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. 1:10-CV-00781 EAW

SHIBUYA HOPPMANN CORP., SHIBUYA KOGYO CO. LTD, and HP HOOD LLC,

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 1:10-cv-00781

(the "Shibuya Action"), Dkt. 112; 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).

On June 1, 2018, defendants in the Oystar Action, the GEA Action, the Nestlé Action, and the Jasper Action jointly moved for partial summary judgment pursuant to Federal Rule of Civil Procedure 56. (Oystar Action, Dkt. 292; GEA Action, Dkt. 506; Nestlé Action, Dkt. 335; Jasper Action, Dkt. 245). That same day, defendants in the Shibuya Action filed their own motion for summary judgment. (Shibuya Action, Dkt. 399). On October 1, 2018, Judge McCarthy issued a Report and Recommendation (Oystar Action, Dkt. 320; Shibuya Action, Dkt. 424; GEA Action, Dkt. 536; Nestlé Action, Dkt. 365; Jasper Action, Dkt. 272) (the "R&R") recommending that the pending motions for summary judgment be "granted to the extent of invalidating claim 40 of [United States Patent No. 6,536,188] and limiting the sterilant in the other 'aseptically disinfecting' claims to hydrogen peroxide, but otherwise be denied." (R&R at 12-13)[1].

Plaintiff filed objections to the R&R in each of the actions. (Oystar Action, Dkt. 329; Shibuya Action, Dkt. 434; GEA Action, Dkt. 548; Nestlé Action, Dkt. 365; Jasper Action, Dkt. 272) (hereinafter "Plaintiff's Objections"). Objections have also been filed by defendants HAMBA Filltec GmbH & Co.KG, OYSTAR Group, OYSTAR Hamba,

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[1] Consistent with Judge McCarthy's practice in the R&R, and for the avoidance of confusion given the multiple dockets at issue, page references in this Decision and Order are to those found on the original documents, and not to those generated by the Court's Case Management/Electronic Case Files system.

OYSTAR North America-Edison, Inc., and Oystar USA, Inc. (collectively the "Oystar Defendants") (Oystar Action, Dkt. 327), defendant Kan-Pak, LLC ("Kan-Pak") (Oystar Action, Dkt. 328), and defendants Shibuya Hoppmann Corporation, Shibuya Kogyo Co., Ltd., and HP Hood LLC (collectively the "Shibuya/Hood Defendants") (Shibuya Action, Dkt. 435).

For the reasons set forth below, the Court declines to adopt the R&R, and instead finds that there are outstanding issues of material fact as to whether claim 40 of United States Patent No. 6,536,188 is invalid for lack of a written description. The Court further finds that, because the R&R's claim construction analysis is inextricably intertwined with the analysis of claim 40's validity, construction of the term "aseptically disinfecting," as used in the patents in suit, is not currently ripe for the undersigned's review. The Court accordingly denies the pending motions for summary judgment without prejudice to renewal on a more fully developed record.

FACTUAL AND PROCEDURAL BACKGROUND

Additional factual and procedural background related to the instant actions is set forth in the R&R, familiarity with which is assumed for purposes of this Decision and Order. The Court has summarized the salient information here for ease of reference.

Plaintiff is the owner of several patents related to methods for aseptically bottling and packaging sterilized food products, including United States Patent No. 6,945,013 (the "'013 Patent"), United States Patent No. 6,702,985 (the "'985 Patent"), United States

Patent No. 6,481,468 (the "'468 Patent"), and United States Patent No. 6,536,188 (the "'188 Patent"). (*See* Oystar Action, Dkt. 238 at 1). Numerous claims in the patents in suit use the term "aseptically disinfecting," the construction of which relates to the conclusions set out in the R&R. (R&R at 1) ("This Report and Recommendation addresses the question of whether the phrase 'aseptically disinfecting,' contained in several claims of the patents in suit, can be validly construed and/or applied to cover the use of a sterilant known as oxonia[.]").

The '188 Patent (among others) provides background information that helps put in context some of the issues in this litigation. As explained in the '188 Patent, "[p]ackaged food products can generally be categorized as high acid products . . . or low acid products[.]" ('188 Patent col. 1, ll. 22-23). Unlike high acid products that naturally inhibit bacterial growth, low acid products must use "more stringent packaging techniques" to extend their shelf lives, and "often require[] refrigeration of the product at the point of sale." (*Id.* col. 1, ll. 23-28). Aseptic packaging is a means of significantly extending the shelf life of low acid products and involves the use of presterilized containers in a sterilized environment. (*Id.* col. 1, ll. 38-45). The FDA regulates aseptic packaging within the United States and requires the use of an FDA-approved sterilant and satisfaction of various other quality control measures. (*See id.* col. 1, l. 46-54).

The patents in suit define the term "aseptic" as "the United States 'FDA level of aseptic.'" *Nestlé USA, Inc. v. Steuben Foods, Inc.*, 686 F. App'x 917, 919 (Fed. Cir. 2017)

(quoting the '013 Patent col. 1 l. 67-col 2. l. 2, col. 4 ll. 28-29). The Federal Circuit has construed "FDA level of aseptic" as defined by "FDA regulations related to aseptic packaging." *Id.* One such regulation is 21 C.F.R. § 113, which states in relevant part that "[a]septic processing and packaging means 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," and that "commercial sterility" is achieved by the application of "heat, chemical sterilant(s), or other appropriate treatment." 21 C.F.R. § 113(a), (e)(2). At the time the patents in suit were filed, the only FDA approved chemical sterilant was hydrogen peroxide. Oxonia, which is a combination of hydrogen peroxide and peroxyacetic acid, and which is used as a sterilant by certain of the defendants in these actions, was not FDA-approved at the relevant time. (*See* R&R at 1-3). Nevertheless, the specifications of several of the patents in suit state that either hydrogen peroxide or oxonia may be used as a sterilant. (*See id.* at 4). Moreover, claim 40 of the '188 Patent specifically describes a method of aseptic packaging wherein the sterilant is oxonia. ('188 Patent at col. 6, ll. 14-15, 25-26).

At his deposition, Thomas D. Taggart ("Taggart"), the listed inventor for each of the patents in suit, was asked whether the term "aseptically disinfecting" requires the use of an FDA-approved sterilant and he responded that it did. (*See* GEA Action, Dkt. 427-11 (hereinafter the "Taggart EBT") at 385:25-386:7 ("Q: In your patents you use the term 'aseptically disinfecting'. . . . As you understand the term 'aseptic disinfecting,' does that

require the use of an FDA-approved sterilant? . . . A: Yes. That's what I think it's supposed to mean."). As Judge McCarthy noted in the R&R, the relevant patent specifications also indicate that "[f]or the aseptic packaging of food products, an aseptic filler must . . . use an FDA (Food and Drug Administration) approved sterilant." (*Id.* at 3 (quoting '013 patent col. 1, ll.48-50; '188 patent col. 1, ll. 46-48)).

Taggart further testified at his deposition that prior to filing the relevant patent applications, he had never used oxonia as a sterilant, nor did he have any knowledge regarding oxonia's effectiveness as a sterilant. (*See* Taggart EBT at 232:10-233:3)[2]. For example, when asked whether peroxyacetic acid could achieve a "6-log reduction in spore organisms,"[3] Taggart replied that he "would think that it could" but that this was "just an opinion." (*Id.* at 173:23-174:10). Taggart further stated that he had never seen oxonia's components used "in a vaporized form as a container sterilant" and that he did not know whether oxonia's components could "be applied in a vapor form and receive approval from the FDA." (*Id.* at 172:9-12, 173:5-8).

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[2] Throughout his deposition testimony, Taggart frequently referred to "peracetic acid." As Judge McCarthy noted in the R&R, the parties have agreed that "peracetic acid" is synonymous with "peroxyacetic acid," which is one of the components of oxonia. (R&R at 4 n.6).

[3] Taggart had testified earlier that at the time the patents in suit were written, the FDA required a 6-log reduction in spore organisms to qualify as aseptic sterilization. (Taggart EBT at 28:7-15).

Judge McCarthy held a *Markman*[4] hearing on January 31, 2018, in order to consider the construction of the term "aseptically disinfecting" as used in the patents in suit. (*See* Oystar Action, Dkt. 273). Thereafter, on February 13, 2018, Judge McCarthy issued a notice pursuant to Federal Rule of Civil Procedure 56(f)(3)[5] in which he indicated that although he and the parties "had planned to defer consideration of validity issues until after claim construction," it "appear[ed] to [him] that the phrase 'aseptically disinfecting' . . . cannot be properly construed without also considering certain validity issues, namely enablement and utility." (Oystar Action, Dkt. 275; Shibuya Action, Dkt. 376; GEA Action, Dkt. 486; Nestlé Action, Dkt. 318; Jasper Action, Dkt. 228) (the "First Rule 56(f)(3) Notice"). Judge McCarthy further gave the parties notice of facts that appeared to be undisputed, and set forth legal reasoning as to why, in his view, these undisputed facts rendered claim 40 of the '188 Patent invalid for lack of enablement and utility and required that the phrase "aseptically disinfecting" in all other relevant claims of the patents in suit be limited to the use of hydrogen peroxide. (First Rule 56(f)(3) Notice at 2-6). Judge McCarthy ordered the parties to, on or before March 6, 2018, "show cause why summary judgment should not be granted: (1) declaring claim 40 of the '188 Patent to be invalid, and (2) limiting the meaning of the phrase 'aseptically disinfecting' as used in the other patent claims to those methods using hydrogen peroxide as the sterilant." (*Id.* at 6). Judge

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4 *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384 (1996).

5 Pursuant to Rule 56(f)(3), the Court may "consider summary judgment on its own after identifying for the parties material facts that may not be genuinely in dispute."

McCarthy subsequently moved the response deadline to March 20, 2018. (*See, e.g.,* Oystar Action, Dkt. 276).

The parties filed responses to the First Rule 56(f)(3) Notice on March 20, 2018. (Oystar Action, Dkt. 278; Oystar Action, Dkt. 279; Shibuya Action, Dkt. 382; Shibuya Action, Dkt. 383; GEA Action, Dkt. 490; GEA Action, Dkt. 491; GEA Action, Dkt. 492; Nestlé Action, Dkt. 321; Nestlé Action, Dkt. 322; Jasper Action, Dkt. 231; Jasper Action, Dkt. 232). On April 3, 2018, Judge McCarthy issued a second Rule 56(f)(3) notice. (Oystar Action, Dkt. 283; Shibuya Action, Dkt. 388; GEA Action, Dkt. 497; Nestlé Action, Dkt. 326; Jasper Action, Dkt. 236) (the "Second Rule 56(f)(3) Notice"). In the Second Rule 56(f)(3) Notice, Judge McCarthy explained that although the First Rule 56(f)(3) Notice had focused on enablement and utility, "a separate question is whether Taggart actually *invented* a system utilizing oxonia – that is, whether he both conceived the invention and reduced it to practice." (*Id.* at 1). Judge McCarthy explained that he had "tentatively conclude[d] that the record clearly and convincingly demonstrates" that Taggart had neither conceived nor reduced to practice the use of oxonia as a sterilant, that claim 40 of the '188 Patent is invalid, and that "even if the phrase 'aseptically disinfecting' can be construed to include oxonia as the sterilant, the patents cannot validly be applied to its use." (*Id.* at 5).

On April 20, 2018, Judge McCarthy entered a Decision and Order setting forth his preliminary construction of the term "aseptically disinfecting." (Oystar Action, Dkt. 287;

Shibuya Action, Dkt. 392; GEA Action, Dkt. 501; Nestlé Action, Dkt. 330; Jasper Action, Dkt. 240) (the "Claim Construction D&O"). In the Claim Construction D&O, Judge McCarthy concluded as follows: (1) "aseptically disinfecting" cannot be construed to preclude the use of oxonia; and (2) the term "aseptically disinfecting" is properly construed "to mean the use of a sterilant capable of being approved by the FDA, as of the effective patent filing date, to satisfy the 'FDA level of aseptic' defined by the Federal Circuit in Nestle USA, Inc. v. Steuben Foods, Inc., 686 Fed. App'x 917, 918-19 (Fed. Cir. 2017)." (*Id.* at 2-5). Judge McCarthy further explained that, based on the record before him, he did not believe that the patents in suit contained a valid written description of a packaging method using oxonia as a sterilant. (*Id.* at 6-11). The Claim Construction D&O indicated that it was not a final document and that Judge McCarthy's construction of the term "aseptically disinfecting" would ultimately be incorporated into a report and recommendation. (*Id.* at 1 n.2).

On April 30, 2018, Judge McCarthy ordered Defendants to file any motions "for summary judgment based upon invalidity for insufficient written description" by no later than June 1, 2018. (Oystar Action, Dkt. 290; Shibuya Action, Dkt. 395; GEA Action, Dkt. 504; Nestlé Action, Dkt. 333; Jasper Action, Dkt. 243). Defendants filed their partial summary judgment motions on June 1, 2018. (Oystar Action, Dkt. 292; Shibuya Action, Dkt. 399; GEA Action, Dkt. 506; Nestlé Action, Dkt. 335; Jasper Action, Dkt. 245). On July 10, 2018, Plaintiff filed a motion pursuant to Federal Rule of Civil Procedure 56(d)

for discovery related to Defendants' pending partial summary judgment motions. (Oystar Action, Dkt. 299; Shibuya Action, Dkt. 404; GEA Action, Dkt. 513; Nestlé Action, Dkt. 343; Jasper Action, Dkt. 251). Judge McCarthy issued a Decision and Order denying the request for discovery on July 11, 2018. (Oystar Action, Dkt. 302; Shibuya Action, Dkt. 407; GEA Action, Dkt. 516; Nestlé Action, Dkt. 346; Jasper Action, Dkt. 254).

That same day, Judge McCarthy issued a third Rule 56(f)(3) notice. (Oystar Action, Dkt. 303; Shibuya Action, Dkt. 408; GEA Action, Dkt. 517; Nestlé Action, Dkt. 347; Jasper Action, Dkt. 255) (the "Third Rule 56(f)(3) Notice"). In the Third Rule 56(f)(3) Notice, Judge McCarthy explained that his "sole focus" in considering whether partial summary judgment in Defendants' favor was warranted would be "on whether Thomas Taggart invented a method for aseptically disinfecting containers using oxonia as a sterilant." (*Id.* at 1). Judge McCarthy incorporated by reference the Second Rule 56(f)(3) Notice, the Claim Construction D&O, and Defendants' motions for partial summary judgment "to the extent that those motions relate to invention by Mr. Taggart," and ordered Plaintiff to "show cause why summary judgment of invalidity should not be entered[.]" (*Id.* at 2).

Plaintiff filed its response to the Third Rule 56(f)(3) notice on August 24, 2018 (Oystar Action, Dkt. 307; Shibuya Action, Dkt. 412; GEA Action, Dkt. 521; Nestlé Action, Dkt. 351; Jasper Action, Dkt. 259), and Defendants filed replies on September 14, 2018 (Oystar Action, Dkt. 312; Oystar Action, Dkt. 313; Shibuya Action, Dkt. 417; GEA Action,

Dkt. 529; Nestlé Action, Dkt. 358; Jasper Action, Dkt. 264; Jasper Action, Dkt. 265). Judge McCarthy held oral argument on September 19, 2018. (*See, e.g.,* Oystar Action, Dkt. 314).

Judge McCarthy issued the R&R on October 1, 2018. (Oystar Action, Dkt. 320; Shibuya Action, Dkt. 424; GEA Action, Dkt. 536; Nestlé Action, Dkt. 365; Jasper Action, Dkt. 272). The R&R reaches the following conclusions: (1) the phrase "aseptically disinfecting . . . cannot validly cover the use of oxonia as the sterilant"; (2) as of the filing date of the patents in suit, Taggart could not have satisfied the FDA's requirements for approval of oxonia as a sterilant; (3) Taggart did not adequately describe the invention defined in claim 40 of the '188 Patent[6]; and (4) "those aseptically disinfecting claims which do not identify the sterilant should be construed to preserve their validity by limiting the sterilant to hydrogen peroxide, the only sterilant which has been properly described." (*Id.* at 2-12). Based on these conclusions, the R&R recommends granting Defendants' motions for partial summary judgment to the extent of finding claim 40 of the '188 Patent invalid and limiting the term "aseptically disinfecting" to the use of hydrogen peroxide as a sterilant in all remaining claims of the patents in suit. (*Id.* at 12-13).

Plaintiff, the Oystar Defendants, Kan-Pak, and the Shibuya/Hood Defendants filed objections to the R&R on November 2, 2018. (Oystar Action, Dkt. 327; Oystar Action,

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[6] Claim 40 of the '188 Patent claims "[a] method for aseptically bottling aseptically sterilized foodstuffs . . . wherein the sterilant is peroxyacetic acid and hydrogen peroxide[.]" ('188 Patent at col. 6, ll. 14-15, 25-26).

Dkt. 328; Oystar Action, Dkt. 329; Shibuya Action, Dkt. 435; GEA Action, Dkt. 548; Nestlé Action, Dkt. 365; Jasper Action, Dkt. 272). Responses were filed on December 3, 2018 (Oystar Action, Dkt. 330; Oystar Action, Dkt. 331; Oystar Action, Dkt. 332; Shibuya Action, Dkt. 436; GEA Action, Dkt. 549; GEA Action, Dkt. 550; Nestlé Action, Dkt. 376; Nestlé Action, Dkt. 377; Nestlé Action, Dkt. 378; Jasper Action, Dkt. 280; Jasper Action, Dkt. 281), and replies were filed on December 21, 2018 (Oystar Action, Dkt. 336; Oystar Action, Dkt. 337; Shibuya Action, Dkt. 442; Shibuya Action, Dkt. 443; GEA Action, Dkt. 555; GEA Action, Dkt. 556; Nestlé Action, Dkt. 383; Nestlé Action, Dkt. 384; Jasper Action, Dkt. 285; Jasper Action, Dkt. 286). With the Court's permission, sur-replies were filed in the GEA and Nestlé Actions on January 16, 2019. (GEA Action, Dkt. 559; Nestlé Action, Dkt. 388).

Oral argument on the pending objections was held on February 26, 2019. (*See* Oystar Action, Dkt. 342). Post-argument, Plaintiff filed a motion seeking leave to file supplemental briefing regarding the impact of a May 8, 2019, decision by the Patent Trial and Appeal Board. (Dkt. 349). The Court granted Plaintiff's motion (Dkt. 350), and the parties filed supplemental briefs on May 24, 2019. (*See* Oystar Action, Dkt. 352; Shibuya Action, Dkt. 457; Shibuya Action, Dkt. 458; GEA Action, Dkt. 571; GEA Action, Dkt. 572; Nestlé Action, Dkt. 402; Nestlé Action, Dkt. 403; Jasper Action, Dkt. 296; Jasper Action, Dkt. 297).

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 Summary Judgment

Rule 56 of the Federal Rules of Civil Procedure provides that summary judgment should be granted if the moving party establishes "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The Court should grant summary judgment if, after considering the evidence in the light most favorable to the nonmoving party, the court finds that no rational jury could find in favor of that party. *Scott v. Harris*, 550 U.S. 372, 380 (2007) (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986)).

"The moving party bears the burden of showing the absence of a genuine dispute as to any material fact. . . ." *Crawford v. Franklin Credit Mgmt. Corp.*, 758 F.3d 473, 486

(2d Cir. 2014). "Where the non-moving party will bear the burden of proof at trial, the party moving for summary judgment may meet its burden by showing the evidentiary materials of record, if reduced to admissible evidence, would be insufficient to carry the non-movant's burden of proof at trial." *Johnson v. Xerox Corp.*, 838 F. Supp. 2d 99, 103 (W.D.N.Y. 2011) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986)). Once the moving party has met its burden, the opposing party "must do more than simply show that there is some metaphysical doubt as to the material facts, and may not rely on conclusory allegations or unsubstantiated speculation." *Robinson v. Concentra Health Servs., Inc.*, 781 F.3d 42, 44 (2d Cir. 2015) (quoting *Brown v. Eli Lilly & Co.*, 654 F.3d 347, 358 (2d Cir. 2011)). Specifically, the non-moving party "must come forward with specific evidence demonstrating the existence of a genuine dispute of material fact." *Brown*, 654 F.3d at 358. Indeed, "the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986).

III. Legal Standard for Claim Construction

The R&R in this matter involves claim construction issues. 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.

Markman v. Westview Instruments, Inc., 517 U.S. 370, 384 (1996) (quotation omitted).

> 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 and citations omitted). "To ascertain the scope and meaning of the asserted claims, [a court] look[s] to the words of the claims themselves, the specification, the prosecution history, and any relevant extrinsic evidence." *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1217-18 (Fed. Cir. 2014). "Claim construction issues are often dispositive of the parties' claims and defenses in a particular case," and the Court therefore reviews a magistrate judge's claim construction determination *de novo* where, as here, objections are made. *Fisher-Price, Inc. v. Kids II, Inc.*, No. 1:10-CV-00988 EAW, 2015 WL 2401887, at *1 (W.D.N.Y. May 19, 2015).

IV. Validity of Claim 40 of the '188 Patent

The primary issue considered by the R&R is whether claim 40 of the '188 Patent is invalid for lack of written description. (*See* R&R at 7-11). This is also the subject matter of the pending motions for summary judgment. (*See* Oystar Action, Dkt. 292; Shibuya

Action, Dkt. 399). Moreover, and as discussed further below, the R&R's construction of the term "aseptically disinfecting" depends upon and is informed by Judge McCarthy's assessment of claim 40's validity. As such, the Court considers the validity issue first.

Plaintiff makes the following objections to the R&R's conclusions regarding the validity of claim 40 of the '188 Patent: (1) the R&R applied an improper legal standard in determining whether the '188 Patent complied with the written description requirement of 35 U.S.C. § 112 and erroneously concluded that the '188 Patent failed to satisfy the written description requirement; and (2) the R&R misapplied the standard for summary judgment in that all reasonable inferences were not drawn in Plaintiff's favor. The Court has considered these arguments *de novo* and finds, for the reasons set forth below, that, at this stage of the proceedings, there are genuine issues of material fact as to whether claim '40 is invalid for a lack of written description. The Court accordingly declines to adopt the R&R.

A. Written Description Requirement

Pursuant to 35 U.S.C. § 112(a), a patent must have a specification that contains:

> [A] written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

Id. As the Federal Circuit has explained, § 112(a) contains three separate requirements that are described "[i]n common parlance . . . as the 'written description requirement,' the

'enablement requirement,' and the 'best mode requirement,' respectively." *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 921 (Fed. Cir. 2004). "Although there is often significant overlap between the three requirements, they are nonetheless independent of each other." *Id.* In particular, "the written description requirement retains independent force, because 'requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described.'" *Petito v. Puritan's Pride, Inc.*, 35 F. Supp. 3d 494, 512 (S.D.N.Y. 2014) (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349-50 (Fed. Cir. 2010)). "The essence of the written description requirement is that a patent applicant, as part of the bargain with the public, must describe his or her invention so that the public will know what it is and that he or she has truly made the claimed invention." *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1298 (Fed. Cir. 2014).

To satisfy the written description requirement, the specification must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Ariad*, 598 F.3d at 1351(quotation omitted and alteration in original). Inherent in the written description requirement is "the fundamental issue whether [the inventor] actually invented the subject matter it claimed in the" contested patent. *Univ. of Rochester*, 358 F.3d at 930 n.10. The written description requirement accordingly requires that the specification "show that the inventor actually invented the invention claimed." *Ariad*, 598

F.3d at 1351. As the Federal Circuit has explained, "[r]equiring a written description of the invention limits patent protection to those who actually perform the difficult work of invention—that is, conceive of and complete the final invention. The written description requirement exists to ensure that inventors do not attempt to preempt the future before it has arrived." *Billups-Rothenberg, Inc. v. Associated Reg'l & Univ. Pathologists, Inc.*, 642 F.3d 1031, 1036 (Fed. Cir. 2011) (internal quotations and citations omitted). The written description requirement, "does not demand either examples or an actual reduction to practice," but does require a "constructive reduction to practice that in a definite way identifies the claimed invention." *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285 (Fed. Cir. 2012) (quotation omitted).

"It is well established that a patent is presumed valid, and the burden of persuasion to the contrary is and remains on the party asserting invalidity." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1303 (Fed. Cir. 2008) (quotation omitted). Accordingly, "invalidating a claim requires a showing by clear and convincing evidence that the written description requirement has not been satisfied." *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1072 (Fed. Cir. 2005) "Compliance with the written description requirement is a question of fact but is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *PowerOasis,* 522 F.3d at 1307.

In this case, applying the law described above, Judge McCarthy found that no reasonable fact finder could conclude that Taggart had actually invented (that is, conceived and constructively reduced to practice) a method for aseptic packaging using oxonia as a sterilant as of the date the patents in suit were filed. (R&R at 7-11). Accordingly, Judge McCarthy concluded that claim 40 of the '188 Patent is invalid for failure to satisfy the written description requirement. (*Id.*).

Having reviewed the record, the R&R, and all the parties' submissions, and upon *de novo* review, the Court finds it to be an exceedingly close question whether the evidence conclusively demonstrates claim 40 of the '188 Patent is invalid for lack of a written description. Ultimately, mindful that compliance with the written description is a question of fact on which summary judgment is appropriate only in narrow circumstances, the Court finds that there are outstanding factual issues that cannot be resolved on the instant record.

Taggart's testimony (and the other undisputed evidence of record) establishes the following: (1) the packaging methods described in the patents in suit require the use of a sterilant that, at a minimum, was capable of achieving FDA approval; (2) as of the date the applications for the patents in suit were filed, oxonia was not an FDA-approved sterilant; (3) as of the date the applications for the patents in suit were filed, Taggart had no knowledge as to whether oxonia could achieve the level of sterilization necessary to satisfy FDA requirements, but instead stated that if "testing was done and the right data was presented to the FDA, they might approve it" (Taggart EBT at 227:4-8); (4) Taggart did

not do any testing to ascertain nor did he ever know "how long you need to expose the bottle to [oxonia's components], what temperature the [components] need[] to be or what the airflows need to be to make [the components] meet FDA standards as a bottle sterilant" (*id.* at 229:9-19); and (5) Taggart had no knowledge of the effectiveness of oxonia as a sterilant (*id.* at 232:6-13). The Court does not disagree with Judge McCarthy that these facts seriously call into question whether Taggart was capable of satisfying the written description with respect to a bottling method in which oxonia was the sterilant.

However, the Court finds merit in Plaintiff's argument that the record lacks information regarding the perspective of a person of ordinary skill in the art, and that further discovery is required on this point. "The standard for satisfying the written description requirement is whether the disclosure allows one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014) (quotation and alteration omitted); *see also Ariad*, 598 F.3d at 1351 (explaining that "whatever the specific articulation, the test [for written description] requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." (emphasis added)). In particular, "the critical inquiry is whether the patentee has provided a description that in a definite way identifies the claimed invention in sufficient detail that a person of ordinary skill would understand that the inventor was in possession of it at the time of filing." *Alcon*, 745 F.3d at 1190-91 (quotation omitted).

In this case, the record is underdeveloped as to what a person of ordinary skill in the art would have known about oxonia's suitability for use as a sterilant in February of 1999, when the applications for the patents in suit were filed. In the Court's view, this underdevelopment of the record prevents a finding of invalidity due to lack of written description at this stage of the proceedings, because what is required to satisfy the written description requirement "varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence," and the amount of "descriptive text" needed depends upon "the state of knowledge in the field and differences in the predictability of the science." *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005). Moreover, while Taggart's testimony clearly establishes that he did not know whether his purported "invention" of an oxonia-based system was actually feasible, "an inventor need not know that his invention will work for conception to be complete." *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). In other words, because it is not *per se* necessary that Taggart knew that an oxonia-based aseptic bottling method could work, and because "[i]n some circumstances, . . . a patentee may rely on information that is well-known in the art for purposes of meeting the written description requirement," *Ajinomoto Co. v. Int'l Trade Comm'n*, 932 F.3d 1342, 1359 (Fed. Cir. 2019) (quotation omitted), further discovery into the state of general knowledge regarding oxonia's suitability as a sterilant at the relevant time is necessary.

To be clear, the Court does not find that claim 40 of the '188 Patent contains a sufficient written description. To the contrary, Taggart's testimony at a minimum creates grave doubts that the written description requirement has been (or could have been) satisfied. The Court particularly rejects Plaintiff's argument that the language of originally-filed claim 12 of the '188 Patent (which identifies oxonia as the sterilant)[7] is, standing alone, sufficient to satisfy the written description requirement or, at a minimum, to preclude entry of summary judgment. (*See* Plaintiff's Objections at 16-17). The Federal Circuit in *Medtronic Navigation, Inc. v. BrainLab Medizinische Computersysteme GmbH*, 222 F. App'x 952 (Fed. Cir. 2007) rejected the argument that this sort of unelaborated "minimal one sentence reference" is sufficient to disclose a claimed invention. *Id.* at 956-57 (finding patent claim invalid where it contained "a minimal dropping of an unenabled reference to an undeveloped [optical] system," but the inventor testified that at the time of his invention he was not "aware of any commercial optical tracking system that was available," and the specification therefore did not contain "a disclosure of an optical system sufficient to support an interpretation of a claim as including an optical system" (emphasis added)). Plaintiff's arguments regarding the language of originally-filed claim 12 are ultimately inconsistent with well-established case law requiring actual invention to comply with the written description requirement. Were the Court to adopt Plaintiff's argument and

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[7] Originally filed claim 12 of the '188 Patent was cancelled pursuant to an *ex parte* reexamination certificate issued under 34 U.S.C. § 307 on September 12, 2013. (*See* Oystar Action, Dkt. 238-5 at 27-30).

hold to the contrary, patentees could effectively preempt future scientific advances by including in their patent applications unelaborated and untested guesses, resulting in precisely the kind of "hunting license" the Supreme Court has warned against. *Brenner v. Manson*, 383 U.S. 519, 536 (1966) ("A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

The Court further rejects Plaintiff's contention that it was improper for Judge McCarthy to consider conception and reduction to practice in the context of the written description requirement. Contrary to Plaintiff's argument that conception and reduction to practice are relevant only to considerations of priority and inventorship (*see* Plaintiff's Objections at 12-15), the Federal Circuit has made it clear that, at a minimum, "a constructive reduction to practice that in a definite way identifies the claimed invention" is required to satisfy the written description requirement. *Ariad*, 598 F.3d at 1352. The Federal Circuit's recent decision in *Centrak, Inc. v. Sonitor Techs., Inc.*, 915 F.3d 1360 (Fed. Cir. 2019), confirms this conclusion. In *Centrak*, the Federal Circuit expressly considered whether the evidence of record demonstrated that the inventors "did not . . . constructively reduce to practice a system with [particular] components" in assessing whether the written description requirement had been satisfied. *Id.* at 1366-67. Accordingly, issues of conception and reduction to practice may be implicated in ascertaining whether the written description requirement has been satisfied.

Moreover, while Plaintiff is correct that "[t]he filing of a patent application serves as conception and constructive reduction to practice of the subject matter described in the application" for purposes of establishing priority of invention, even in that context, the Federal Circuit has explained that the application must "meet the requirements of . . . §112[.]" *Hyatt v. Boone*, 146 F3d. 1348, 1352 (1998). In other words, the case law establishes that a patent application that satisfies the written description requirement is adequate proof of conception and constructive reduction of practice; however, this case law does not apply where the written description requirement has not been satisfied. On a fuller record, it may well be the case that a person of ordinary skill in the art could not discern from the language of claim 40 of the '188 Patent that Taggart actually conceived of, or constructively reduced to practice, an oxonia-based system.

For all these reasons, and having reviewed the matter *de novo*, the Court declines, at this stage of the proceedings, to adopt the R&R's conclusion that claim 40 of the '188 Patent is invalid for lack of written description. The Court further denies, without prejudice to renewal following additional discovery, the pending summary judgment motions.

V. Construction of "Aseptically Disinfecting"

In addition to assessing the validity of claim 40 of the '188 Patent, the R&R also addresses the construction of the phrase "aseptically disinfecting," as it is used in the patents in suit. (*See* R&R at 2, 11-12). In particular, Judge McCarthy concluded that "whatever else it may mean, the phrase cannot validly cover the use of oxonia as the

sterilant." (*Id.* at 2). Judge McCarthy further concluded that "those 'aseptically disinfecting' claims which do not identify the sterilant should be construed to preserve their validity by limiting the sterilant to hydrogen peroxide, the only sterilant which has been properly described." (*Id.* at 12).

Judge McCarthy's claim construction analysis was informed by and relied upon his assessment of claim 40 of the '188 Patent's validity. (*See* First Rule 56(f)(3) Notice at 1 (explaining that, in Judge McCarthy's view, "the phrase 'aseptically disinfecting' . . . cannot be properly construed without also considering certain validity issues"); Third Rule 56(f)(3) Notice at 1 (stating that "the court's sole focus at this time will be on whether Thomas Taggart invented a method for aseptically disinfecting containers using oxonia as the sterilant")). Importantly, Judge McCarthy did not reach a determination on the "various constructions of 'aseptically disinfecting'" that the parties had proposed, but instead reached a more limited conclusion based on his validity analysis. (R&R at 2). Under these circumstances, given the Court's conclusion that further discovery as to claim 40 of the '188 Patent's validity is required, the Court does not consider the claim construction issue ripe for review. Instead, the Court anticipates that, after further discovery and consideration of the validity issue on a fuller record, Judge McCarthy will be in a position to also reassess the claim construction issue, after which time the parties may seek review from the undersigned if they so choose.

CONCLUSION

For the reasons set forth above, the Court declines to adopt the R&R (Oystar Action, Dkt. 320; Shibuya Action, Dkt. 424; GEA Action, Dkt. 536; Nestlé Action, Dkt. 365; Jasper Action, Dkt. 272), and denies without prejudice Defendants' motions for partial summary judgment (Oystar Action, Dkt. 292; Shibuya Action, Dkt. 399; GEA Action, Dkt. 506; Nestlé Action, Dkt. 335; Jasper Action, Dkt. 245).

SO ORDERED.

ELIZABETH A. WOLFORD
United States District Judge

Dated: September 16, 2019
Rochester, New York