aseptic" denotes the United States FDA level of aseptic.**

Ex. 1001, Col, 1. 64 - Col. 2, l. 2. The Summary of the Invention reiterates the need for FDA-compliance, stating that "[m]any features are incorporated into the aseptic processing apparatus of the present invention in order to meet the various United States FDA aseptic standards and the 3A Sanitary Standards and Accepted Practices." Ex. 1001 at Col. 2, ll. 10-14.

Because the multiple instances of clear lexicography and the clear description of the invention cannot be trumped by claim differentiation, the term "aseptic" must be interpreted to require the FDA level of aseptic, which in turn require no more than a 0.5 ppm of residual hydrogen peroxide.

VII. PETITIONER HAS FAILED TO SET FORTH A PRIMA FACIE CASE OF OBVIOUSNESS

Petitioner's challenge fails for three independent reasons. First, the Bosch brochures are akin to a General Motors pamphlet showcasing a car that can achieve 100 miles per gallon without the use of electric motors. That claim is well and good, but without the trade secret information enabling the design there is no way an artisan

of ordinary skill could build that car. Second, the Bosch references do not even claim to have achieved a 6 log reduction (claim 19) in microorganisms as that would be measured by the FDA ("aseptic" being defined as the FDA levels of aseptic). Rather, the Bosch references teach only about a 3-4 log reduction in the relevant spore organism, i.e., the one most resistant to the sterilant being used. Third, the notion that a skilled artisan could readily improve upon the Bosch system so that it met FDA standards is far-fetched. History has shown us that ordinary artisans could not achieve the proposed improvements: numerous competitors failed in their multi-year attempts to build H_2O_2 aseptic bottling machines that met FDA standards.

A. THE KEY DETAILS NECESSARY TO REPLICATE THE BOSCH MACHINES WERE KEPT AS TRADE SECRETS

The author of three of the four primary Bosch references, Dr. Buchner, testified that Bosch kept the key operational details of the Bosch machines a trade secret.

> The information in my articles, for example in Pharma Technologie Journal [Ex. 1006], intended to inform about the achieved technical success, show what Bosch has achieved and create interest at possible customers of the machines. **I avoided, however, to publish sufficient knowledge and details which could enable a competitor to successfully build a machine with the same or a higher output**. All my publications were checked thoroughly before publishing by Bosch-

authorities whether they were corresponding to these demands as long as I was employed by Bosch.

Ex. 1017 at ¶ 18 (emphasis added).

Bosch's effort to keep its technology as a trade secret was successful. As noted above, in the two decades following the publication of Exhibits 1006-1009, numerous companies tried and failed to achieve what Bosch claimed to do in those brochures and promotional articles. *See* discussion *supra* at 16-20. Even GEA, Petitioner's equipment supplier, concluded that hydrogen peroxide systems like the Bosch machines were simply not capable of exceeding a 5 log reduction in spore organisms in a reasonable block footprint. Ex. 2021 at 5, 6, 10; Ex. 2025 at ¶ 29. Significantly, GEA's presentation never suggests that such systems could approach 6 log reductions even with unreasonable block footprints. Exhibit 2021 at 5, 6, 10. That is consistent with the fact that over the course of twenty-five years Bosch is believed to have had only a single customer for its aseptic bottling system in the United States. Ex. 2053. Bosch likely found it necessary to re-design the system to achieve the 6 log reduction, just like Hamba, GEA, and KHS.

Just as Bosch's Dr. Buchner explained, the key operational details were omitted from the Bosch references. Ex. 1017 at ¶18; Ex. 2025 at ¶ 35. This can be appreciated most clearly by a close examination of Biewendt the reference, which at first blush, contains the most technical detail. In the key section, the one pertaining to bottle sterilization, nothing is said about 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.

> 2.2 Bottle sterilization machine, Type RQT 5090 BT
>
> The machine is comprised of a clean room that is subdivided into 12 successive treatment stations, each with 9 side-by-side parallel chambers. Cover plates delimit each of the chambers at the top; each of said cover plates has a central opening. A so-called bottle deposit (Fig. 2 (2)) is at the input of the machine, and a bottle output is located at the exit (Fig. 2 (4)). Each has an upstream and downstream aseptic lock to protect the clean room from the external atmosphere.
>
> The bottles are automatically separated on the conveyer belt and guided to the bottle deposit table of the machine, which is arranged transversely to the running direction of the machine. This is where 9 each bottles are taken simultaneously and introduced head first into the clean room via the aseptic lock.
>
> During further transport, heating with sterile warm air first continues from the outside, and then [the bottles] are sprayed with hydrogen peroxide (H_2O_2). Inside the chambers, the sterilizing H_2O_2 warm air mixture flows around the entire surface area of the bottles introduced into the chambers, and is then suctioned off through the cover plate openings and separated again in catalysts located outside of the clean room. After passing through all 12 treatment stations, the bottles are placed upright again on the conveyer belt when they are removed via the aseptic lock.

Ex. 1008 at 4. The preceding section (2.1) describes the temperature of the bottles, but only before they start down the conveyor (exposed to the factory environment) toward the sterilization unit. *Id.*

Petitioner claims that the addition of Biewendt is significant given its disclosure of using a 33 percent hydrogen peroxide solution and air heated to at least 80 ºC. However, the concentration of the hydrogen peroxide in the tank is of little import; as conceded by Petitioner's expert, it is the concentration of the sterilant in vaporized,

airborne form in the sterilization chamber that matters. Ex. 2024 at 276, l. 1 – 278, l. 13. Biewendt, of course, says nothing about that. As for air being heated to at least 80 ºC, that (deliberately) says very little about the actual air temperature used by Bosch and says nothing about the flow rates, which are of great importance. Ex. 2025 at ¶ 39.

Dr. Sharon notes that Petitioner's contention that Biewendt provides more detail than ZFL, Bosch, and Buchner is illusory. In particular, Dr. Sharon notes that "[w]hile at first glance the Biewendt reference appears to offer a number of details and figures concerning the design of the aseptic packaging line described in the reference, upon further examination it is seen that the detailed description in fact does not relate to the design of the sterilization machine but rather focuses primarily on the cleaning of the machine, the process for starting up the machine and the testing of the machine." Ex. 2025 at ¶ 34. Biewendt, however, is mostly silent on how the actual sterilization of the bottles is achieved. *Id.*

Dr. Sharon explains that Biewendt only outlines basic sterilization steps without providing any meaningful detail on how the bottle sterilization is actually achieved. Dr. Sharon explains:

> In fact, the reference offers only four short paragraphs on the sterilization process out of the 26 pages in the reference. Those four paragraphs are very vague offering conspicuously little detail. For example, one of the four paragraphs simply states the bottles "are universally fogged with a warm hydrogen peroxide (H_2O_2) air mixture of

> defined concentration for a specified period of time and then universally blown dry with heated air." Exhibit 1008 at 17. This is not enough information to even begin the machine design process. It is clear that Bosch did not want to release any details about the actual sterilizing process. This is validated by the sharp contrast between the process description above and the description about cleaning the machine (e.g., "7 minutes rinsing with cold water, 18 minutes rinsing with 1.5 % NaOH solution at 60 to 80° C, 9 minutes rinsing with hot water at 60 to 80° C, 12 minutes rinsing with 1.5% HNO3 solution at 60 to 80 ° C…"). Exhibit 1008 at 16.

Ex. 2025 at ¶ 35.

Even if the disclosure of Biewendt is combined with Buchner, ZFL, and Bosch, from an engineering perspective at least 39 variables necessary to construct the aseptic bottling apparatus disclosed therein are missing. Ex. 2026 at ¶50. In many cases, those variables are interdependent on, and coupled to, other key variables that are likewise omitted. *Id.* In order to overcome this hurdle, a person of ordinary skill in the art would be required to first determine the relevant operating range for a given unknown variable, and then determine how it effects each dependent variable. This process will leave a person of ordinary skill in the art with little, if any, expectation of success in solving all 39 missing variables. Ex. 2026 at ¶50.

Petitioner argues that the Elliott reference provides a person of ordinary skill in the art with all the necessary design parameters to design an LAASF system. But Elliott does nothing more than identify a list of variables. In particular, Petitioner and

Dr. Heldman point to Figure 2 of Elliott as disclosing the window of operation within which one can aseptically disinfect bottles. However, "that window of operation is just a graphical way of explaining the narrow path referred to by David." Ex. 2025 at ¶ 30. Dr. Sharon explains:

> Figure 2 does not provide a mechanical engineer with any reasonable expectation of success in constructing an aseptic sterilization and filling machine. Exhibit 1013 at 118. To the contrary, it simply invites a mechanical engineer to conduct multi-dimensional experiments to define the window. Figure 2 simply tells a mechanical engineer to use sterilant, and use enough to get a desired kill, but not too much so that it cannot be adequately removed in order to meet the FDA residual peroxide requirement of 0.5ppm. Also, the heated air temperature must be high enough for an effective kill, but not too hot that it will deform the package. In other words, it 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.

Id.

Beyond simply inviting experimentation, Elliot explains that the experiments relative to, for example a log reduction, disclosed therein "may not be meaningful under production conditions." *Id.*; Ex. 1013 at 6. Based on that, Dr. Sharon concludes that a person of ordinary skill in the art well-versed in the engineering complexity underlying LAAASF "would realize that Elliott does not provide any real

answers," which Dr. Sharon explains "is consistent with the failures discussed above." Ex. 2025 at ¶ 30.

Also of note is the fact that Bosch's early claim that it might achieve 200 bottles per minute appears, from the objective evidence, to never have actually been realized. Exhibits 1007 and 1009, published in 1990, claim that bottle speeds of 200 BPM would or could be achieved. However, six years later Ex. 1008 (Biewendt) makes no mention of 200 bottles per minute. Given that, as Dr. Buchner explained, the articles were intended to promote the Bosch system it can be inferred that the 1996 publication would have advertised the 200 BPM rate if it had in fact been achieved.

At the end of the day, the Bosch brochures are like a General Motors pamphlet showcasing a car than can achieve 100 miles per gallon without the use of electric motors. That claim is well and good, but without the trade secret information enabling the design there is no way an artisan of ordinary skill could build that car. The company simply is not going to include enough technical detail to enable competitors to even begin the design process. And that's exactly where the Bosch references leave an artisan of ordinary skill.

B. THE BOSCH MACHINES DO NOT ACHIEVE FDA LEVELS OF ASEPTIC

To achieve FDA levels of sterility for low-acid food packaging, an applicant must demonstrate that that the system achieves a certain log reduction of the spore organism, which is most resistant to the sterilant being used. Ex. 2040 at 234-235; Ex. 2041 at 178; Ex. 2021 at 23; Ex. 2025 at ¶ 58. For "hydrogen peroxide . . . the test

organism is Bacillus subtilis . . . ." Ex. 1001, Col. 4, l. 39; Ex. 2040 at 234-235; Ex. 2025 at ¶ 58. For sterilants containing peracetic acid (oxonia) the test organism is *b. cereus*. Ex. 2021 at 30-32, 38; Ex. 2046 at 263; Ex. 2025 at ¶ 58.

At the time of filing (February 2, 1999) a skilled artisan would have understood that a machine manufacturer should demonstrate that a 6 log reduction of spore organisms was achieved on the packaging material. Indeed, various references at the time suggested that the 6 log reduction was mandatory. Ex. 2050 ("the germ killing effect on the inside of the packaging shall be 6 log cycles (6 D) for the Bacillus subtilis."); Ex. 2051 at 159 ("A reduction of 6 D as required for products with a pH >4.5 is attained with … hydrogen peroxide processes."); Ex. 2025 at ¶ 31. A skilled artisan would also have been aware that hydrogen peroxide was the only FDA approved sterilant at the time of filing and, as such, that the target organism was *bacillus subtilis* in light of the discussion above.

Claim 19 specifically requires the 6 log reduction. Claim 19 recites "aseptically disinfecting the bottles at a rate greater than 100 bottles per minute, wherein the aseptically disinfected plurality of bottles are sterilized to a level producing at least a 6 log reduction in spore organism."

The Bosch machines discussed in Exhibits 1006-1008 do not achieve FDA levels of aseptic as they do not demonstrate a 6 log reduction of **any** spore organism, much less of *bacillus subtilis*. Neither the Bosch Brochure nor Biewendt even mention a log reduction on the packaging material and, therefore, cannot be cited as teaching a

6 log reduction in any spore organism. The Buchner reference mentions a 5 log reduction in *bacillus subtilis* but does not explain how it is achieved. In any case, a 5 log reduction falls an entire order of magnitude short of the claimed 6 log reduction. Ex. 2025 at ¶¶ 53, 68-69. The only reference that discloses anything greater than a 6 log reduction is ZFL. However, a close examination of ZFL shows that it discloses only a 5.1 log reduction as it would be measured by the FDA (which is in turn required by the claims).

ZFL discloses certain test results that were achieved through the sterilization of glass bottles in the system discussed by the ZFL reference. In particular, Table 1, reproduced to the right, discloses certain log reductions achieved by the upstream bottle rinser alone as well as results achieved by the upstream rinser in combination with hydrogen peroxide treatment. As can be seen from the figure, the rinser in combination with the hydrogen peroxide treatment, achieved an 8 log reduction in *bacillus cereus*. Ex. 2025 at ¶59. The rinser itself achieved a 2.9 log reduction. *Id.* According to Dr. Heldman, this indicates that the hydrogen peroxide treatment itself results in a 5.1 log reduction in spore organisms. Ex. 2024 at 109, ll. 6-22. Thus, when the steam rinser is not applied, a 5.1 log reduction is achieved.

Table 1: Sterilizing results for glass bottles

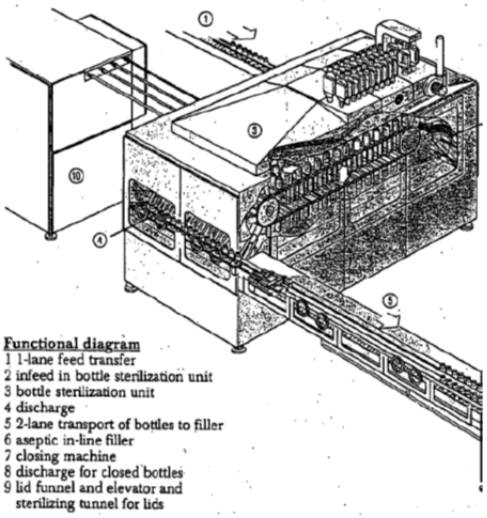
Type of germ	Decimal reduction
Sterilization in upstream rinser	
- Yeasts (*Sacch cerevisiae*)	>6D
- Molds (*Asp. niger*)	>6D
- *Streptococcus faecalis*	5.4 D
- Bac. cereus	2.9 D
Total sterilization by rinser + H_2O_2-treatment	
- *Streptococcus faecalis*	>9D
- *Bac. cereus*	>8D

In the related GEA IPRs, GEA offered Mr. Spinak as its lead expert. Mr. Spinak is a former FDA employee who devoted his career to the validation of LAASF

systems. During his deposition, Mr. Spinak explained that the **FDA would not consider the results of the precleaner/rinser step** in determining whether LAASF equipment was able to achieve the FDA level of aseptic. In particular, Patent Owner asked Mr. Spinak about the precleaner or rinser used in the Bosch machine disclosed in ZFL. In response, Mr. Spinak stated:

> A. The OSITAs at the time **would not consider the rinsing practice in the validation**. Even though it may be done, they would understand it, but we're going to – we're going to let it come out of the rinsing station and we're going to enter the bottles at that point. So any pretreatment is – is a proactive procedure, a prevent, but –
>
> Q. Understood.
>
> A. We're not going to do it. We're not going to do the validation to take credit for that section.

Ex. 2020 at 326, ll. 4-17 (emphasis added); Ex. 2025 at ¶ 66. Because the FDA would not consider the precleaner results, it would have no basis on which to conclude that anything higher than a 5.1 log reduction could be obtained by the Bosch system disclosed in the ZFL references. The FDA's refusal to consider the precleaner results makes sense given the fact that after the bottles are cleaned in the precleaner they are exposed to the ambient factory environment which could contain spore organisms. This can be seen clearly at reference (1) in the figure at right. Ex. 1009 at 2. The



bottles enter the bottle sterilizer from the ambient atmosphere. *Id.*; Ex. 2025 at ¶ 66. This is consistent with the statement in Biewendt that the bottles move to the sterilizer on a conveyor belt without mentioning any housing or enclosure. Ex. 1008 at 4; Ex. 2025 at ¶ 67.

The reasoning behind the FDA's refusal to consider the precleaner results stems from the universal caution against the potential for recontamination. Ex. 2053 at 135; Ex. 2025 at ¶ 66; Ex. 1010 at 58. Aseptic packaging systems are designed to eliminate the risk of recontamination that can occur when a package or food product is exposed to a nonsterile environment and then reintroduced into the sterile environment. Indeed, Mr. Spinak explained that the European equipment manufacturer ultimately did not achieve FDA validation because its process involved the potential for a container to be exposed to a nonsterile environment after the initial sterilization step and prior to a secondary sterilization step. Exhibit 2020 at 12, l. 21 – 13, l. 1. This is the exact problem created by the Bosch system.

In light of the foregoing it is clear that a person of ordinary skill in the art would recognize that, for FDA purposes, the ZFL system obtained only a 5.1 log reduction of *b. cereus* through the use of hydrogen peroxide. This falls short of the 6 log reduction recited in the claims.

Even more importantly, when the prior art is viewed through the lens of FDA levels of aseptic, the relevant question is whether the ZFL system achieved a 6 log reduction in *bacillus subtilis* because the sterilant used was hydrogen peroxide. Given

the well-known fact that *bacillus cereus* was less resistant to hydrogen peroxide than *bacillus subtilis*, a person of ordinary skill in the art would recognize that any microbial reduction achieved by the Bosch system disclosed in the ZFL reference relative to *bacillus subtilis* would necessarily be lower than the microbial reduction achieved relative to *bacillus cereus*. Dr. Heldman agrees. Ex. 2024 at 109, l. 24 – 111, l. 3.

Dr. Sharon expands on this indisputable fact, explaining that a person of ordinary skill in the art would understand that the **hydrogen peroxide treatment itself could only achieve about a 4 log or less reduction of *bacillus subtilis***. Ex. 2025 at ¶ 59. Dr. Sharon explains that the 4 log or less reduction in *bacillus subtilis* is a conservative estimate with the actual number being somewhere between 3-4 logs. *Id.* Dr. Sharon's conclusion is substantiated by a paper authored by Hilgren. *Id.* Hilgren conducted side-by-side experiments concerning the relative resistance of *bacillus cereus* to hydrogen peroxide as compared with *bacillus subtilis*. *Id.* The experiments revealed that *bacillus cereus* was .5 – 1.75 log (3.16 – 56 times) less resistant than *bacillus subtilis* to hydrogen peroxide. *Id.* at ¶ 60.

The data disclosed by ZFL substantiates the Hilgren results demonstrating that hydrogen peroxide is about three orders of magnitude more effective on *bacillus cereus* than *bacillus subtilis*. Ex. 2025 at ¶ 61. Dr. Sharon explains that ZFL claims to have obtained a reduction of 5D for *bacillus subtilis* and a reduction of 8D for *bacillus cereus*. *Id.* To support this, Dr. Sharon infers that "the same treatment to test *bacillus subtilis* and *bacillus cereus* was used to achieve results that were about three orders of

magnitude different." *Id.* Based on the foregoing, Dr. Sharon "interpret[s] ZFL as suggesting that their machine which utilizes hydrogen peroxide, is about three orders of magnitude more effective on *bacillus cereus* than *bacillus subtilis*." *Id.* Indeed, the Hilgren study, coupled with ZFL's own results suggest that the log reduction obtained by the hydrogen peroxide alone relative to *bacillus subtilis* could be as low as 3.35. *Id.* at ¶ 63.

In sum, Petitioner has failed to establish that the Bosch system achieved a 6 log reduction of any spore organism, much less the relevant organism, *bacillus subtilis*. Rather, GEA was right to conclude that "vapor H_2O_2 cannot reach 5 log reduction on peroxide-resistant microorganisms." Ex. 2021 at 6.

C. THE OBJECTIVE EVIDENCE SHOWS THAT ARTISANS OF ORDINARY SKILL WERE NOT ABLE TO IMPROVE UPON THE RESULTS CLAIMED IN THE BOSCH PROMOTIONAL LITERATURE

Section 103 generally "requires that a skilled artisan have reasonably expected success in achieving [a desired] goal." *Institut Pasteur v. Focarino*, 738 F.3d 1337, 1346 (Fed. Cir. Dec. 30, 2013). Indeed, "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." *Ex parte Howell*, 2014 WL 4060134, *4 (PTAB July 31, 2014). Further, simply identifying a motivation to combine elements allegedly disclosed by the prior art is not enough. Instead, "a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device,

or carry out the claimed process; (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success." *Par Pharm., Inc. v. TWI Pharm., Inc.*, 2014 WL 6782649, at *8 (Fed. Cir. Dec. 3, 2014).

The Federal Circuit in *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009) explained that 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. *Id.* 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.*

Petitioner's entire obviousness case rests upon an alleged motivation in the prior art to achieve increased sterility levels (6 log reduction) and throughputs (greater than 100 bottles per minute). Petitioner's brief is completely silent on how a person of ordinary skill in the art would reasonably expect to achieve such increased throughput and sterility. Indeed, the motivation identified by Petitioner is nothing more than an invitation to experiment in a complex and unpredictable art, which is insufficient to support a finding of obviousness. Identifying a motivation is a step toward an obviousness conclusion, but if all that was required to make a claim

obvious were an alleged motivation to improve a known system, then it is hard to think of a case where a patent would not be found to be obvious.

Petitioner's argument that any artisan of ordinary skill could readily design a system which met FDA standards is belied by the evidence that so many companies failed in the attempt. More than a decade after the Bosch promotional articles and brochures were published a European equipment manufacturer failed in its attempt to attain FDA validation of an aseptic sterilization and filling apparatus, even with the help of a former-FDA official working as a consultant. Ex. 2020 at pp. 11-14; Ex. 2025 at ¶ 28. GEA Procomac similarly abandoned a multi-year effort to develop a peroxide-based aseptic sterilization and filling machine (like the Bosch systems) and switched to a different sterilant and system design. Ex. 2021 at pp. 5, 6, and 11; Ex. 2025 at ¶ 29. Hamba Filltec GmbH & Co., a well-established manufacturer of aseptic cup filling equipment, was unable to deliver an aseptic bottling machine which could meet FDA standards. Ex. 2022 at ¶¶ 20-25; Ex. 2025 at ¶¶ 28, 57. As recently as 2009, another European aseptic equipment manufacturer abandoned a five-year long effort to install a functioning an aseptic sterilization and filling machine. Ex. 2019 at ¶¶ 11; 41; Ex. 2025 at ¶ 28.

1. A Person of Ordinary Skill in the Art Would Not Reasonably Expect to Increase the Microbial Reduction of a Given Population of Spore Organisms Using Multiple Sequential Sterilizers

Petitioner proposes the use of sequential sterilizers to sterilize the bottles twice in order to achieve a 6 log reduction in spore organisms. However, Petitioner fails to address the impact a tailing effect would have on the multiple sequential sterilizers. The tailing effect suggests that using multiple sequential sterilizers will not necessarily result in any additive sterilization effect. Ex. 2025 at ¶ 51-53; Ex. 2023; Ex. 2038 at 12. This is consistent with the fact that GEA itself and several other companies tried and failed to develop peroxide-based aseptic bottling machines that achieved the FDA-required 6 log reduction of *bacillus subtilis*.

Petitioner and its expert assume that the addition of a sterilizer will have a linear effect by doubling the degree of sterilization that has taken place. Ex. 2024 at 245, l. 20 – 246, l. 10. That is incorrect. Ex. 2025 at ¶ 51.

Rather, a person of ordinary skill in the art would understand that each sterilizer has a set capability with respect to the sterilization levels it can achieve. Ex. 2025 at ¶ 51. If the first sterilizer is only capable of achieving a 3-4 log reduction of the relevant organism (as in ZFL), then the second sterilizer is only capable of achieving the same log reduction if it is truly duplicative of the first sterilizer. *Id.* This does not mean, however, that one can assume that the two sterilizers in sequence achieve any significant additive results. *Id.*

The literature reveals a tailing effect that demonstrates that assumptions cannot be made about the ability of an additional sequential sterilizer to achieve further log reductions. Ex. 2037 at 1;Ex. 2038 at 11-12; Ex. 2025 at ¶ 52. In particular, a paper by Cerf explains that in a given colony of microorganisms, there may be certain organisms that are more resistant to a given treatment than others. Ex. 2039 at 3; Ex. 2023 at 1; Ex. 2025 at ¶ 52. This creates a tailing effect such that after a given treatment time, the treatment is ineffective on the more resistant microorganisms. Ex. 2039 at 11-12, Fig. 3; Ex. 2025 at ¶ 53. A further paper by Cerf suggests that such a tailing effect could be infinite. *Id; id.* In other words, Cerf suggests that adding sterilizers in sequence may not provide any additional sterilization.

Based on the tailing effect, a person of ordinary skill in the art would not simply assume that adding sterilizers in sequence would increase the sterilization effect of ZFL from 3-4 log in *bacillus subtilis* to a 6 log reduction *bacillus subtilis*. Ex. 2025 at ¶ 51. While a sequential sterilization treatment might have some increased sporicidal effect, there is no reason to believe that such an effect would result in an increase of sterilization efficacy by two to three orders of magnitude (as would be required to enable the Bosch systems, which only achieved a 3-4 log reduction in *b. subtilis*, to meet claim 19's recitation of a 6 log reduction). *Id.*

Based on the explanation in Cerf, a mechanical engineer involved in machine design would realize that any prediction as to the capacity of sequential sterilizer

treatments to achieve an additional log reduction would require concrete testing and data. None of the prior art offers any such data.

Petitioner simply assumes that no tailing effect would not be present when using two sequential sterilizers from the Bosch references. However, Petitioner's expert acknowledges that there is no evidence to support that assumption:

> Q. So you accept it as true that Bacillus cereus, the survivor curve of Bacillus cereus with respect to hydrogen peroxide was log-linear?
> A. I've interpreted those results in that way, yes.
> Q. Did you do anything to independently ascertain whether they were – that's true?
> A. I would have no way of doing that.

Ex. 2024 at 266, l. 23 – 267, l. 10.

The prior art strongly suggests that Petitioner's assumption is incorrect. Cerf found a tailing effect after a 4 log reduction of *bacillus subtilis* when hydrogen peroxide was used as the sterilant. Ex. 2039 at 11; Ex. 2038 at 13; Ex. 2025 at ¶ 53. This would explain why GEA found in 2006 that "vapor H_2O_2 cannot reach 5 log reduction on peroxide-resistant microorganisms" and why Dr. Buchner found that in laboratory experiments hydrogen peroxide "did not achieve a 6 log reduction in spore organisms (bac. Subtillus var. globigii)." Ex. 2021 at 6; Ex. 1017 at ¶¶ 5, 24-25; Ex. 2025 at ¶69. It would also explain why manufacturers tried and failed in their

attempts to achieve the 6 log reduction required by the FDA. *See* discussion *supra* at 16-20.

Another paper by Cerf explains that after a 5 log reduction in *bacillus cereus*, the "number of survivors stabilizes." Ex. 2038 at 13; Ex. 2025 at ¶ 55. In other words, the literature establishes that the efficacy of hydrogen peroxide against *bacillus cereus* was prone to a tailing effect after a 5 log reduction – an almost identical number to that disclosed in ZFL. This demonstrates the danger in Dr. Heldman's assumptions. The very microbe Dr. Heldman argued could be reduced through the use of sequential sterilizers is prone to a tailing effect after a 5 log reduction.

In sum, there is simply no evidence that adding additional sterilizers would provide any additional reduction of spore organisms. To the contrary, the evidence strongly suggests that adding additional sterilizers would not enable hydrogen peroxide to achieve over a 5 log kill of spore organisms.

2. A PERSON OF ORDINARY SKILL IN THE ART WOULD NOT REASONABLY EXPECT TO BE SUCCESSFUL IN INCREASING THE THROUGHPUT OF THE BOSCH SYSTEMS BY ADDING LANES

At the outset, the objective evidence suggests that that Bosch wasn't able to achieve speeds in excess of 100 bottles per minute by adding lanes. Biewendt, published about 6 years after the Bosch Brochure makes no mention of a line speed of over 100 bottles per minute, much less the 200 bottle per minute speed projected in Bosch's 1990 promotional literature. Ex. 2025 at ¶44. Moreover, the public record only indicates that Bosch had a single customer for its bottling equipment in the

United States. Petitioner fails to cite a single reference that establishes that the Bosch bottling technology actually achieved bottling speeds greater than 100 bottles per minute. This all suggests that Bosch failed in its attempt to achieve that which was projected in its 1990 promotional materials. *See, e.g., In re Magat*, 240 F.2d 351, 353 (CCPA 1957) (modification of prior art process not obvious where alleged teaching to modify was available to a skilled artisan but not used); *In re Wiggins*, 397 F.2d 356, 362 (CCPA 1968) (same).

A close examination of the science underlying the aseptic process confirms that adding lanes to a system would be just as likely to reduce throughput by creating discontinuities in process conditions across the width of the line, which in turn causes excess or inadequate sterilization application or insufficient rinsing or removal of the sterilant. Expanding lanes will have various effects on fluid handling within the aseptic system. Ex. 2025 at ¶ 43-44; Ex. 2031 at 13. For example, when lanes are added, additional sterilant conduits and nozzles will need to be added to the sterilant delivery system, which commonly relies on a distribution manifold. *Id.* The addition of additional conduits to the manifold will result in a pressure drop that will result in less fluid going to the conduits dispensing sterilant to the lanes furthest away from the sterilant holding tank. Ex. 2025 at ¶ 45; Ex. 2031 at 13. Indeed, Dr. Buchner explained that this was a challenge in designing the original Bosch system. Ex. 1017 at ¶ 22.

Beyond impacting the sterilant distribution system, expanding the tunnel will have an effect on airflow throughout the tunnel. Ex. 2025 at ¶¶ 43-44. The airflows throughout the sterile tunnel are particularly important to understand and often behave in an unpredictable manner. Consequently, modification of the tunnel will require study of the impact the new airflow patterns will have on the system.

These two issues could be interpreted as being separate and distinct; however, the distribution of sterilant will be impacted both by the pressure drop resulting from the inclusion of additional manifolds as well as by the new airflow patterns in the tunnel. Dr. Sharon explains that even if you are able to figure out one issue or the other in isolation, such a solution does not mean that a person of ordinary skill in the art could reasonably expect to be successful in integrating the solution achieved in a vacuum into a LAASF system where most variables have an effect on each other. Dr. Sharon explains:

> For example, the temperature of the hot sterile air and the drying time are highly dependent on each other. While in isolation it may require say 10 experiments to identify the best temperature for a given drying time, and say 10 experiments to identify the most effective drying time at a given temperature, it will take 100 experiments to identify the best combination of temperature and drying time. Of course, there are more than two parameters involved in designing an aseptic sterilization and filling apparatus, such as sterilant concentration, temperature, flow rates, pressure, etc. From the scant disclosure in the art that does not provide a roadmap, a mechanical engineer involved in machine design could very

quickly be faced with an exponential number of experiments in order to converge on a successful design.

Ex. 2025 at ¶ 47.

Dr. Sharon also explains that in a system with parallel processing lanes, each lane has its own failure or success rate. Ex. 2025 at ¶ 44; Ex. 2031 at 13. Accordingly, maintaining yield across a number of lanes is not a trivial matter. Ex. 2025 at ¶ 44.

In sum, the notion that adding lanes could increase throughput appears to be an early theory of Dr. Buchner which was never realized. The actual experiences (and failures) in the industry show that a person of ordinary skill in the art would not have any reasonable expectation of success in adding lanes to increase throughput of the Bosch fillers disclosed in Exhibits 1006-1008.

3. A PERSON OF ORDINARY SKILL IN THE ART WOULD NOT REASONABLY EXPECT TO INCREASE THE THROUGHPUT OF THE BOSCH FILLERS DISCLOSED IN EXHIBITS 1006-1008 BY USING SMALLER BOTTLES

Here again the Bosch references need to be read carefully. They never state that the sterilization speed would increase when smaller bottles were used. Rather, they merely indicate that bottle size can affect overall line speed, which makes sense given that larger bottles take longer to fill given that it is important to avoid splashing during the fill operation, for example. The Bucher reference explains that the bottling speed went down from 70 to 50 BPM when larger bottles were used, which is consistent with slowing the line down to accommodate a longer fill time. Ex. 2025 at ¶ 70.

There is no evidence that Bosch was able to increase its sterilization speed by reducing the bottle size. Indeed, that premise is not supported by the underlying science. Contrary to Petitioner's argument, a smaller bottle will not allow for increased sterilant removal time. Dr. Buie explains that a smaller bottle will not heat up any faster than the larger bottle in the Bosch systems. Ex. 2026 at ¶¶ 41-42. Because the sterilant is removed largely through an evaporation effect facilitated by heat, the smaller bottle will not allow a skilled artisan to remove the sterilant any more quickly than in a larger bottle. *Id.* Dr. Sharon further explains:

> While filling throughput is directly related to the volume of the bottle, sterilization throughput is only minutely related to the volume of the bottle. Sterilization throughput is directly related to the time it takes the sterilant to kill the pathogens and the time it takes to remove the sterilant such that less than 0.5 parts per million remains, as required by the FDA. This is largely independent of the bottle volume within the practical range of bottle sizes used in food packaging. Thus, a mechanical engineer would understand that simply decreasing the size of the bottle would not increase the overall throughput in a linear system, such as that described in ZFL. In order to increase throughput, the sterilization throughput, which is the bottleneck, must be increased, but ZFL does not provide sufficient process information for a mechanical engineer to even begin designing the sterilizer of ZFL, let alone increase its throughput.

Ex. 2025 at ¶ 70. In a properly designed system, the sterilization and drying process occurs evenly over the surface of the bottle; the size of the surface is simply not determinative to the sterilization speed.

Consistent with this, bottle size is nowhere mentioned in any reference as having an effect on sterilization speed. Indeed, the Bosch references do not mention any suggestion of increasing conveyor belt speed to increase throughput as would be necessary. This makes sense given that bottle sterilization is carefully controlled requiring precise timing. Moreover, Elliot discusses various design parameters but does not mention container size. David and Chambers also mention throughput and make no suggestion that bottle size is a factor.

In contrast to the reasoned opinions of Professors Sharon and Buie, Dr. Heldman again makes conclusory assumptions as to the effect of using smaller bottles. Most notably, Dr. Heldman assumes that one could double the throughput of the Bosch fillers disclosed in Exhibits 1006-1008 simply by using a bottle that is half the size. Ex. 2024 at 290 l. 20 – 291, l. 17. Such an assumption makes little sense in a complicated art. In fact, the data in the Buchner reference suggests that the alleged relationship between bottle size and throughput would be far from linear as the overall line speed only increased from 50 to 70 BPM when the size of the bottle is reduced by a factor of 5. Ex. 2025 at ¶ 70 ("This is also supported by Buchner (Exhibit 1006) as he states that for wide-necked containers (which are easier to sterilize), their plant output ranged between 3,000 bottles per hour for 500 mL

containers, to 4200 for 90 mL containers."); Ex. 1006 at 25. Dr. Heldman's assumption is unsupported and simply incorrect.

4. THE STERILIZATION PROCESS OF BUCHNER CANNOT BE COMBINED WITH THAT OF ZFL, BOSCH, AND BIEWENDT

Petitioner's argument is that the sterilization method of Buchner, which according to Petitioner is the most detailed discussion among the four Bosch references, can be readily incorporated into Biewendt to achieve the same results. However, Petitioner and its expert Dr. Heldman incorrectly assume that the sterilization processes in the Bosch references are the same. They are not.

The ZFL and Biewendt machines describe peroxide treatment followed by sterile air rinsing. Ex. 1005 at ¶ 30. However, the Buchner process includes six stations which are used in connection with the application of a sterile water rinse. Ex. 2024 at 96, l. 1 – p. 97, l. 1.

During cross examination it became clear that Dr. Heldman did not even know that a sterile water rinse was employed by Buchner or when the sterile water was applied in the Buchner process, claiming first that it was used to prepare the bottles, and later stating that the sterile water was used to rinse residual peroxide. Ex. 2024 at 96, l. 1 – 113, l. 8. Dr. Heldman admitted that the sterile water rinse was important to achieving the described microbial reduction. . Ex. 2024 at p. 98, ll. 2-5. He further conceded that the sterile water rinse was used as a redundant and functional

equivalent to the sterile air rinse used to remove the peroxide from the bottles. Ex. 2024 at p. 100 ll. 9-16; 112, l. 24 – 113, l. 8.

Given that the sterile water rinse is necessary to achieve both the microbial reduction (5 log) and the residual peroxide levels (0.5ppm) disclosed by Buchner, it is not reasonable to simply assume that any skilled artisan could achieve the sterilization levels described in the Buchner reference by using the sterilization processes described in ZFL, Bosch, or Biewendt (which describe only an air rinse). Indeed, Procomac in 2006 explained that a sterile water rinse provides the clearest path to reaching the FDA requirement of less than 0.5ppm on the bottle. Ex. 2021 at 11. Here it is important to remember that neither ZFL, Bosch, nor Biewendt claim to achieve even a 5 log reduction in relevant spore organisms, which was acceptable in Europe but not the United States.

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

The conjecture infused into Petitioner's obviousness argument is further exemplified by Dr. Heldman's bald assertion that a mere graduate student would be able to fully design an FDA-compliant hydrogen-peroxide based aseptic bottling machine with reference to only the Buchner, ZFL, Bosch and Biewendt articles. The

credibility of that assertion is laid bare by the fact that Hamba, GEA, and other companies failed in their multi-year attempts to achieve this same objective. Dr. Sharon explains that Dr. Heldman's opinion concerning his graduate students "was especially striking" and "speaks to Dr. Heldman's lack of understanding of machine design, let alone design of complex aseptic packaging machinery." Ex. 2025 at ¶ 15; Exhibit 2024 at 221, l. 19 – 222, l. 9. This makes sense as Dr. Heldman admitted that he had **zero** experience in designing complex industrial machines, such as an aseptic packaging and sterilization system. Ex. 2024 at 238, ll. 9-15. Indeed, various authors have observed that, in the real world, developments in the field of aseptic processing are the results of years of trial and error. Ex. 2018 at 1; Ex. 2025 at ¶¶ 15, 21.

VIII. CONCLUSION

The petition should be deemed untimely because a privy of Petitioner was served with a complaint alleging infringement of the '013 patent more than a year before the filing of the petition. Moreover, Petitioner has failed to carry its burden of proving that the claims are unpatentable.

Date: March 9, 2015

/Greg Gardella/
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies service of Patent Owner's Response on the counsel of record for the Petitioner by filing this document through the Patent Review Processing System as well as delivering a copy via electronic mail to the following address:

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