UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

STEUBEN FOODS, INC.,

Plaintiff,

v. 1:10-CV-00780 EAW

OYSTAR USA, INC., *et al*.,

Defendants.

STEUBEN FOODS, INC.,

Plaintiff,

v. 1:12-CV-00904 EAW

GEA PROCESS ENGINEERING, INC., and GEA PROCOMAC S.P.A.,

Defendants.

STEUBEN FOODS, INC.,

Plaintiff,

v. 1:13-CV-00892 EAW

NESTLÉ, U.S.A.,

Defendant.

STEUBEN FOODS, INC.,

Plaintiff,

v. 1:13-CV-01118 EAW

JASPER PRODUCTS, LLC,

Defendant.

INTRODUCTION

In the above-captioned actions, which have been consolidated for purposes of discovery and claim construction, plaintiff Steuben Foods, Inc. ("Plaintiff") has sued the defendants for patent infringement under 35 U.S.C. §§ 100 *et seq*. Each matter has been referred to United States Magistrate Judge Jeremiah J. McCarthy for hearing and disposition of all non-dispositive motions or applications, supervision of discovery, and to hear and report upon dispositive motions for consideration by the district judge. (Civil Action No. 1:10-cv-00780 (the "Oystar Action"), Dkt. 100; Civil Action No. 12-cv-00904 (the "GEA Action"), Dkt. 82; Civil Action No. 1:13-cv-00892 (the "Nestlé Action"), Dkt. 18; Civil Action No. 13-cv-01118 (the "Jasper Action"), Dkt. 18).

Currently pending before the Court are objections to a Report and Recommendation entered by Judge McCarthy on March 16, 2020, regarding construction of the disputed claim terms "aseptically disinfecting" and "at a rate greater than 100 bottles per minute" (Oystar Action, Dkt. 373; GEA Action, Dkt. 599; Nestlé Action, Dkt. 431; Jasper Action,

Dkt. 317) (the "March 16th R&R") and objections to a Report and Recommendation entered by Judge McCarthy on September 3, 2020, regarding construction of the disputed claim terms "a feedback control system for maintaining aseptic bottling conditions," "disinfecting the bottles . . . with hot hydrogen peroxide spray," and "a residual level of hydrogen peroxide . . . less than 0.5 PPM." (Oystar Action, Dkt. 394; GEA Action, Dkt. 619; Nestlé Action, Dkt. 452; Jasper Action, Dkt. 338) (the "September 3rd R&R") (collectively the "R&Rs"). In particular, Plaintiff has filed objections to the March 16th R&R (Oystar Action, Dkt. 375; GEA Action, Dkt. 601; Nestlé Action, Dkt. 434; Jasper Action, Dkt. 319) and Plaintiff and defendant Jasper Products LLC ("Jasper") have filed objections to the September 3rd R&R (Oystar Action, Dkt. 398; Oystar Action, Dkt. 399; GEA Action, Dkt. 623; Nestlé Action, Dkt. 459; Jasper Action, Dkt. 342; Jasper Action, Dkt. 343). Also pending before the Court is defendant Nestlé USA, Inc.'s ("Nestlé") motion to strike a notice of supplemental authority filed by Plaintiff. (Nestlé Action, Dkt. 453).

For the reasons discussed below, the Court: (1) denies Nestlé's motion to strike; (2) adopts Judge McCarthy's recommendation as to the claim term "aseptically disinfecting"; (2) modifies Judge McCarthy's recommendation as to the claim term "at a rate greater than 100 bottles per minute"; (3) declines to adopt Judge McCarthy's recommendation as to the claim term "a feedback control system for maintaining aseptic bottling conditions" and finds that this term takes its plain and ordinary meaning in the art; (4) adopts Judge

McCarthy's recommendation as to the claim term "disinfecting the bottles . . . with hot hydrogen peroxide spray"; and (5) adopts Judge McCarthy's recommendation as to the claim term "a residual level of hydrogen peroxide . . . less than 0.5 PPM." The Court further modifies the referral orders in this case to provide that dispositive matters shall be heard directly by the undersigned.

FACTUAL AND PROCEDURAL BACKGROUND

Additional factual and procedural background related to the instant actions is set forth in this Court's Decision and Order dated September 16, 2019 (Oystar Action, Dkt. 355; GEA Action, Dkt. 577; Nestlé Action, Dkt. 409; Jasper Action, Dkt. 299) (the "September 16th D&O"), as well as the March 16th R&R and the September 3rd R&R, familiarity with all of which is assumed for purposes of this Decision and Order.

I. The March 16th R&R

"The phrase 'aseptically disinfecting' appears in several claims of the patents in suit." (March 16th R&R at 1). Judge McCarthy held a claim construction hearing as to the construction of "aseptically disinfecting" pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), on January 31, 2018. (*Id.* at 1-2). This claim term has been the subject of extensive litigation, the details of which are discussed at length in the September 16th D&O. (*See* September 16th D&O at 5-12). After entry of the September 16th D&O, Judge McCarthy ordered additional submissions regarding this claim term. On February 24, 2020, Judge McCarthy issued a Report and Recommendation

regarding the construction of "aseptically disinfecting." (Oystar Action, Dkt. 369; GEA Action, Dkt. 595; Nestlé Action, Dkt. 427; Jasper Action, Dkt. 313). That Report and Recommendation was superseded by the March 16th R&R. (March 16th R&R at 1). In the March 16th R&R, Judge McCarthy recommends that "aseptically disinfecting" be construed to require the use of a sterilant that had been approved by the Food and Drug Administration ("FDA") as of February 2, 1999. (*Id.* at 6).

The phrase "at a rate greater than 100 bottles per minute" also appears in several claims of the patents in suit. (*Id.* (citing claims 1 and 18-20 of United States Patent No. 6,945,013 (the "'013 Patent") and claims 19 and 40 of United States Patent No. 6,536,188 (the "'188 Patent"))). Judge McCarthy issued a Report and Recommendation regarding construction of this phrase on February 11, 2020. (Oystar Action, Dkt. 368; GEA Action, Dkt. 594; Nestlé Action, Dkt. 425; Jasper Action, Dkt. 312). That Report and Recommendation was superseded by the March 16th R&R. (March 16th R&R at 1). In the March 16th R&R, Judge McCarthy recommends that "at a rate greater than 100 bottles per minute" be construed to mean "at a rate ranging from greater than 100 bottles per minute to an infinite (that is, indefinite) number of bottles per minute." (*Id.* at 11).

Plaintiff filed objections to the March 16th R&R on April 24, 2020. (Oystar Action, Dkt. 375; GEA Action, Dkt. 601; Nestlé Action, Dkt. 434; Jasper Action, Dkt. 319). Jasper, Nestlé, and defendants GEA Process Engineering, Inc. and GEA Procomac S.p.A. (collectively "GEA") filed responses to Plaintiff's objections on May 22, 2020. (Oystar

Action, Dkt. 378; Oystar Action, Dkt. 379; GEA Action, Dkt. 604; GEA Action, Dkt. 605; GEA Action, Dkt. 606; Nestlé Action, Dkt. 437; Nestlé Action, Dkt. 438; Jasper Action, Dkt. 322; Jasper Action, Dkt. 323). Plaintiff filed a combined reply on June 11, 2020. (Oystar Action, Dkt. 380; GEA Action, Dkt. 608; Nestlé Action, Dkt. 440; Jasper Action, Dkt. 325). Jasper, GEA, and Nestlé filed sur-replies on June 18, 2020. (Oystar Action, Dkt. 383; Oystar Action, Dkt. 384; Oystar Action, Dkt. 385; GEA Action, Dkt. 611; GEA Action, Dkt. 612; GEA Action, Dkt. 613; Nestlé Action, Dkt. 443; Nestlé Action, Dkt. 444; Nestlé Action, Dkt. 445; Jasper Action, Dkt. 328; Jasper Action, Dkt. 329; Jasper Action, Dkt. 330).

II. The September 3rd R&R

Judge McCarthy held a *Markman* hearing as to the '013 Patent on June 16, 2020. (September 3rd R&R at 1). The September 3rd R&R recommends construction of the following phrases: "a feedback control system for maintaining aseptic bottling conditions," found in claim 9 of the '013 Patent; "disinfecting the bottles . . . with hot hydrogen peroxide spray," found in claim 20 of the '013 Patent; and "a residual level of hydrogen peroxide . . . less than 0.5 PPM," found in claim 20 of the '013 Patent. (*Id.*). Judge McCarthy recommends that: (1) "a feedback control system for maintaining aseptic bottling conditions" be considered a means-plus-function limitation and determined to lack corresponding structure, thus rendering claim 9 of the '013 Patent indefinite; (2) "disinfecting the bottles . . . with hot hydrogen peroxide spray" be construed to mean that

"the hydrogen peroxide must be heated to its vaporization phase immediately before being applied to the container"; and (3) "a residual level of hydrogen peroxide . . . less than 0.5 PPM" be construed to mean "the level determined in accordance with 21 C.F.R. § 178.1005(d)." (*Id.* at 1-10).

Plaintiff and Jasper filed objections to the September 3rd R&R on October 8, 2020. (Oystar Action, Dkt. 398; Oystar Action, Dkt. 399; GEA Action, Dkt. 623; Nestlé Action, Dkt. 459; Jasper Action, Dkt. 342; Jasper Action, Dkt. 343). On November 6, 2020, Plaintiff, Jasper, and defendant Kan-Pak, LLC ("Kan-Pak") filed responses. (Oystar Action, Dkt. 402; Oystar Action, Dkt. 403; Oystar Action, Dkt. 404; GEA Action, Dkt. 624; Nestlé Action, Dkt. 460; Jasper Action, Dkt. 347; Jasper Action, Dkt. 348). Plaintiff filed a reply to Kan-Pak's response on November 23, 2020. (Oystar Action, Dkt. 406).

III. Nestlé's Motion to Strike

On September 2, 2020, Plaintiff filed a "Notice of Supplemental Authority and Concurrent Proceeding" with respect to the March 16th R&R. (Oystar Action, Dkt. 392; GEA Action, Dkt. 617; Nestlé Action, Dkt. 450; Jasper Action, Dkt. 336) ("Plaintiff's Notice"). Plaintiff's Notice advised the Court of the Federal Circuit's decision in *Baxalta Inc. v. Genentech, Inc.*, 972 F.3d 1341 (Fed. Cir. 2020), and of certain claim construction rulings related to the same patents at issue in this case issued by the United States District Court for the District of Delaware in *Steuben Foods, Inc. v. Shibuya Kogyo Co. Ltd.*, No.

1:19-cv-02181-CFC-CJB (the "Delaware Action")[1]. (Plaintiff's Notice at 1-3). Nestlé moved to strike Plaintiff's Notice on September 9, 2020. (Nestlé Action, Dkt. 453). Plaintiff file a response on September 30, 2020. (Nestlé Action, Dkt. 456).

DISCUSSION

I. Standard of Review for Reports and Recommendations

Pursuant to 28 U.S.C. § 636(b)(1)(C), where a party makes specific objections to a magistrate judge's report and recommendation, the district judge must "make a de novo determination of those portions of the report or specified proposed findings or recommendations to which objection is made." 28 U.S.C. § 636(b)(1)(C). "The Court reviews unobjected-to findings for clear error." *Am. Ins. Co. v. City of Jamestown*, 914 F. Supp. 2d 377, 384 (W.D.N.Y. 2012). After conducting its review, the Court may "accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge." 28 U.S.C. § 636(b)(1)(C).

II. Legal Standard for Claim Construction

The issue before the Court is the construction of certain disputed claim terms. As the Supreme Court has explained:

> The[re] [are] two elements of a simple patent case, construing the patent and determining whether infringement occurred. . . . The first is a question of law, to be determined by the court, construing the letters-patent, and the description of the invention and specification of claim annexed to them. The second is a question of fact, to be submitted to a jury.

[1] The Delaware Action was originally commenced in this District as *Steuben Foods, Inc. v. Shibuya Kogyo Co. Ltd.*, Civil Action No. 1:10-00781 (the "Shibuya Action") but was subsequently transferred.

Markman, 517 U.S. at 384 (quotation omitted). "[C]laim construction analysis, an issue of substantive patent law, is governed by Federal Circuit law." *Uni-Sys., LLC v. United States Tennis Ass'n Nat'l Tennis Ctr. Inc.*, No. 17-CV-147(KAM)(CLP), 2020 WL 3960841, at *2 (E.D.N.Y. July 13, 2020). Under the law of the Federal Circuit:

> In construing [patent] claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to particularly point out and distinctly claim the subject matter which the patentee regards as his invention. The words used in the claims are examined through the viewing glass of a person skilled in the art. In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art.

Brookhill-Wilk 1, LLC. v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 (Fed. Cir. 2003) (quotation, citations, and original alterations omitted); *see also Source Vagabond Sys. Ltd. v. Hydrapak, Inc.*, 753 F.3d 1291, 1299 (Fed. Cir. 2014).

"In determining the proper construction of a claim, the court has numerous sources that it may properly utilize for guidance. These sources . . . include both intrinsic evidence (*e.g.,* the patent specification and file history) and extrinsic evidence (*e.g.,* expert testimony)." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "[I]n interpreting an asserted claim, the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history. Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Id.* (citation omitted). Importantly, where

the specification provides an express definition for a disputed claim term, "the patentee acted as his own lexicographer, and the patentee's definition trumps the ordinary and customary meaning that otherwise would have attached." *Int'l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1373 (Fed. Cir. 2004).

III. Nestlé's Motion to Strike

Before turning to the disputed claim terms, the Court must resolve Nestlé's motion to strike Plaintiff's Notice. Nestlé argues that Plaintiff's Notice should be stricken because it contains "substantive commentary," in violation of a prior order of the Court. (Nestlé Action, Dkt. 453-1). Nestlé is correct that on May 20, 2019, the Court entered a Text Order stating that supplemental authority "may be brought to the Court's attention via the filing of a notice of supplementary authority, without any substantive commentary by the filing party." (*Id.,* Dkt. 401). However, the Court disagrees that Plaintiff's Notice contains "substantive commentary." Plaintiff did briefly summarize the *Baxalta* decision and the claim construction determinations reached in the Delaware Action. (Plaintiff's Notice at 1-3). However, Plaintiff did not offer any arguments as to the impact of these supplemental authorities on the instant actions. Further, it was not, as Nestlé seems to suggest, improper for Plaintiff to attach to Plaintiff's Notice a copy of the transcript of the claim construction hearing in the Delaware Action, which is a judicial record that the Court could have readily obtained on its own. Nestlé's request that Plaintiff's Notice be stricken lacks merit and is denied.

The Court further denies Nestlé's alternative request that it be permitted to file a response to Plaintiff's Notice, as well as Plaintiff's request that the Court allow supplemental briefing on *Baxalta* and the decision in the Delaware Action. The briefing in this matter has already been voluminous. The Court is fully capable of reviewing the supplemental authorities presented by Plaintiff and ascertaining how and if they are relevant to the issues pending before it and has done so below. No further argument by the parties is required.

IV. The Disputed Claim Terms

A. Aseptically Disinfecting

The Court considers first the construction of the phrase "aseptically disinfecting." As noted above, Judge McCarthy has recommended that the Court construe this phrase to require the use of a sterilant that had been approved by the FDA as of February 2, 1999 (the effective filing date of the patents in suit).

Plaintiff objects to Judge McCarthy's recommendation, contending that it is erroneous in "two principal ways." (*See* Oystar Action, Dkt. 375 at 17). Plaintiff first argues that "aseptically disinfecting" does not require the use of an FDA approved sterilant at all. (*Id.*). Plaintiff's second contention is that, at a minimum, the sterilant need not have been FDA approved on February 2, 1999. (*Id.*). Having reviewed the matter *de novo*, the Court agrees with Judge McCarthy that the phrase "aseptically disinfecting" requires the use of a sterilant that had been approved by the FDA on February 2, 1999.

The Federal Circuit has considered the construction of the term "aseptic" as used in the patents in suit and has held that it is defined, by binding lexicography, as "the 'FDA level of aseptic,'" which is further defined by reference to "FDA regulations related to aseptic packaging." *Nestlé USA, Inc. v. Steuben Foods, Inc.*, 686 F. App'x 917, 919 (Fed. Cir. 2017) ("*Nestlé I*"). "Where the Federal Circuit has already construed the claims . . . disputed, then that higher Court's construction is binding, and this Court cannot modify its holding." *Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 494 F. Supp. 2d 54, 60 (D. Mass. 2007). As such, the Court's construction of "aseptically disinfecting" must be consistent with the Federal Circuit's holding in *Nestlé I*. Further examination of that decision is thus required.

Nestlé I was an appeal by Nestlé of a decision by the Patent Trial and Appeal Board ("PTAB") finding that claims 18-20 of the '013 Patent "were not obvious in view of certain prior art." 686 F. App'x at 918. Nestlé had petitioned the PTAB for *inter partes* review ("IPR") of claims 18-20 of the '013 Patent. *Id.* The PTAB "instituted IPR and construed the term 'aseptic,' as used in claims 18-20, to mean 'aseptic to any applicable United States FDA standard, and in the absence of any such standard, aseptic assumes its ordinary meaning of free or freed from pathogenic microorganisms.'" *Id.* On appeal, Plaintiff argued that "'FDA level of aseptic' incorporates the full 'panoply of FDA standards,'" but the Federal Circuit disagreed. *Id.* at 919. The Federal Circuit instead found that "FDA level of aseptic" incorporates "FDA regulations related to aseptic packaging," including 21

C.F.R. § 113.3(a). *Id.* 21 C.F.R. § 113.3 states that aseptic processing and packaging requires "commercial sterility," which is achieved by "application of heat, chemical sterilant(s), or other appropriate treatment[.]" 21 C.F.R. § 113.3(e) (1998).[2] In a subsequent decision, *Nestlé USA, Inc. v. Steuben Foods, Inc.*, 884 F.3d 1350 (Fed. Cir. 2018) ("*Nestlé II*"), the Federal Circuit held that its construction of the term "aseptic" applied to Plaintiff's related patents in addition to the '013 Patent. *Id.* at 1352.

Plaintiff argues that the Federal Circuit's decision in *Nestlé I* is both the beginning and the end of the claim construction process for "aseptically disinfecting"—this claim term must mean "disinfecting in compliance with the FDA Regulations related to aseptic packaging." (Plaintiff's Objections at 18). The Court agrees that its analysis must begin with the holding in *Nestlé I*, but disagrees that *Nestlé I* conflicts with the claim construction recommended by Judge McCarthy. To the contrary, for the reasons set forth below, the decision in *Nestlé I* leads directly to the conclusion that "aseptically disinfecting," as defined in the patents in suit, cannot include the use of a chemical sterilant that is not approved by the FDA.

As the *Nestlé I* court noted, the '013 Patent explains that the innovation represented therein is a system capable of providing "a high output aseptic filler that complies with the

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[2] Consistent with the Federal Circuit's approach, the Court has considered the version of the applicable FDA regulations in effect as of February 2, 1999. *See Nestlé I*, 686 F. App'x at 919 (considering the FDA's regulations in effect "at the time of the application"). The Court further notes that the Code of Federal Regulations was not updated until April 1, 1999, and so the 1998 edition was current in February 1999.

stringent United States FDA standards for labeling a packaged product as 'aseptic.'" 686 F. App'x at 919 (quoting '013 Patent, col. 1 ll. 64-67). Accordingly, the relevant inquiry for what constitutes an "FDA level of aseptic" is whether a particular FDA standard relates to whether or not a packaged product could lawfully be denoted "aseptic." So, as the *Nestlé I* court concluded, a regulation that provided that all food products must have less than 0.5 ppm of hydrogen peroxide residue would not fall within the definition, because compliance with this standard has no bearing on whether or not the FDA would permit a packaged product to be labeled as aseptic.

However, a review of the relevant statutes and regulations demonstrates that whether or not a packaged product used an FDA approved sterilant is directly relevant to whether or not the FDA would permit it to be labeled aseptic. In February 1999, 21 C.F.R. § 113.3(a) provided that "aseptic processing and packaging" required achieving commercial sterility. 21 C.F.R. § 113.3(a) (1998); (*see also* Nestlé Action, Dkt. 305 at 3 (Plaintiff acknowledging that "[t]he FDA regulates aseptic packaging systems to determine whether a proposed system has a demonstrated capability of achieving 'commercial sterility' while meeting any necessary residual tolerances if a chemical sterilant is used.")). "Commercial sterility" with respect to "equipment and containers used for aseptic processing and packaging of food" was in turn defined as "the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment that renders the equipment and containers 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." 21 C.F.R. § 113.3(e)(2) (1998). In other words, under the applicable regulations, a packaged food could be labeled "aseptic" if it was packaged using a process in which a chemical sterilant was used to achieve commercial sterility.

Unsurprisingly, the FDA did not and does not allow the use of any and every potential chemical sterilant to achieve commercial sterility. To the contrary, under 21 U.S.C. § 348, a food additive may be used for a particular purpose—including to achieve chemical sterility—only if the FDA issues either a regulation or food contact notification setting forth the conditions under which the additive may safely be used. 21 U.S.C. § 348(a). As of February 2, 1999, 21 C.F.R. § 178.1005(e) provided that hydrogen peroxide could be used "to attain commercial sterility . . . as provided for in part 113 of this chapter." 21 C.F.R. § 178.1005(e) (1998). No other chemical sterilant had been approved by the FDA for use in attaining commercial sterility as of February 2, 1999.

Considering the foregoing, the Court finds that as of February 2, 1999: (1) complying with the FDA's standards for labeling a packaged product as aseptic required using "heat, chemical sterilant(s), or other appropriate treatment," 21 C.F.R. § 113.3(e)(2) (1998), to achieve commercial sterility; and (2) to the extent a chemical sterilant was to be used to achieve commercial sterility, it was necessary to use a chemical sterilant as to which the FDA had issued either a regulation or food contact notification permitting such use. In

other words, using a chemical sterilant that had not been approved for use in achieving commercial sterility in an aseptic packaging system would not have comported with the FDA's standards. As such, the binding lexicography in the patents in suit incorporating "the United States FDA level of aseptic" necessarily requires the use of an approved sterilant for disinfecting.

Further examination of the intrinsic evidence confirms this conclusion. In addition to defining "aseptic" with reference to the FDA's standards, the specification of the '013 Patent expressly states that "[f]or the aseptic packaging of food products, an aseptic filler must . . . use an FDA (Food and Drug Administration) approved sterilant[.]" '013 Patent, col. 1 ll. 48-50 (emphasis added). This explicit statement by the patentee comports with the Court's conclusion that the use of an approved sterilant is a necessary component of complying with the FDA standards for aseptic packaging of food.

Further, as Judge McCarthy noted in the March 16th R&R, "arguments made during prosecution shed light on what the applicant meant by its various terms." (March 16th R&R at 3 (quoting *Springs Window Fashions LP v. Novo Industries, L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003))); *see also Iridescent Networks, Inc. v. AT&T Mobility, LLC*, 933 F.3d 1345, 1352-53 (Fed. Cir. 2019) (explaining that even in the absence of disclaimer, "any explanation, elaboration, or qualification presented by the inventor during patent examination is relevant, for the role of claim construction is to capture the scope of the actual invention that is disclosed, described, and patented" (quotation and alteration

omitted))[3]. Here, Plaintiff repeatedly explained during prosecution that an approved sterilant must be used to meet the FDA's definition of aseptic. For example, in a brief filed with the Patent and Trademark Office ("PTO") on October 23, 2002, Plaintiff stated that "in order to meet the FDA definition of aseptic the aseptic filler must, *inter alia*, use an FDA approved sterilant. . . ." (GEA Action, Dkt. 417-18 at 13 (internal quotation marks omitted); *see also* GEA Action, Dkt. 426-11 at 36 (brief Plaintiff submitted to the PTO distinguishing prior art using chlorine as the chemical sterilant: "At the time the application that matured into the '013 Patent was filed, the only FDA approved sterilant for use in low acid packaging was hydrogen peroxide, as such chlorine could not have been used in aseptic packaging as claimed by the '013 patent.")). Plaintiff's own statements, like the specification, confirm that the FDA level of aseptic cannot be achieved with the use of an unapproved chemical sterilant.

Plaintiff's arguments to the contrary, as set forth in its objections, are unavailing. Plaintiff argues that § 348 cannot provide any guidance as to the meaning of "aseptically disinfecting" because it is a statute and not a regulation. (GEA Action, Dkt. 601 at 20). This argument misreads the holding in *Nestlé I*. While it is true that the *Nestlé I* court

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[3] Some of the defendants have also argued, and Judge McCarthy agreed, that Plaintiff expressly disclaimed the use of an unapproved sterilant during prosecution. (*See* March 16th R&R at 3). The Court finds it a close call whether the statements at issue amount to Plaintiff having "unequivocally and unambiguously disavow[ed] a certain meaning," *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013), as is necessary to support a finding of disclaimer. However, the Court need not and does not reach this issue in light of its conclusions as to the express lexicography found in the patents in suit.

spoke in terms of "FDA regulations related to aseptic packaging," that was to distinguish the same from "regulations that apply to foods that are not aseptically packaged." 686 F. App'x at 919. No statutes were at issue in *Nestlé I*, and the *Nestlé I* court did not hold, as Plaintiff seems to suggest, that a statute could never play a role in determining the FDA's standards for aseptic packaging.

Moreover, unlike the generally applicable regulation at issue in *Nestlé I*, which had no bearing on whether a packaged food could be labeled aseptic, § 348 indisputably governs which chemical sterilants can lawfully be used to achieve commercial sterility, and commercial sterility in turn is required to achieve aseptic packaging. Thus, unlike the residual hydrogen peroxide level at issue in *Nestlé I*, the use of an approved chemical sterilant is a direct component of the FDA's requirements for aseptic packaging. Plaintiff acknowledged this clear fact before the PTO. (GEA Action, Dkt. 417-18 at 13 ("[I]n order to meet the FDA definition of aseptic the aseptic filler must, *inter alia*, use an FDA approved sterilant. . . ." (internal quotation marks omitted and emphasis added))).

Plaintiff also argues that it is error to construe "aseptically disinfecting" to require the use of an FDA approved sterilant because "[c]ertain of [Plaintiff's] patent claims explicitly recite the use of oxonia," a chemical sterilant that was not approved for use by the FDA in February 1999. (GEA Action, Dkt. 601 at 25). Plaintiff points out that the specification of the '188 Patent, for example, describes oxonia as a usable sterilant. (*Id*. at 26-27). Plaintiff is correct that a court "normally do[es] not interpret claim terms in a way

that excludes disclosed examples in the specification." *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007). However, this rule is not absolute, and the court must "interpret[] claims to exclude embodiments where those embodiments are inconsistent with unambiguous language in the patent's specification or prosecution history." *Sinorgchem Co., Shandong v. Int'l Trade Comm'n*, 511 F.3d 1132, 1138 (Fed. Cir. 2007). More specifically, where, as here, the patentee has elected to act as its own lexicographer and has provided an express definition of a disputed claim term, the fact that the definition provided excludes a particular disclosed embodiment does not render it nonbinding. *Id.*; *see also Trustees of Columbia Univ. in City of New York v. Symantec Corp.*, 811 F.3d 1359, 1366 (Fed. Cir. 2016) ("The patentee cannot rely on its own use of inconsistent and confusing language in the specification to support a broad claim construction which is otherwise foreclosed.") (affirming claim construction analysis that rendered certain claims indefinite); *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357 (Fed. Cir. 1999) (court cannot redraft claims to "circumvent . . . the clear definition of the disputed claim language"). Here, as the Federal Circuit made clear in *Nestlé I*, it is binding lexicography that "aseptic" means satisfying the FDA's standards for aseptic packaging. It is further clear that those standards require the use of an approved sterilant for disinfecting. The Court cannot disregard Plaintiff's chosen definition for "aseptic" simply because Plaintiff also attempted to claim oxonia as a potential sterilant.

The Federal Circuit's recent decision in *Baxalta* is not to the contrary. In *Baxalta*, the district court had adopted a claim construction that excluded certain explicitly claimed embodiments on the basis of lexicography and disclaimer. 972 F.3d at 1343-45. The Federal Circuit reversed, "[b]ecause [it] reject[ed] the premise that the excerpt of column 5 [of the patent at issue] is definitional, and [did] not view the prosecution history as sufficiently clear and unmistakable" to amount to disclaimer. *Id*. at 1348. In other words, *Baxalta* does not contradict the long-standing case law establishing that a claim construction that excludes particular claimed embodiments is appropriate where required by either binding lexicography or disclaimer—the Federal Circuit simply found that those criteria were not met in that particular case. However, in this case, the Federal Circuit itself has concluded that binding lexicography is present, and the Court's claim construction must follow therefrom, notwithstanding the fact that a construction that excludes claimed embodiments is generally disfavored.

Plaintiff further argues that even if aseptically disinfecting requires the use of an FDA approved sterilant, it does not require the use of a sterilant that was approved on February 2, 1999. Instead, Plaintiff contends, oxonia should be considered within the scope of the claims as an "after-arising technology." (GEA Action, Dkt. 601 at 41-43). The Court disagrees.

Plaintiff's argument is based on *SuperGuide Corp. v. DirecTV Enters., Inc*., 358 F.3d 870 (Fed. Cir. 2004), wherein the Federal Circuit considered whether the claim term

"regularly received television signal" would include digital signals. The district court had concluded that because "the only type of television signals that were broadcast" when the patent at issue was filed were analog signals, the term "regularly received television signal" did not include digital signals. *Id*. at 876-77. The Federal Circuit reversed, finding that the term "regularly received television signals" was "broad enough to encompass both formats and those skilled in the art knew both formats could be used for video." *Id*. at 880.

In reversing the district court decision in *SuperGuide*, the Federal Circuit distinguished its decision in *Kopykake Enters., Inc. v. Lucks Co*., 264 F.3d 1377 (Fed. Cir. 2001). In *Kopykake*, the claim term at issue involved "screen printing" of images on food products. 264 F.3d at 1380. The Federal Circuit found that "screen printing" did not include ink jet methods of printing, because the specification limited screen printing to "'any . . . conventional printing process and any other conventional means and methods' for applying pictorial images to foodstuffs," and ink jet printing was not "conventional" at the time the patent was filed. *Id*. at 1382-83. The *Kopykake* court explained that "when a claim term understood to have a narrow meaning when the application is filed later acquires a broader definition, the literal scope of the term is limited to what it was understood to mean at the time of filing." *Id*. at 1383. In distinguishing *Kopykake*, the *SuperGuide* court explained that, unlike in *Kopykake*, the patentees in *SuperGuide* "did not explicitly limit the disputed claim language to technologies that were 'conventional' at the time of the invention." 358 F.3d at 879.

Contrary to Plaintiff's arguments, the instant case is analogous to *Kopykake* and not *SuperGuide*. As previously discussed at length, the express lexicography in this case requires aseptic disinfecting to use an FDA approved sterilant, not merely one that was capable of achieving such approval but had not yet done so—indeed, using such an unapproved sterilant would have resulted in a packaged food product that could not lawfully be labeled aseptic. "FDA approved," like "conventional," had a fixed, narrow definition at the time of filing, and that definition is not expanded by later developments in the field.

Plaintiff also argues that Judge McCarthy relied on outdated and unsupported expert testimony in construing "aseptically disinfecting" and that it was improper for Judge McCarthy to consider issues of utility while engaging in claim construction. (GEA Action, Dkt. 601 at 39-41, 43-45). However, on *de novo* review, the Court has not relied on the expert testimony in question, nor has it considered issues of utility. Accordingly, these aspects of Plaintiff's objections do not require any further discussion by the Court.

Finally, the Court acknowledges that the district judge in the Delaware Action construed "aseptically disinfecting" as "[d]isinfecting in compliance with the United States FDA level of aseptic." (Oystar Action, Dkt. 392-2 at 2). However, as Plaintiff acknowledges, the defendants in the Delaware Action "did not argue that [Plaintiff] had defined 'aseptic' or 'aseptically disinfecting' so as to exclude the use of oxonia and/or [require] the use of a sterilant that had already been approved by the FDA as of February

2, 1999." (Plaintiff's Notice at 2 n.1). As such, the judge in the Delaware Action had no occasion to consider whether "disinfecting in compliance with the United States FDA level of aseptic" requires the use of an FDA approved chemical sterilant. The Court does not view the decision in the Delaware Action as conflicting with its conclusions set forth above.

For all these reasons, the Court adopts Judge McCarthy's recommendation and construes "aseptically disinfecting" as requiring the use of a chemical sterilant approved by the FDA as of February 2, 1999.

B. <u>At A Rate Greater Than 100 Bottles Per Minute</u>

The Court turns next to the disputed claim term "at a rate greater than 100 bottles per minute." In the March 16th R&R, Judge McCarthy recommended that the Court construe this claim term to mean "at a rate ranging from greater than 100 bottles per minute to an infinite (that is, indefinite) number of bottles per minute." (March 16th R&R at 11).

Plaintiff takes the position that the claim term "at a rate greater than 100 bottles per minute" requires no construction "because the words are clear and easy to understand." (GEA Action, Dkt. 601 at 46). However, Plaintiff's argument misapprehends the Court's claim construction obligation. "A determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008). In particular, it is not appropriate for the Court to avoid claim construction

where the parties "dispute[] not the *meaning* of the words themselves, but the *scope* that should be encompassed by [the] claim language." *Id.*

That is the case here. The parties plainly dispute whether the "ordinary meaning" of the term "at a rate greater than 100 bottles per minute" has an implicit upper limit. This is not an academic dispute, as its resolution may have implications for the validity of the claims using this term. As such, the Court cannot, as Plaintiff urges, merely determine that this claim term takes its plain and ordinary meaning—the Court must resolve the parties' dispute.

The question for the Court, then, is whether a person of ordinary skill in the art would understand "at a rate greater than 100 bottles per minute" to have an implicit upper limit. The Court agrees with Judge McCarthy that such a person would not have that understanding. Plaintiff has pointed to no intrinsic evidence supporting the conclusion that such an implicit limit exists, and as Judge McCarthy explained in the March 16th R&R, the defendants' experts unanimously opined that a person of ordinary skill in the art would not understand the claim language to impose an upper limit on the rate requirements. (March 16th R&R at 8).

Plaintiff also takes issue with the language recommended by Judge McCarthy, stating that it "does not fully understand what is meant by the recommended construction" and arguing that because the recommended construction uses the word "infinite," it "assumes that there is a numerical upper limit to the claim. . . ." (GEA Action, Dkt. 601 at

47-48). Unlike Plaintiff, the Court has no trouble understanding what Judge McCarthy meant by his proposed construction—Judge McCarthy correctly articulated that there is no mathematically ascertainable upper limit inherent in the claim language. However, for the avoidance of any doubt, the Court will slightly modify the recommended construction, and construe "at a rate greater than 100 bottles per minute" to mean "at a rate greater than 100 bottles per minute, with no upper limit on said rate."

Plaintiff also argues that Judge McCarthy improperly considered issues of enablement and invalidity in recommending a construction of "at a rate greater than 100 bottles per minute." (GEA Action, Dkt. 601 at 48-51). However, on *de novo* review, the Court has not considered any issues of enablement and invalidity, and has arrived at the same conclusion as Judge McCarthy. Further, the Court does not view any arguments as to enablement and invalidity as ripe for review at this stage of the proceedings. Accordingly, these aspects of Plaintiff's objections require no further consideration by the Court.

C. A Feedback Control System For Maintaining Aseptic Bottling Conditions

The next term the Court considers is "a feedback control system for maintaining aseptic bottling conditions." As Judge McCarthy explained in the September 3rd R&R, the parties disagree as to whether this claim term describes a means-plus-function limitation. "Under means plus function claiming, an inventor may draft a claim element in a manner that only describes a function without describing a particular structure that

performs that function." *Uni-Sys.,* 2020 WL 3960841, at *11 (quoting *Integrity Worldwide, LLC v. Rapid-EPS LTD*, No. 17-CV-55, 2018 WL 3609430, at *4 (N.D. Tex. May 29, 2018)). As the Federal Circuit has explained:

> Means-plus-function limitations are governed by 35 U.S.C. § 112, ¶ 6, which provides: An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure in support thereof, and such claim shall be construed to cover the corresponding structure described in the specification and equivalents thereof.

Chicago Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC, 677 F.3d 1361, 1367 (Fed. Cir. 2012) (original alterations omitted). The Federal Circuit has further explained that "§ 112, ¶ 6 represents a *quid pro quo* by permitting inventors to use a generic means expression for a claim limitation provided that the specification indicates what structure(s) constitute(s) the means." *Id*. (quotation omitted).

"Interpretation of an asserted means-plus-function limitation involves two steps. First, [the Court] determine[s] if the claim limitation is drafted in means-plus-function format." *MTD Prods. Inc. v. Iancu*, 933 F.3d 1336, 1344 (Fed. Cir. 2019). When determining as a threshold matter whether a limitation is a means-plus-function limitation, "the use of the word 'means' in a claim element creates a rebuttable presumption that § 112, para. 6 applies. Applying the converse, . . . the failure to use the word 'means' also creates a rebuttable presumption—this time that § 112, para. 6 does not apply." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (citation omitted). However, the presumption is not strong, and the Court must be careful not to "blindly elevate[] form over

substance when evaluating whether a claim limitation invokes § 112, para. 6"—"the essential inquiry is not merely the presence or absence of the word 'means' but whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure." *Id*.

If the Court concludes that a claim term is a means-plus-function limitation, it must then engage in a further two-step process to construe the term. "First, the court must identify the claimed function. Second, the court must identify the corresponding structure in the specification that performs the recited function." *Chicago Bd.*, 677 F.3d at 1367. "The specification must be read as a whole to determine the structure capable of performing the claimed function." *Budde v. Harley–Davidson, Inc*., 250 F.3d 1369, 1379 (Fed. Cir. 2001).

In the September 3rd R&R, Judge McCarthy recommended that the Court conclude that "a feedback control system for maintaining aseptic bottling conditions" is a means-plus-function limitation, that it fails to adequately disclose corresponding structure, and that claim 9 of the '013 Patent is accordingly indefinite. (September 3rd R&R at 1-6). Plaintiff objects to this recommendation, contending that the presumption that "feedback control system" is not a means-plus-function limitation has not been rebutted and that even if it is such a limitation, indefiniteness has not been established. (Jasper Action, Dkt. 343 at 6-28). For the reasons set forth below, the Court agrees with Plaintiff that the presumption has not been overcome and that this claim term should not be treated as a

mean-plus-function limitation. The Court accordingly declines to adopt Judge McCarthy's recommended construction.

On *de novo* review, the Court must first determine whether "a feedback control system for maintaining aseptic bottling conditions" is a means-plus-function limitation. This claim term does not use the word "means," and thus the rebuttable presumption that it is not a means-plus-function limitation applies. The Federal Circuit has held that: "[g]eneric terms such as 'mechanism,' 'element,' 'device,' and other nonce words that reflect nothing more than verbal constructs may be used in a claim in a manner that is tantamount to using the word 'means' because they 'typically do not connote sufficiently definite structure' and therefore may invoke § 112, para. 6." *Williamson*, 792 F.3d at 1350 (quoting *Mass. Inst. of Tech. & Elecs. for Imaging, Inc. v. Abacus Software*, 462 F.3d 1344, 1354 (Fed. Cir. 2006) ("*MIT*")); *see also Verint Sys. Inc. v. Red Box Recorders Ltd.*, 166 F. Supp. 3d 364, 381 (S.D.N.Y. 2016) ("'System' standing alone is a nonce word that does not describe a structure. . . .").

However, "a structural modifier further describing a nonce term can imbue said nonce term with sufficient structure to place it beyond 35 U.S.C. § 112 ¶ 6." *Uni-Sys.*, 2020 WL 3960841, at *13. "[I]t is sufficient if the claim term is used in common parlance or by persons of skill in the pertinent art to designate structure, even if the term covers a broad class of structures and even if the term identifies the structures by their function." *MIT*, 462 F.3d at 1356 (citation omitted). Here, the word "system" is modified by

"feedback control." Accordingly, the Court must assess whether Defendants have presented sufficient evidence that a person of ordinary skill in the art would not understand "feedback control system" as designating structure to overcome the presumption. *See Diebold Nixdorf, Inc. v. Int'l Trade Comm'n*, 899 F.3d 1291, 1298 (Fed. Cir. 2018) ("Where, as here, a claim term lacks the word 'means,' the presumption can be overcome and § 112, para. 6 will apply if the challenger demonstrates that the claim term fails to 'recite sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function.'" (quoting *Williamson*, 792 F.3d at 1349)). "Ultimately, whether claim language invokes § 112, ¶ 6 depends on how those skilled in the art would understand the structural significance of that claim language, assessed against the presumptions that flow from a drafter's choice to employ or not employ the term 'means.'" *Inventio AG v. ThyssenKrupp Elevator Ams. Corp*., 649 F.3d 1350, 1360 (Fed. Cir. 2011), *overruled on other grounds by Williamson*, 792 F.3d 1339.

Here, the Court finds that a person of ordinary skill in the art would understand "feedback control system" to designate structure. Plaintiff's expert witness Dr. Cullen Buie, who holds a Ph.D. in mechanical engineering from Stanford University and is an associate professor in the mechanical engineering department at the Massachusetts Institute of Technology, has opined that the term "feedback control system" would "connote[] definite structure to a skilled artisan." (Shibuya Action, Dkt. 334-6 at ¶ 10). Dr. Buie further explains that control systems are "ubiquitous in manufacturing" and identifies

technical references that describe feedback control systems. (*Id*. at ¶¶ 10-17). The Court finds Dr. Buie's opinion well-reasoned and persuasive. In particular, the Court notes that Dr. Buie cites to the Chambers Dictionary of Science and Technology, which provides an express definition for a feedback control system. (*Id*. at ¶ 10). "[T]he extrinsic dictionary definition strongly supports a finding" that the term "feedback control system" "connotes definite structure to one of skill in the art." *Canon, Inc. v. TCL Elecs. Holdings Ltd*., No. 2:18-CV-546-JRG, 2020 WL 2098197, at *15 (E.D. Tex. May 1, 2020) (finding that "control unit" would connote a sufficiently definite structure to a person of ordinary skill in the art to avoid application of § 112, ¶ 6); *see also Linear Tech. Corp. v. Impala Linear Corp*., 379 F.3d 1311, 1320 (Fed. Cir. 2004) ("Technical dictionaries, which are evidence of the understandings of persons of skill in the technical arts, plainly indicate that the term 'circuit' connotes structure."). As Dr. Buie explains, a person of ordinary skill in the art would understand "feedback control system" as referring to a class of structures wherein a controlled quantity is measured and compared with a desired standard and feedback is applied to the system based on that comparison. (Shibuya Action, Dkt. 334-6 at ¶ 10).

The Court notes that at the time claim construction briefing in this matter was submitted, the Shibuya Action had not yet been transferred to the District of Delaware, and the defendants in that case submitted the expert declaration of Dr. Kenneth R. Swartzel. (Shibuya Action, Dkt. 346-9). Dr. Swartzel, who holds a "D.Phil. in Biological and Agricultural Engineering, with a minor in Mechanical and Aerospace Engineering," from

North Carolina State University ("NCSU") and is a professor emeritus in and former head of the department of food science at NCSU, opined that the term "feedback control system" does not connote a definite structure. (*Id*. at ¶ 13). However, Dr. Swartzel's opinion is not persuasive. It does not even address all the technical references identified by Dr. Buie, and further fails to acknowledge that a non-means-plus-function limitation need not identify a single structure, but instead "need only educate a skilled artisan on the type of structure being described." *Shure, Inc. v. ClearOne, Inc*., No. 17 C 3078, 2019 WL 4014231, at *5 (N.D. Ill. Aug. 25, 2019) (emphasis added); *see also Apple Inc. v. Motorola*, 757 F.3d 1286, 1300 (Fed. Cir. 2014) ("The limitation need not connote a single, specific structure; rather, it may describe a class of structures."), *overruled on other grounds* by *Williamson*, 792 F.3d at 1349.

Further, the Court does not find that this is a case in which the patent recites function without reciting sufficient structure for performing that function. While the specification of the '013 Patent does not expressly use the phrase "feedback control system," as Dr. Buie explains, it provides a detailed description of a system that uses various sensors to monitor and maintain air pressure, temperature, bottle positioning, and flow rates. (Shibuya Action, Dkt. 334-6 at ¶¶ 12-14 (citing '013 Patent, col. 13 l. 64 through col. 14 l. 16)). Accordingly, the Court concludes that "a feedback control system for maintaining aseptic bottling conditions" is not a means-plus-function limitation, and thus declines to adopt Judge McCarthy's recommendation to the contrary.

The Court is further unpersuaded by Kan-Pak's alternative argument that claim 9 of the '013 Patent is indefinite because it "contains both method step limitations as well as an apparatus limitation[.]" (Oystar Action, Dkt. 404 at 8).[4] "[R]eciting both an apparatus and a method of using that apparatus renders a claim indefinite under section 112, paragraph 2." *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005). This is so because combining these "two separate statutory classes of invention" means that "a manufacturer or seller of the claimed apparatus would not know from the claim whether it might also be liable for contributory infringement because a buyer or user of the apparatus later performs the claimed method of using the apparatus." *Id.*

The Court disagrees that claim 9 of the '013 Patent improperly mixes apparatus and method claims. The Federal Circuit has made it clear that the concern identified in *IXPL Holdings* is not implicated where a method claim "recite[s] the physical structures of a system in which the claimed method is practiced," *Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 520 F.3d 1367, 1374 (Fed. Cir. 2008), which is the case here. Claim 9 of the '013 Patent would be infringed only by an individual "*practicing* the claimed method in a . . . [system] possessing the requisite structure," *id.* at 1375, and the ambiguity driving the analysis in *IXPL Holdings* is not present. A party claiming indefiniteness must show the same by clear and convincing evidence, *see Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1377 (Fed. Cir. 2015), and Kan-Pak has not borne that burden here.

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[4] Judge McCarthy did not reach this argument, due to his resolution of the means-plus-function issue.

For all these reasons, the Court agrees with Plaintiff that "a feedback control system for maintaining aseptic bottling conditions" is not a means-plus-function limitation, is not indefinite, and does not require further construction. Instead, this term takes its plain and ordinary meaning in the art.

D. Disinfecting The Bottles . . . With Hot Hydrogen Peroxide Spray

The next disputed claim term is "disinfecting the bottles . . . with hot hydrogen spray." In the September 3rd R&R, Judge McCarthy recommended that this claim term be construed "to mean that the hydrogen peroxide must be heated to its vaporization phase immediately before being applied to the container." (September 3rd R&R at 8). Both Plaintiff and Jasper object to this recommendation. Plaintiff argues that the term needs no construction and that the construction proposed by Judge McCarthy "creates a potential for confusion through its inclusion of the word 'immediately.'" (Jasper Action, Dkt. 343 at 28-29). Jasper argues that "the term is incapable of construction because 'hot' is indefinite." (Jasper Action, Dkt. 347 at 1).

The Court disagrees with Plaintiff that no further construction of this term is required. Plaintiff has not demonstrated that "hot," as used in this term, has a singular plain and ordinary meaning in the art, and the Court is obliged to resolve the parties' dispute as to what "hot" means in this context. *See O2 Micro*, 521 F.3d at 1360.

The Court further does not find the use of the word "immediately" problematic. As the Supreme Court has explained, the "inherent limitations of language" mean that

"absolute precision is unattainable" in drafting patents, *Nautilus, Inc. v. Biosig Instruments, Inc*., 572 U.S. 898, 909-10 (2014), and the same is equally true of construing claim terms. Courts frequently use the word "immediately" in claim construction, notwithstanding that it is not a mathematically precise unit of measure, and the Court finds no error in Judge McCarthy's recommendation on this basis.

Turning to Jasper's arguments, Jasper acknowledges that it, along with GEA and Nestlé, originally took the position that "hot hydrogen peroxide spray" should be construed to "require[] hydrogen peroxide to be heated to its vaporization phase and applied to the bottles in its vaporization phase." (Jasper Action, Dkt. 342 at 4). However, Jasper now takes the position that requiring vaporization improperly imports a limitation from the specification. (*Id*. at 5). Setting aside the procedural propriety of Jasper's change in position (*see* Jasper Action, Dkt. 348 at 4-10 (Plaintiff argues that Jasper is judicially estopped from making the arguments it now makes)), the Court disagrees. As Judge McCarthy explained in the September 3rd R&R, the evidence of record supports the conclusion that a person of ordinary skill in the art would understand "hot hydrogen peroxide spray," in the context of the specification and prosecution history of the '13 Patent, to mean heated to the vaporization phase. (September 3rd R&R at 7).

Jasper's arguments to the contrary are not persuasive. Jasper contends that the claim terms "hot atomized hydrogen peroxide" as used in claim 1 of '013 Patent and "the hot hydrogen peroxide spray" as used in claim 20 of the '013 Patent should be construed to

have the same meaning. (Jasper Action, Dkt. 342 at 5-6). However, these claim terms use different language, and the Court finds no basis to conclude that they should be treated as meaning the same thing. *See Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008) ("Our precedent instructs that different claim terms are presumed to have different meanings.").

Jasper's argument that the word "hot" must always mean the same thing wherever it is used in the '013 Patent fares no better. While it is true that "the usage of a term in one claim can often illuminate the meaning of the same term in other claims," *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005), the definition of "hot" necessarily depends on context. Indeed, Jasper itself has previously recognized this fact, having joined in GEA and Nestlé's argument that a person of ordinary skill in the art would "understand that 'hot' in the patent has different meanings depending on the context where it is used. . . . The meaning of 'hot' . . . depends on the substance being heated and the purpose for which it is heated." (Jasper Action, Dkt. 194 at 43; *see also* Jasper Action, Dkt. 195 at 44 and Dkt. 196 at 5).

For the foregoing reasons, and having reviewed the matter *de novo*, the Court agrees with Judge McCarthy that the claim term "disinfecting the bottles . . . with hot hydrogen peroxide spray" must be construed "to mean that the hydrogen peroxide must be heated to its vaporization phase immediately before being applied to the container." (September 3rd R&R at 8).

E. A Residual Level of Hydrogen Peroxide . . . Less Than 0.5 PPM

The final disputed claim term the Court must construe is "a residual level of hydrogen peroxide . . . less than 0.5 PPM." Judge McCarthy recommended that the Court construe "the residual level of hydrogen peroxide" to mean "the level determined in accordance with 21 C.F.R. § 178.1005(d)." (September 3rd R&R at 10).

Plaintiff argues that no construction of this claim term is necessary. (Jasper Action, Dkt. 343 at 29). The Court disagrees. As Judge McCarthy explained, Jasper has argued that this claim term is indefinite because it fails to provide reasonable clarity as to the manner in which the residual level is to be measured. (September 3rd R&R at 9). Judge McCarthy's proposed construction resolves this dispute, and Plaintiff acknowledges that "[t]he claim recites the well-known FDA requirement for residual hydrogen peroxide as reflected in 21 C.F.R. § 178.1005(d)." (Jasper Action, Dkt. 343 at 29). The Court adopts Judge McCarthy's proposed construction as to this term.

V. Modification of Referral Orders

When these actions were transferred to the undersigned from another district judge over six years ago, that judge had referred the actions to Judge McCarthy both for non-dispositive matters and to hear and report on dispositive matters. (Oystar Action, Dkt. 100; GEA Action, Dkt. 82; Nestlé Action, Dkt. 18; Jasper Action, Dkt. 18). As the parties have been previously advised, issuing a dispositive referral order is not the undersigned's typical practice, but the dispositive referral orders were left in place for various reasons that

seemed to make sense at the time. Unfortunately, despite Judge McCarthy's exhaustive efforts to keep these matters on track, the complexity of the subject matter and the parties' litigation tactics have resulted in significant delay—indeed, the Oystar Action was commenced more than 10 years ago. The undersigned no longer believes that a dispositive referral order makes sense, and it is noted that this conclusion was reached after consulting with Judge McCarthy, who also agrees with that conclusion. Therefore, for the sake of efficiency, the Court finds it necessary to modify the referral orders in each of these actions. Judge McCarthy shall continue to supervise all non-dispositive matters, including case management, discovery, and scheduling issues. However, dispositive matters, including resolution of claim construction disputes, are no longer referred but will be handled in the first instance by the undersigned.

CONCLUSION

For the reasons set forth above, the Court: (1) denies Nestlé's motion to strike (Nestlé Action, Dkt. 453); (2) adopts in part and modifies in part the March 16th R&R (Oystar Action, Dkt. 373; GEA Action, Dkt. 599; Nestlé Action, Dkt. 431; Jasper Action, Dkt. 317); (3) adopts in part and declines to adopt in part the September 3rd R&R (Oystar Action, Dkt. 394; GEA Action, Dkt. 619; Nestlé Action, Dkt. 452; Jasper Action, Dkt. 338); and (4) modifies the referral orders (Oystar Action, Dkt. 100; GEA Action, Dkt. 82; Nestlé Action, Dkt. 18; Jasper Action, Dkt. 18) to provide that dispositive matters shall be heard directly by the undersigned. The Court's construction of the claim terms at issue is

as follows: (1) "aseptically disinfecting" is construed to require use of a sterilant approved by the FDA for achieving commercial sterility as of February 2, 1999; (2) "at a rate greater than 100 bottles per minute" is construed to mean "at a rate greater than 100 bottles per minute, with no upper limit on said rate"; (3) "a feedback control system for maintaining aseptic bottling conditions" takes its plain and ordinary meaning in the art; (4) "disinfecting the bottles . . . with hot hydrogen peroxide spray" is construed to mean that the hydrogen peroxide must be heated to its vaporization phase immediately before being applied to the container; and (5) "a residual level of hydrogen peroxide . . . less than 0.5 PPM" is construed such that the "residual level of hydrogen peroxide" refers to the level determined in accordance with 21 C.F.R. §178.1005(d).

SO ORDERED.

ELIZABETH A. WOLFORD
United States District Judge

Dated: February 18, 2021
Rochester, New York