2017-1193

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

NESTLÉ USA, INC.,
Appellant,

v.

STEUBEN FOODS, INC.,
Appellee.

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2015-00249

REPLY BRIEF OF APPELLANT NESTLÉ USA, INC.

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CERTIFICATE OF INTEREST

Counsel for Appellant Nestlé USA, Inc. certifies the following:

1. The full name of every party or amicus represented by me is:

Nestlé USA, Inc.

2. The name of the real party in interest represented by me is:

Nestlé HealthCare Nutrition, Inc.
Nestec S.A.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

Nestlé S.A.
NIMCO US, Inc.
Nestlé Holdings, Inc.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

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STATEMENT OF RELATED CASES

There have been no other appeals in this matter. Several related cases are pending before U.S. district courts and this Court, as indicated in the Opening Brief of Appellant, Nestlé USA, Inc. ("NUSA"). Since the Opening Brief was filed, the posture of one related case—IPR2014-01235—has been changed.

IPR2014-01235 is an *inter partes* review (IPR) proceeding concerning U.S. Patent No. 6,945,013 ("the '013 patent"), which claims priority to the same U.S. Provisional Application as U.S. Patent No. 6,481,468 ("the '468 patent"), the subject of IPR proceeding currently on appeal. The Final Written Decision from IPR2014-01235 was appealed to this Court in appeal no. 16-1750, which appeal resulted in a May 9, 2017, order vacating and remanding for further proceedings. On June 8, 2017, Appellee, Steuben Foods, Inc. ("Steuben"), petitioned this Court for panel rehearing and rehearing *en banc*. A decision has not yet been issued on Steuben's petition.

ARGUMENT IN REPLY

This Court has already answered the key questions in this case in a related matter. Those answers require deciding this appeal in NUSA's favor.

Specifically, in Appeal No. 2016-1750, this Court considered the Patent Trial and Appeal Board's determination regarding the patentability of a related Steuben patent. The Board's decision hinged on its construction of the claim term "aseptic" as requiring compliance with "any applicable United States FDA standard," including the FDA's regulations governing hydrogen peroxide residue in packaged foods. On appeal, this Court rejected the Board's construction and vacated. *See Nestlé USA, Inc. v. Steuben Foods, Inc.*, Slip Op., No. 2016-1750 (Fed. Cir. May 9, 2017) ("the '1750 decision"). As the Court explained:

> [T]he Board construed the phrase to incorporate "any applicable United States FDA standard." [This] interpretation[] ha[s] the effect, according to [the Board] of requiring anything "aseptically" packaged to satisfy the regulatory requirement of 21 C.F.R. § 178.1005(d) that the final product have a hydrogen peroxide residue of less than 0.5 ppm.
>
> **We disagree**.

Id. at 4 (emphasis added). The Court observed that, "[w]here the patentee wished to claim embodiments requiring less than 0.5 ppm of hydrogen peroxide residue, it did so using express language." *Id.* "Moreover," the Court reasoned, "the FDA's hydrogen peroxide residue standard applies to *all* foodstuffs, regardless of whether they are aseptically packaged. Accordingly, the scope of 'aseptic' cannot include

regulations that apply to foods that are not aseptically packaged." *Id.* "Instead," the Court held, "we confine an 'FDA level of aseptic' to FDA regulations *related to aseptic packaging*." *Id.* (emphasis added).

In this case, the Board applied the same construction for the same claim terms—"aseptic" and "aseptically disinfecting"—that the Court rejected in the prior appeal. The patent in the prior appeal and the patent in this case include identical disclosures regarding the meaning of "aseptic." Moreover, the Board in this case expressly adopted the reasoning it applied in making its prior—now vacated—decision. Thus, this Court's '1750 decision addressed the very same claim construction issue raised in the present case, and, for the same reasons, the Board's claim construction must be vacated.

Steuben's brief acknowledges the '1750 decision, but contorts it to argue that the decision supports affirming the instant case. Red Br. 19 n.1. To get there, Steuben ignores the '1750 decision's holding—that the proper construction of "aseptic" does *not* include the FDA's 0.5 ppm hydrogen peroxide residual requirements. '1750 decision at 4. Nothing in Steuben's brief supports a different construction here. This error also poisoned the Board's patentability determination, which erroneously included the FDA's 0.5 ppm residual requirement as an implicit claim limitation. Thus, under a proper construction, the Board's patentability decision cannot stand.

I. The Court should vacate the Board's construction of "aseptic" for the same reasons that it did in IPR2014-01235

In its decision below, the Board expressly adopted its construction of "aseptic" from IPR2014-01235, holding that:

> [T]he broadest reasonable construction of "aseptic" as would be understood by one of skill in the art in the context of the '468 patent is: aseptic to any applicable United States FDA standard in the context of the claimed subject matter, and in the absence of any such standard, aseptic assumes its ordinary meaning of "free or freed from pathogenic microorganisms." Moreover, we conclude that "aseptically disinfecting" means "disinfecting the plurality of bottles in compliance with any applicable FDA regulation."

Appx0033 [FWD 33]; *compare with* IPR2014-01235, Paper 63 at 14 (appearing in No. 2016-1750 at Dkt. No. 43 [Joint Appendix] at Appx00014). The Board repeated the rationale from IPR2014-01235, explaining that the rationale applied to '468 patent claim 9 because it recites "aseptically disinfecting" bottles. Appx0032-0033 [FWD 32-33]. Under that rationale, the Board held that as to claim 9, "when hydrogen peroxide is used to sterilize food packaging material (e.g., bottles), the FDA limitation on residual hydrogen peroxide is applicable." *Id.* at 33.

Importing the FDA's hydrogen peroxide residue requirement into claim 9 was erroneous for the same reasons that it was erroneous in IPR2014-01235. And because the Board in this case simply adopted its prior rationale (Appx0032-0033, Appx0056 [FWD 32-33, 56]), there is nothing in the Board's decision that justifies

a different construction here. Moreover, the intrinsic evidence of the '468 patent defining "aseptic" is identical to the intrinsic evidence of the '013 patent at issue in IPR2014-01235. *Compare* Appx0097 ['468 patent, 2:13-34] *and* Appx0099 [5:41-57] *with* Appeal No. 2016-1750, Dkt. No. 43 [Joint Appendix] at Appx00050 ['013 patent, 1:57-2:2] *and* Appx00051 [4:24-40].[1] Indeed, the two patents share a priority claim to the same provisional patent application. Thus, the evidence does not support a different claim construction of the same term that was at issue in IPR2014-01235.

A. The '468 patent defines "aseptic" in terms of the FDA standards specific to "aseptic" processing—not in terms of FDA standards of general applicability

Consistent with the written description of the '468 patent, FDA standards generally applicable to food packaging are not incorporated into the patent's definition of "aseptic," which the patent confines to the FDA's aseptic standards. As this Court noted in the '1750 decision, "[t]his approach is supported by the specification's explanation that the prior art systems failed to 'provi[de] a high output aseptic filler that complies with the stringent United States FDA standards

[1] Although the '013 patent is not part of the record in this IPR, it is a public document properly subject to judicial notice—to the extent necessary—given its relationship to the '468 patent in this case. *See Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 954 and n.27 (Fed. Cir. 1993) (taking judicial notice of a party's patent that was not included in the record on appeal) (citing *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 514 n. 3 (Fed.Cir.1990), in support of taking judicial notice of PTO correspondence which is part of the public record).

for labeling a packaged product as 'aseptic.'" '1750 Decision at 4 (emphasis added).

The Court properly identified two FDA regulations that are specific to aseptic processing and, thus, limit Steuben's "aseptic" claims. *Id.* at 4-5. First, the FDA defines "aseptic processing and packaging" as "the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms." *Id.* at 4 (quoting 21 C.F.R. § 113.3(a) (1999)). Second, the FDA defines "commercial sterility" as "free of viable microorganisms having public health significance, as well as microorganisms of nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution." *Id.* (quoting 21 C.F.R. § 113.3(e) (1999)). As the Court noted, "[t]hese regulations are consistent with the specification, which itself describes certain microorganism reduction features of the invention immediately after defining the term 'aseptic.'" *Id.* at 4-5 (citing '013 patent, 4:29-33). Identical language appears in the '468 patent. Appx0099 ['468 patent, 5:46-51].

In addition, the '468 patent identifies certain FDA standards—beyond commercial sterilization of packaging and food—that determine whether a process qualifies as "aseptic" (and not simply whether a process meets general FDA food requirements). According to the '468 patent, "[f]or the aseptic packaging of food

products, an aseptic filler must, for example, use an FDA (Food and Drug Administration) approved sterilant" and "use a sterile tunnel or clean room." Appx0097 ['468 patent, 2:13-21]. As the '468 patent suggests, not all packaged foods must meet such requirements—only packaged foods that are to qualify as "aseptic." The '1750 decision properly recognized that key distinction, while the Board's decision did not.

B. The FDA's hydrogen peroxide residual regulation (21 C.F.R. § 178.1005(d)) applies generally to *all* packaged foods—it is not specifically an "aseptic" standard

The parties have never disputed that "aseptic" packaged foods must meet the FDA's hydrogen peroxide residual regulation. Prior to this appeal, Steuben also never disputed that other packaged foods (e.g., extended shelf life ("ESL") foods) *also* are subject to that regulation. Accordingly, NUSA was surprised to see the argument in Steuben's red brief that "Nestlé incorrectly asserts that 'the FDA's hydrogen peroxide regulations apply to all food processing,'" as well as Steuben's suggestion that non-aseptic processes are exempt from the regulation (Red Br. 32-34).

Steuben's argument that 21 C.F.R. § 178.1005(d) applies *only* to "aseptic" processes is entirely new. This argument is Steuben's transparent attempt to shoehorn the FDA's residual regulation into this Court's construction of "aseptic," which excludes "regulations that apply to foods that are not aseptically packaged."

'1750 decision at 4. Thus, while Steuben complains that "the record was never developed" regarding the scope of 21 C.F.R. § 178.1005(d) (Red Br. 36), any such deficiency arose only because *Steuben* never presented its deviant interpretation of the regulation below.

In any event, the record amply demonstrates that the FDA's residual regulation is not limited to "aseptic" processes. In the intrinsic record of the '468 patent and Steuben's related patents, Steuben treated sterilant residue levels differently from the FDA's aseptic standards. The distinction flows logically from the language and administrative history of § 178.1005(d), which plainly applies beyond "aseptic" uses of hydrogen peroxide. Steuben wrongly argues that NUSA's *Markman* briefing in the related infringement litigation conceded the regulation's limited application to "aseptic" processes. Red Br. 36-37. NUSA's *Markman* briefing and its arguments here are entirely consistent. Indeed, NUSA's *Markman* submissions reveal that not even the *inventor* of the '468 patent agrees with Steuben's new position. For those reasons, under a proper construction of "aseptic," the FDA's residual regulation does not limit claim 9.

1. The '468 patent and related '013 patent treat the FDA's "aseptic" standards differently from the hydrogen peroxide residual regulation

Tellingly, the '468 patent never describes the 0.5 ppm residual regulation as an "aseptic" standard. In fact, the '468 patent never identifies the 0.5 ppm residual

as a standard *at all* (let alone an FDA "aseptic" standard). Five times, the '468 patent refers to "0.5 ppm" residuals, either on bottle surfaces or lids. *See* Appx0099, Appx0100, Appx0103, Appx0106-0107 [6:4-8, 8:40-42, 14:15-17, 20:66-21:2, 21:36-38]. Never does the '468 patent state that those residual levels are an "aseptic" requirement of the FDA. In contrast, the '468 patent describes various FDA standards that an aseptic filler "must" meet, e.g., "use an FDA[-]approved sterilant" and "use a sterile tunnel or clean room." If the residual requirement were indeed the *sine qua non* of FDA "aseptic" processing, as Steuben now urges, then the '468 patent would have said so. It did not.

In fact, Steuben's patents acknowledge the differences between the FDA's "aseptic" standards and residual hydrogen peroxide regulation by reciting them separately in the claims. Just like claim 9 of the '468 patent here, the '013 patent claims at issue in the '1750 appeal recited "aseptically disinfecting" bottles. *See*, *e.g.*, Appeal No. 2016-1750, Dkt. No. 43 [Joint Appendix] at Appx00057 ['013 patent, 16:33-62 (claims 18-20)]. One of those claims ('013 patent claim 20) adds that "a residual level of hydrogen peroxide is less than 0.5 PPM." *Id.* Applying the well-established principle of claim differentiation, this Court observed that "[w]here [Steuben] wished to claim embodiments requiring less than 0.5 ppm of hydrogen peroxide residue, it did so using express claim language." '1750 decision at 4; *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-15 (Fed. Cir. 2005), *cert.*

denied, 546 U.S. 1170 (2006) (en banc) ("Differences among claims can also be a useful guide in understanding the meaning of particular claim terms."). Claims 18 and 19 of the '013 patent—which do *not* recite "0.5 PPM"—are not so limited. '1750 decision at 4. Nor is claim 9 here.

The Court's claim differentiation analysis in the '1750 decision applies equally to claim 9 of the '468 patent in this appeal, because "unless otherwise compelled . . . the same claim term in the same patent or related patents carries the same construed meaning." *See In re Rambus Inc.*, 694 F.3d 42, 48 (Fed. Cir. 2012) (*quoting Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003)). In *Rambus*, the Court consulted two different patents related to the patent under review. *Id.* The Court concluded that claim differentiation in the related patents established a claim meaning applicable to the patent under review, and construed the claims accordingly. *Id.*

In this case, claim differentiation in the '013 patent confirms that "aseptic" does *not* include the FDA's hydrogen peroxide residual regulation. Had Steuben wished to limit claim 9 to compliance with the residual regulation, it could have done so by specifically reciting the "0.5 ppm residual" requirement. It did just that in claim 20 of the '013 patent. Claim 9 of the '468 patent, however, includes no such limitation.

2. The hydrogen peroxide residual regulation applies broadly to *all* uses of hydrogen peroxide to sterilize food packaging

Contradicting the intrinsic record of the ’468 patent and related ’013 patent, Steuben now declares that the FDA’s hydrogen peroxide regulation (21 C.F.R. § 178.1005) “*governs* aseptic packaging.” Red Br. 6 (emphasis added). This regulation, however, actually proves NUSA’s point and demonstrates the error in the Board’s decision. On its face, this regulation is an FDA regulation of general applicability—a fact confirmed by the administrative history. In other words, the hydrogen peroxide residual regulation is not limited to only “aseptic” processes.

When the application for the ’468 patent was filed, the FDA regulated all uses of “hydrogen peroxide solution” to sterilize food packaging as an “indirect food additive.” *See* 21 C.F.R. Part 178 (1998) (titled “Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers”). Specifically, the regulation stated that “[h]ydrogen peroxide solution identified in this section may be safely used to sterilize polymeric food-contact surfaces identified in [the regulation].” 21 C.F.R. § 178.1005 (1998). The regulation defined the compositions that would qualify as “hydrogen peroxide” for purposes of package sterilization, and it prohibited residues in excess of 0.5 ppm in filled containers. § 178.1005(a)-(d) (1998). None of the foregoing subsections limit their applicability to “aseptic” container sterilization.

Steuben's argument hinges on subsection (e) of the hydrogen peroxide regulation, which states that hydrogen peroxide "may be used" to treat packaging "to attain *commercial sterility* at least equivalent to that attainable by thermal processing for metal containers as provided for in part 113 [i.e., the 'aseptic' regulation] of this chapter," but only if the general requirements to use hydrogen peroxide are met. § 178.1005(e) (emphasis added). Citing this subsection, Steuben argues that "[u]nder the FDA's regulatory scheme, the only instance in which a chemical sterilant is used to achieve commercial sterility of a container is in the aseptic packaging process governed by 21 C.F.R. § 113." Red Br. 31.

Steuben's argument depends on linking "commercial sterility," as recited in § 178.1005(e), to the "commercial sterility" requirements of the FDA's aseptic regulation. But only § 178.1005**(e)** recites "commercial sterility" and is limited to "aseptic packaging." The rest of the hydrogen peroxide regulation—including the 0.5 ppm hydrogen peroxide residue restriction in § 178.1005(d)—is not so limited. Rather, by its own terms, the 0.5 ppm residual requirement of § 178.1005**(d)** applies to any "use of hydrogen peroxide solution in the sterilization of food packaging material." In other words, subsection (d) governs using hydrogen peroxide for package "*sterilization*," generally. Subsection (e), in contrast, governs using hydrogen peroxide specifically to achieve "*commercial sterility*," i.e., aseptic sterilization. It makes perfect sense that the FDA would regulate hydrogen

peroxide residues for both "aseptic" and non-aseptic processes. After all, the safety concerns associated with hydrogen peroxide residues in packaged food would be the same whether or not the food was packaged "aseptically." Simply because the FDA specifies that a regulation of general applicability also applies to "aseptic" package sterilization does not mean that the regulation defines "aseptic."

Despite the clear language of § 178.1005, Steuben argues that the administrative history of the regulation limits the regulation to "aseptic" food packaging applications. Red Br. 31. But the cited Federal Register entry shows that the FDA was addressing the human health concerns associated with hydrogen peroxide added to food—not the capabilities of hydrogen peroxide as an "aseptic" sterilant. 46 FR 2341-42. The FDA reviewed the literature concerning the safety of ingesting or otherwise encountering hydrogen peroxide, and concluded that, "because the use of hydrogen peroxide in sterilizing packaging material could result in the migration of residues to food, a tolerance is being imposed for hydrogen peroxide when it is used *for the packaging of food*." *Id.* (emphasis added). Thus, the FDA's rationale for imposing residual tolerances applies generally to food packaging, and (like § 178.1005) is *not* limited specifically to "aseptic" applications. Certainly the FDA's human health concerns would arise regardless of whether hydrogen peroxide is used in an "aseptic" or non-aseptic process.

Steuben further argues that because § 178.1005 was enacted in response to a petition from Brik Pak, Inc., it must be an "aseptic" regulation. Red Br. 31. Contrary to Steuben's arguments, the Federal Register gives no indication that Brik Pak is an "aseptic" packaging company or that Brik Pak was motivated to file its petition "so that it could introduce its aseptic packaging equipment into the United States." Red Br. 31. But even if Brik Pak were so motivated, the Federal Register gives no indication that the FDA constrained § 178.1005 solely to "aseptic" uses of hydrogen peroxide. *See* 46 FR 2341-42. Indeed, the Federal Register mentions "aseptic" only once, in noting that, "aseptic packaging" is but *one* of the contemplated uses of hydrogen peroxide in food processing. *Id.* ("Hydrogen peroxide has been used outside of the United States in food and on food-packaging materials for the purpose of controlling the growth of microorganisms. In addition to prolonging the shelf-life of dairy products [i.e., ESL packaging[2]], hydrogen peroxide has been used successfully in the aseptic packaging of shelf-stable food such as milk, fruit juice, soft drinks, and other products."). The Federal Register's specific reference to "prolonging the shelf-life of dairy products" (i.e., ESL) in addition to "aseptic packaging" confirms that § 178.1005 is a regulation of *general* applicability—*not* an "aseptic" standard.

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[2] *See* Appx0097 ['468 patent, 1:64-2:12 (discussing "extended shelf life" packaging relative to "aseptic" packaging)].

Steuben also argues that the regulation must be limited to "aseptic packaging" because other regulations exist that apply to non-aseptic or non-food-packaging processes. Red Br. 33-34. That argument is a non sequitur. And Steuben cites no regulations that would override or supersede the FDA's general prohibition in § 178.1005(d) against excessive hydrogen peroxide residue in packaged foods. Steuben cites 21 C.F.R. § 178.1010 as applicable to "sanitizing solutions" and states without citation that "[a]ll other types of packages," i.e., non-aseptic packages, "can be 'sanitized' because they will still require constant refrigeration from the time they are produced through the point of sale." Red Br. 33. But whether or not a package is "constant[ly] refrigerated" does not change whether levels of hydrogen peroxide residue are unsafe. Moreover, unlike § 178.1005(d)—the hydrogen peroxide residue regulation—the "sanitizing solution" regulation does not address the use of hydrogen peroxide to disinfect "food packaging." Indeed, the "sanitizing solution" regulation does not address "hydrogen peroxide" *at all*, except in combination with other chemicals. 21 C.F.R. § 178.1010(b)(30), (38), (45) (1998). Thus, there is no reason to credit Steuben's contention that § 178.1010 somehow renders § 178.1005 applicable only to "aseptic packaging."

Steuben's citations to §§ 184.1366(d) and 173.315 are even more strained. Neither regulation concerns the disinfection of food packaging.

Section 184.1366(d) concerns various uses of hydrogen peroxide to treat food itself—including milk (for making cheese), tripe, beef feet, herring, wine, and instant tea. The regulation requires hydrogen peroxide to be "removed by appropriate physical and chemical means during the processing of food." 21 C.F.R. § 184.1366(d) (1998). Section 173.315 permits using hydrogen peroxide with acetic acid to form *peroxyacetic acid*—a different chemical—for use in washing fruit. None of Steuben's cited regulations displace the FDA's general requirement in § 178.1005(d) that when hydrogen peroxide is used in food packaging there can be no more than 0.5 ppm residue in the packaged food product.

3. NUSA's *Markman* submissions regarding the FDA's hydrogen peroxide residual regulation are fully consistent with the proper scope of the regulation

Steuben concludes by requesting that the Court take judicial notice of NUSA's *Markman* submissions in parallel district court litigation, and by suggesting that the submissions somehow concede that 21 C.F.R. § 178.1005(d) is limited to "aseptic" processes. Red Br. 36-37 and n.2. The quoted language, however, is fully consistent with NUSA's arguments on appeal and accurately reflects the reach of the regulation.

As noted in NUSA's *Markman* brief, 21 C.F.R. § 178.1005 "defined 'hydrogen peroxide' for aseptic food packaging." *See Steuben Foods, Inc. v. Nestlé USA, Inc.*, No. 1:13-cv-892-EAW-JJM (W.D.N.Y.), ECF No. 272 at 32 (Mar. 6,

2017). That is true. Just as § 178.1005(e) extends the general residual regulation of § 178.1005(d) to "aseptic" uses of hydrogen peroxide (see Section I.B.2 above), it likewise extends the regulation's generally applicable definitions and specifications of "hydrogen peroxide" for package sterilants to "aseptic" applications. Specifically, § 178.1005**(a)** and **(c)** defined "hydrogen peroxide" for *all* uses to sterilize polymeric packaging, and subsection (e) extended those definitions to "aseptic" applications. 21 C.F.R. § 178.1005(e) ("Hydrogen peroxide solution identified in and complying with the specifications in this section may be used . . . to attain commercial sterility" as provided for in the aseptic regulation.). Contrary to Steuben's argument, the definitions of "hydrogen peroxide" in 21 C.F.R.§ 178.1005 are not limited only to "aseptic" package sterilization, and NUSA's *Markman* brief never suggests otherwise.

Steuben also ignores the rest of NUSA's *Markman* submission, which critically undermines Steuben's argument about the scope of the residual regulation. NUSA submitted with its *Markman* brief the deposition testimony of Thomas Taggart, the sole named inventor of the '468 patent, Steuben's former employee, and Steuben's current consultant in its patent dispute against NUSA. Mr. Taggart testified that the FDA's 0.5 ppm hydrogen peroxide residual requirement applies to *any food processing* that uses hydrogen peroxide as the sterilant:

> Q. So the .5 ppm [hydrogen peroxide] residual applies to ESL [extended shelf life] machines as well as aseptic; correct?
>
> A. That's correct.
>
> Q. Indeed, does it not apply, "it" being the residual requirement for hydrogen peroxide, apply to any food processing where you use hydrogen peroxide as the sterilant?
>
> A. That's correct.

Taggart Dep. Tr. 113:14-113:21 (*filed in Steuben Foods, Inc. v. Nestlé USA, Inc.*, No. 1:13-cv-892-EAW-JJM (W.D.N.Y.), ECF No. 272-15 (Mar. 6, 2017)). Mr. Taggart's deposition was defended by Thomas J. Fisher, in his role as attorney for Steuben Foods, Inc., and was attended by Cook Alciati, Steuben's in-house counsel. *Id.* at 13:10-13. Both Messrs. Fisher and Alciati represent Steuben in the current appeal. Accordingly, Steuben and its attorneys had full knowledge of Mr. Taggart's testimony when they submitted their appeal brief. Nonetheless, they ignored the testimony entirely.

Mr. Taggart's deposition was taken on August 18, 2016, well after the record was closed in this case. The transcript, however, forms part of NUSA's *Markman* briefing. Thus, if the Court takes judicial notice of NUSA's *Markman* submissions as Steuben requests (Red Br. 37 n.2), it should take notice of and specifically consider Mr. Taggart's deposition. Mr. Taggart's testimony can be readily verified from the transcript of his deposition—a source "whose accuracy

cannot reasonably be questioned" given (i) Steuben's attorneys' participation in the deposition, as well as (ii) Mr. Taggart's status as named inventor of the '468 patent, Steuben's former employee, and Steuben's current consultant in litigation asserting the '468 patent. *See* Fed. R. Evid. Rule 201(b)(2).

II. The Board's erroneous construction of "aseptic" to require compliance with the FDA's 0.5 ppm residual hydrogen peroxide requirement was not a finding of fact

In an effort to shield the Board's decision with deference on appeal, Steuben characterizes the Board's claim construction as a finding of fact. Specifically, Steuben suggests that this Court should defer to the Board's "finding" that the scope of "aseptic" encompasses the FDA's hydrogen peroxide residual regulation. But in reaching this conclusion, the Board plainly was construing the term "aseptic."

Steuben's argument is undercut by its inconsistency. At first, Steuben characterizes the Board's determination as a claim construction, contending that "the Board construed the term 'aseptically disinfecting' to mean 'disinfecting the plurality of bottles in compliance with any applicable FDA regulation.'" Red Br. 28. Immediately thereafter, Steuben explains what it asserts the Board's construction to mean—i.e., "*The Board's construction* here is referring to the applicable FDA aseptic packaging regulations, which . . . include 21 C.F.R. §§ 113 and 178.1005 [the hydrogen peroxide regulation]." *Id.* (emphasis added). Later,

Steuben argues that the Board's determination was really a "factual finding that the FDA's residual peroxide regulation applies to the term 'aseptically disinfecting.'" *Id.* at 37. Steuben then urges the Court to give deference to that "finding." *Id.* at 38.

Steuben never explains why it (sometimes) believes that the Board's legal determination of the scope of the claims qualifies as a "fact finding" entitled to deference rather than a "claim construction." Steuben's cited authority applied *de novo* review to the construction at issue. *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1297 (Fed. Cir. 2015) ("In this case, because the intrinsic record fully determines the proper construction, we review the Board's claim constructions de novo."). Here, the '468 patent purports to define "aseptic" in terms of "the United States FDA level of aseptic." Red Br. 4. The question of *which* particular FDA standards the '468 patent thereby incorporated is a matter of claim construction, answered based on the '468 patent's intrinsic record, and, thus, subject to *de novo* review. *See Microsoft*, 789 F.3d at 1297.

The Board reviewed the intrinsic record and then construed "'[a]septically disinfecting' as claimed" to mean "disinfecting the plurality of bottles in compliance with *any applicable* FDA regulation." Appx0030, Appx0033 [FWD, 30, 33] (emphases added). In the '1705 decision, this Court reviewed the intrinsic record of the related '013 patent, determined that the "any applicable FDA regulation" construction was unsupported by the specification, and limited the term

to "FDA regulations *related to aseptic packaging*." '1705 Decision at 4 (emphasis added). In that case, the Court properly reviewed the underlying decision as presenting legal questions of claim construction and scope, which are entitled to no deference. *See id.* at 3 (detailing standards of review). The Court's approach was consistent with its precedent from similar cases in which claim terms were defined based on regulatory standards.

For example, in *Liberty Ammunition, Inc. v. United States*, the Court granted no deference to the district court's construction of a claim term that the specification defined in terms of existing ammunition size standards. 835 F.3d 1388, 1395 (Fed. Cir. 2016), *cert. denied*, No. 16-1101, 2017 WL 948830 (U.S. Apr. 24, 2017). The district court erroneously construed the claim to incorporate *all* ammunition size standards for the relevant caliber rounds—i.e., "a traditional jacketed lead bullet of calibers .17 through .50 BMG." *Id.* Applying *de novo* review, this Court reversed. *Id.* at 1395-97. The Court noted that the specification invoked a *specific* ammunition size standard—i.e., the NATO 5.56 mm M855 round—and accordingly limited the claims by reference to that specific standard. *Id.* at 1396-97. As the Court explained, the "trial court's construction to the contrary is incorrect because it does not properly capture the specification's discussion of conventional projectiles." *Id.* at 1397. The Court also noted that the trial court's construction effectively incorporating *all* ammunition size standards

likely would be indefinite. *Id.* at 1397-98 (citing *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370–71 (Fed. Cir. 2014), *cert. denied*, -- U.S. --, 136 S.Ct. 59 (2015)).

The current case and the case of the '1750 decision are analogous to *Liberty*. As in *Liberty*, Steuben's patent specification defines a claim term based on a *specific* standard—i.e., "'aseptic' denotes the United States FDA level of aseptic." Appx0097 ['468 patent, 2:29-34]; '1750 decision at 3; Appeal No. 2016-1750, Dkt. No. 43 [Joint Appendix] at Appx00050 ['013 patent, 1:67-2:2]. Also as in *Liberty*, the construction under review erroneously incorporates *all* standards, contrary to the specification—i.e., the Board construed "aseptic" to require compliance with "any applicable FDA regulation," regardless of whether the regulation is an "aseptic" regulation. Appx0033 [FWD 33]; '1750 decision at 4. Furthermore, the Board's construction in this case raises indefiniteness concerns, as did the construction in *Liberty*, because holding claim 9 to compliance with "any applicable FDA standard" leaves undefined (1) *which* standards are "applicable" and (2) *how* compliance with those myriad standards can be determined. *See Nestlé USA, Inc. v. Steuben Foods, Inc.*, Oral Hr'g Tr. at 5:56-6:41, No. 2016-1750 (Fed. Cir. Apr. 4, 2017) (J. Hughes commenting that "if ['aseptic' is] any FDA standard, how is the patent even definite? Because the FDA can change standards that weren't even . . . in existence at the time."). Accordingly, this Court should apply

the same *de novo* review as it applied in *Liberty* and in the '1750 decision, and construe "aseptic" to incorporate *only* the FDA's "aseptic" standards, as the '468 patent instructs.

Steuben also attempts to frame the Board's claim construction as predicated on a question of fact—whether 21 C.F.R. § 178.1005 is "related to aseptic packaging." But it was this Court in the prior appeal—not the Board in this IPR—that construed "aseptic" in terms of the FDA's standards "related to aseptic packaging." Thus, the Board cannot have "found" that 21 C.F.R. § 178.1005 is "related to aseptic packaging." Moreover, it is nonsensical to suggest that determining the scope of 21 C.F.R. § 178.1005—a regulation having the effect of law—is a question of "fact." The hypothetical person of ordinary skill in the art does not get to decide whether 21 C.F.R. § 178.1005 applies only to "aseptic" systems, or more broadly to the use of hydrogen peroxide as a sterilant. That is a legal question for the courts to decide. And the Board's erroneous answer to that question is not entitled to deference.

III. Under the proper construction of "aseptic," the Board's determination is not supported by substantial evidence

Claim 9 depends from claim 1, which the Board determined to be unpatentable as both anticipated and obvious. Appx0001-0064 [FWD]. Steuben has not appealed the Board's determination with respect to claim 1. Accordingly, the patentability of claim 9—which depends from claim 1—hinges entirely on

whether using a known valve in combination with "aseptically disinfecting a plurality of bottles to a level producing at least about a 6 log reduction in spore organisms," as recited in claim 9, was obvious.

The Board identified no flaws in NUSA's evidence that achieving a "6 log reduction" was known and obvious, and the Board's Final Decision in no way retreated from its preliminary findings in the Institution Decision regarding that limitation. In the Institution Decision, the Board found that a 6-log reduction in spore organisms was likely obvious for two reasons. First, the Board credited NUSA's arguments and evidence that the prior-art *ZFL* reference taught to achieve 1:10,000 maximum unsterility rate in bottles containing 100 germs per bottle—which mathematically equates to a 6-log reduction. Appx2155-2156 [ID 26-27]. Second, the Board credited NUSA's arguments and evidence that "ZFL discloses adjusting sterilant to achieve disinfection requirements." Appx2156 [ID at 27].

In its Final Decision, the Board determined that NUSA failed to prove that claim 9 was unpatentable based entirely on the Board's erroneous claim construction. More specifically, the Board held that "in order to show that the method of claim 9 was rendered obvious, where Petitioner relies upon prior art that utilizes hydrogen peroxide as the sterilant, that process must be carried out in a manner that results in no greater than 0.5 ppm hydrogen peroxide residue in the packaging." Appx0055 [FWD 55]. The Board acknowledged NUSA's evidence

showing "how sterilization would be carried out, utilizing hydrogen peroxide as the sterilant, to create a 6-log reduction in spore organisms"—i.e., the actual limitations of claim 9—but found that NUSA failed to "address how that sterilization would comply with the residual hydrogen peroxide requirement." Appx0056, Appx0059 [*Id.* at 56, 59]. That allegedly missing feature, however, is not required by claim 9.

Steuben's patentability arguments also are premised on the erroneous proposition that claim 9 requires compliance with the FDA's 0.5 ppm limit on residual hydrogen peroxide. Red Br. 11. Steuben alleges that the art refers to a "'narrow path' to successfully achieving an FDA-compliant packaging system," i.e., "the aseptic packager must be able to navigate the tension between using enough sterilant to sterilize the bottle to achieve commercial sterility, while at the same time being able to sufficiently remove the sterilant such that the product will meet the exacting FDA regulations governing aseptic packaging and be safe for the consumer." *Id.* (citing Appx2865). Steuben repeats its "narrow path" mantra seven times in its brief, emphasizing its contention that the FDA's residual requirements *create* the alleged difficulties in achieving microbial kill (i.e., the 6-log reduction). Red Br. 11, 14, 18, 19, 36, 47, 50.

Far from supporting Steuben's position, the reference originating the "narrow path" phrase specifically teaches, in the very next sentence, that achieving

both FDA-compliance and microbial kill "*can be done*." Appx2865 (emphasis added). More to the point in this appeal, Steuben's "narrow path" premise does *not* apply to claim 9, because under a proper construction, claim 9 does not require compliance with the FDA's residual regulation. Unconstrained by claim limits on hydrogen peroxide residue, the "path" to achieving a 6-log reduction would be quite wide indeed. And claim 9 imposes no other limits as to how a 6-log reduction would be achieved. Thus, a POSITA would have had boundless options to modify parameters—as taught by the prior art—to achieve whatever log reduction may be desired. *See* Appx2500 [*ZFL*, 3]; Appx2322-2323 [Heldman Decl. ¶ 82]. For example, as Steuben's expert admitted, the art knew that, in general: (i) "increasing the concentration of the sterilant would increase its effectiveness on sterilization," (ii) "increasing the temperature within certain ranges would increase the effectiveness," and (iii) "as you increase [time of exposure to the sterilant] you're increasing . . . the kill rate." Appx2651 [Sharon Dep. Tr., 44:18-45:2]; Appx2652-2653 [Sharon Dep. Tr., 49:19-50:2]; Appx2653-2654 [Sharon Dep. Tr., 53:20-54:1]. "Such experimentation," to modify known process parameters, "is routine and cannot render an otherwise obvious claim valid." *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1349 n.2 (Fed. Cir. 2009) (citing *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1368 (Fed. Cir. 2007)).

Thus, the record supports granting a full reversal once the proper claim construction is applied, as set forth in NUSA's Blue Brief. NUSA has not "misrepresent[ed]" the record or the Board's decision, contrary to Steuben's inflammatory accusations. Red Br. 54-55. But if the Court concludes that the Board should first address the patentability of claim 9 under a proper claim construction, then the Board's decision should be vacated and remanded.

CONCLUSION

For the reasons stated above and in NUSA's Blue Brief, the Board's determinations that claim 9 is not unpatentable as obvious over (i) *Biewendt*, *Takei*, and *ZFL* or (ii) *ZFL*, *Takei*, and *Bev Tech*, below should be reversed or, to the extent necessary, remanded for further proceedings.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 30, 2017, this Reply Brief of Appellant Nestlé USA, Inc. was filed electronically using the CM/ECF system and served via the CM/ECF system on registered counsel for Appellee, including the following principal counsel:

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) or Federal rule of Appellate Procedure 28.1(e)(2). This brief contains 5,873 words, excluding the parts of the brief exempted by Federal Rules of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) or Federal Rule of Appellate Procedure 28.1(e)(2) and the type style requirements of Federal rule of Appellate Procedure 32(a)(6). This brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman.

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