NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHIESI USA, INC., *et al.*, Plaintiffs, v. **AUROBINDO PHARMA USA, INC., *et al.*,** Defendants.	Civil Action No. 3:19-cv-18756-ZNQ-LHG **CLAIM CONSTRUCTION OPINION**

QURAISHI, District Judge

In this claim construction Opinion, the Court construes disputed claim terms in three patents directed to formulations of clevidipine. The parties' submitted the following briefs: Plaintiffs' Opening Brief (ECF No. 47), Defendants' Opening Brief (Corrected) (ECF No. 48), Defendants' Response Brief (ECF No. 49), and Plaintiffs' Response Brief (ECF No. 50). After reviewing the parties' briefs and exhibits, as well as the transcript and the parties' presentation materials from a *Markman* hearing conducted before the Honorable Freda L. Wolfson, U.S.C.D.J., the Court construes the disputed terms as set forth herein.

I. PROCEDURAL HISTORY

Plaintiffs Chiesi USA, Inc., and Chiesi Farmaceutici S.P.A. (collectively, "Plaintiffs" or "Chiesi") brought this patent infringement suit against Defendants Aurobindo Pharma USA, Inc., and Aurobindo Pharma, Ltd. (collectively, "Defendants" or "Aurobindo") for infringement of United States Patent Nos. 8,658,676 ("the '676 Patent"), 10,010,537 ("the '537 Patent"),

11,103,490 ("the '490 Patent") [1] (collectively, "the patents in suit")[2] based on Aurobindo's filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food & Drug Administration ("FDA") seeking to market a generic version of Cleviprex® clevidipine emulsion before expiration of the patents in suit. *See generally* Amended Complaint (ECF No. 148.) The parties submitted briefs disputing the construction of five claim terms in the patents in suit. They later reached agreement as to three terms: "emulsifier," "co-emulsifier," and "about." Pl. Op. Br. at 3 n.4; Pl. Resp. Brief at 12; Def. Resp. Brief at 1. They request that the Court adopt their jointly proposed constructions as part of this Opinion. Pl. Op. Br. at 3 n.4.[3] The Court held a hearing on October 8, 2020 as to the two remaining terms in dispute: "pharmaceutical formulation" and "resistant to microbial growth."

II. FACTUAL BACKGROUND

Clevidipine is an anti-hypertensive drug administered by injection to a patient to reduce blood pressure when "oral therapy is not feasible or not desirable," Pl. Op. Br. at 2, such as "in the emergency room . . . if somebody has a stroke or a heart attack." Transcript of October 2020 Markman Hearing ("Markman Tr.") at 9:16–18 (ECF No. 52). As a drug product, clevidipine is formulated as an oil-in-water emulsion rather than a conventional solution because it has low solubility in water but higher solubility in lipids. '676 Patent, col. 1 lines 28–32. Given its route of admission, clevidipine emulsion is packaged in vials for injection. Once a vial had been opened, however, prior clevidipine oil-in-water emulsions were prone to two problems: (1) degradation of

[1] The '490 Patent was issued by the USPTO in August of 2021. Amended Complaint ¶ 38. On consent of the parties, Chiesi amended its Complaint to include it among the asserted patents. (ECF Nos. 147.)

[2] The Court notes that while the '537 Patent issued more than four years after the '676 Patent, its application was filed first. In fact, the later patent application was a continuation in part of the earlier one, although the specifications are substantially identical. Def. Op. Br at 5–6; Plf. Op. Br at 6 n.6.

[3] To avoid confusion, this Opinion cites to the parties' submissions using their internal pagination rather than the one imposed by the Court's CM/ECF system.

the active pharmaceutical ingredient and (2) microbial growth. As a result, they had to be discarded within four hours of first use. Pl. Op. Br., at 2. To address these problems, the inventors developed a clevidipine formulation consisting of "EDTA, a lipid, an emulsifier, a tonicity modifier, and water." *Id.* This formulation replaced ingredients derived from egg yolk, which contributed to the previous product's initially poor stability, making the drug easier to handle and decreasing waste. Markman Tr., at 9:19–25, 10:1–8. The '676 Patent issued in 2014. Am. Compl. ¶ 36, Ex. A. The '537 Patent issued in 2018. *Id.* ¶ 37, Ex. B. The '490 Patent issued in 2021. *Id.* ¶ 38, Ex. C. The first two patents in suit were issued to The Medicines Company, who later assigned its rights to Chiesi. *Id.* ¶ 36–37. The final patent was issued to Chiesi. *Id.* ¶ 38

As set forth above, in 2019 Aurobindo sought FDA approval to market a generic version of Cleviprex via an Abbreviated New Drug Application. Am. Compl. ¶ 31. Aurobindo's application included a paragraph IV certification that the '676 Patent and the '537 Patent were invalid, unenforceable and/or will not be infringed by its proposed ANDA product. *Id.* ¶¶ 31–32. In response, Chiesi filed this patent infringement suit in October 2019. In accordance with this district's Local Patent Rules, the parties exchanged proposals for how to construe the claim terms of the patents in suit, and later exchanged evidence supporting their respective proposed constructions. They then filed a joint claim construction and prehearing statement. (ECF No. 41.)

The parties originally disputed the meaning of five terms: (1) "pharmaceutical formulation," (2) "resistant to microbial growth," (3) "about" (4) "emulsifier," and (5) "co-emulsifier." They have since agreed that the terms "emulsifier" and "co-emulsifier" mean "pharmaceutically acceptable surfactant used in the formulations" and "a second pharmaceutically acceptable surfactant that may be included in the formulations of the invention," respectively. *See* Pl. Op. Br. at 3 n.4. They have also agreed that the word "about" in the phrase "an antimicrobial

agent, EDTA, present at about 0.001 to about 1.5% w/v" means "approximately." *See* Pl. Resp. Br. at 12, Ex. 13; Def. Resp. Br. at 1. Hence, on the present motion, two terms remain at issue: (1) "pharmaceutical formulation" and (2) "resistant to microbial growth." Markman Tr. at 6:23–24.

III. LEGAL STANDARD

A patent infringement case involves two steps: construing the claims and determining whether the accused product infringes the claims. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996); *Hormone Research Found., Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1562 (Fed. Cir. 1990), *cert. dismissed*, 499 U.S. 955 (1991).

Claim construction is primarily a question of law. *See Teva Pharm. U.S.A., Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325–26 (2015). It begins with the claim language. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004); *Markman*, 52 F.3d at 980. Claim language is generally "given [its] ordinary and customary meaning." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention."); *see also Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("In construing 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.'") (quoting 35 U.S.C. § 112). Ordinary meaning is determined by "a person of ordinary skill in the art in question at the time of the

invention."[4] *Phillips v. AHW Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (collecting cases); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 (Fed. Cir. 2003). However, if a patentee has used the claim language in some manner other than its ordinary meaning, as indicated by the balance of intrinsic evidence, such as the specification, then that meaning controls. *See, e.g.*, *Phillips*, 415 F.3d at 1226; *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1366 (Fed. Cir. 2001); *Allen Engineering Corp. v. Bartell Industries, Inc.*, 299 F.3d 1336, 1344 (Fed. Cir. 2002) ("It is thus necessary to review [intrinsic evidence] to determine whether the patentee has assigned any special meaning to claim terms.").

Because "there is no magic formula or catechism" for determining ordinary meaning, nor a "rigid algorithm" or "specific sequence," *Phillips*, 415 F.3d at 1324, a court must read claims in context. *See Medrad Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005) ("We cannot look at the ordinary meaning of the term . . . in a vacuum."); *see also DeMarini Sports, Inc. v. Worth*, 239 F.3d 1314, 1324 (Fed. Cir. 2001). To this end, a court must consider "the written description and prosecution history," *Medrad*, 401 F.3d at 1319, "the specification," *Phillips*, 415 F.3d at 1313, which is "always highly relevant to the claim construction analysis," *Vitronics*, 90 F.3d at 1582, because it "may reveal whether the patentee has used a term in a way different from its plain meaning," *Brookhill-Wilk*, 334 F.3d at 1298, and "the surrounding words of the claim." *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003).

In addition to "the words of the claims themselves, the remainder of the specification, [and] the prosecution history," a court may also consider "extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Innova*, 381 F.3d at 1116; *see also Gemstar-TV Guide Int'l, Inc. v. Int'l Trade Comm'n*, 383 F.3d 1352, 1364 (Fed.

4 The parties disagree on the proper definition of a person of ordinary skill in the art, but concede that the Court need not decide that issue for the purposes of their present claim construction dispute. *See* Markman Tr., at 31:6–25.

Cir. 2004). Even "[o]ther claims of the patent in question, both asserted and unasserted, can [] be valuable sources of enlightenment as to the meaning of a claim term." *Vitronics*, 90 F.3d at 1582. In short, the "entire patent" matters, *Phillips*, 415 F.3d at 1313; *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998), and "[t]he construction that stays true to the claim language" while "most naturally align[ing] with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

IV. DISCUSSION

As set forth above, the parties dispute the terms "pharmaceutical formulation" and "resistant to microbial growth." The '676 Patent includes a single independent claim. It illustrates the patents' use of both disputed terms. Claim 1 recites:

> 1. A ***pharmaceutical formulation*** comprising
> (a) an effective amount of clevidipine, or a pharmaceutically acceptable salt or ester,
> (b) an antimicrobial agent, EDTA, present at about 0.001 to about 1.5% w/v,
> (c) a lipid,
> (d) an emulsifier,
> (e) a tonicity modifier, and
> (f) water
> wherein the formulation is ***resistant to microbial growth***.

A. "Pharmaceutical Formulation"

The Court first considers the proper construction of "pharmaceutical formulation." The term appears regularly throughout the claims of the patents in suit. Plaintiffs contend the intrinsic record makes clear "pharmaceutical formulation" refers to an "emulsion formulation for parenteral administration." Pl. Op. Br. at 5. They break their proposal for its construction into two subparts, discussing first "emulsion formulation" and then "for parenteral administration." As to the first portion, the bases for Plaintiffs' position are relatively straightforward. They quote the

specification[5] itself, which states: "The pharmaceutical formulations of the present invention are emulsion formulations." *Id.* at 6. As further support, Plaintiffs point to every example disclosed in the specification, each of which, they say, uniformly "describes a clevidipine emulsion formulation." *Id.* (citing all five disclosed examples).

In support of their position that the emulsion formulation is "for parenteral administration," Plaintiffs cite to language from the specification: "[i]n each embodiment of the invention, the pharmaceutical formulation is for parenteral administration," and "[a]s the formulations are intended for parenteral administration, the skilled artisan will understand that one or more additional components used in parenteral formulations may be included." *Id.* Plaintiffs cite to two further passages describing the parenteral modes of administration contemplated by the inventors, including suitable delivery devices and dosage forms. *Id.*

Plaintiffs argue that the prosecution history of the '676 Patent also supports their construction for "pharmaceutical formulation." They contend that as part of responding to a rejection by the USPTO, the inventors articulated a distinction between their invention and prior art clevidipine formulations cited by the USPTO. Specifically, they characterized their invention as an "oil-in-water emulsion composition that must be intravenously injected into the blood stream," which stands "in sharp contrast" to a prior art inhalable formulation disclosed by a published patent application to Chaudry ("Chaudry")[6] cited by the patent examiner. Plf. Op. Br. at 7. The inventors later reiterated the same distinction during the prosecution of the '537 Patent application when the USPTO again cited Chaudry more than two years later. *Id.*

---

[5] For the sake of clarity, the Court notes that Plaintiffs cite to the specification of the '676 Patent. As set forth above, the disclosures of the patents in suit are substantially identical.

[6] The parties' submissions do not identify the nature of the Chaudry reference. The Court infers, based on the record before it, that it is patent publication 2006/0104913 to Chaudry that is identified among the references cited by the USPTO on the face of the patents in suit.

Defendants have a different view. They would construe "pharmaceutical formulation" more broadly to mean "the combination of different chemicals substances, including the active drug, combined to produce a final medicinal product." Def. Op. Br. at 10. They maintain that the term "pharmaceutical formulation" appears only in the preamble of Claim 1 and is "just introductory and does not further define the elements of the body of the claim." *Id.* In support, Defendants cite the legal principle that generally the preamble does not limit the claims. Def. Res. Br. at 2. They also cite the Court's broad interpretation of the same term in an unrelated case. *Id.* at 4 (citing *Otsuka v. Torrent*, Civ. No. 14-1078, ECF No. 166 (D.N.J. Nov. 16, 2015)). Defendants contend their broader interpretation is also more consistent with the specification because it includes no explicit language limiting "pharmaceutical formulation" in the way that Plaintiffs seek. Def. Op. Br. at 11. They also cite various language from the specification intended to support their proposed construction. Def. Op. Br. at 11–12; Def. Resp. Br. at 5–6. And Defendants dispute Plaintiffs' reliance on particular statements in the specification or during the prosecution history. According to Defendants, these fail to rise to the level required for either an explicit disclaimer or a consistently implied definition. Def. Resp. Br. at 7. Under the circumstances, say Defendants, the broader definition of "pharmaceutical formulation" is the proper one here. *Id.*

Both parties insist that the extrinsic evidence—in the form of expert testimony each provided—supports their own claim construction.

1. The Claim Language

On its face, the term "pharmaceutical formulation" is a relatively straightforward one. It is therefore not surprising that Defendants urge the Court to apply its plain and ordinary meaning. To that end, they cite a *Markman* opinion in another matter doing exactly this. Def. Op. Br. at 10 (citing *Otsuka Pharm. v. Torrent Pharm.*, Civ. No. 14-1078, Docket Entry No. 166 at 50 (D.N.J.

November 16, 2015) (maintaining court's prior assignment of plain and ordinary meaning to "pharmaceutical formulation")). As a general rule, a claim term is indeed given its ordinary and customary meaning, *i.e.*, the one that a person of ordinary skill in the art would ascribe to it at the time of the invention. *Phillips*, 415 F.3d at 1312–3. There are, however, two exceptions to that general rule: (1) when a patentee acts as his own lexicographer, and (2) when a patentee surrenders the full scope of a claim term in the specification or during prosecution. *Hill-Rom Services, Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) (citing *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)). Here, neither side posits that lexicography took place. The question is therefore whether the inventors disavowed all pharmaceutical formulations that are not emulsion formulations for parenteral administration. This is not an easy criterion to meet because "[t]he standard for disavowal of claim scope is . . . exacting." *Thorner*, 669 F.3d at 1366. It can, however, be accomplished by "clear, repeated, and consistent statements." *SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1203 (Fed. Cir. 2013); *see also Poly-America, L.P. v. API Industries, Inc.*, 839 F.3d 1131, 1136 (Fed. Cir. 2016).

2. The Specification

The Court has carefully reviewed the specification of the patents in suit. To begin, it is conspicuously titled "Clevidipine Emulsion Formulations Containing Antimicrobial Agents." The Field of the Invention states that "[t]he instant invention relates to a stable, *pharmaceutical oil-in-water emulsion formulation for parenteral administration that includes clevidipine* and an antimicrobial agent." '676 Patent col.1, lines 12–13.

The Background of the Invention expresses the then-existing "need for a stable *clevidipine emulsion formulation* that is resistant to microbial growth." *Id.* col. 1, lines 48–51.

The Summary of the Invention opens by stating that "it is the object of the present invention to provide a *clevidipine emulsion formulation* that is not only stable against formation of impurities

but having a reduced propensity for microbial contamination." *Id.* col. 1, lines 59–62. The Summary then proceeds to describe four embodiments of the invention, and various aspects thereof, all of which are clevidipine emulsions. *Id.* col. 1, line 63 – col. 3, line 18. It concludes by observing that "[i]n each embodiment of the invention, *clevidipine and the emulsion* maintain their stability in the formulation. In each embodiment of the invention, the Summary asserts that *the pharmaceutical formulation is for parenteral administration.*" *Id.* col. 3, lines 13–15.

The Detailed Description of the Invention states that "[t]he pharmaceutical formulations of the present invention are emulsion formulations." *Id.* col. 4, lines 66–67. It also notes that "[a]s *the formulations are intended for parenteral administration,* the skilled artisan will understand that one or more additional components used in parenteral formulations may be included." *Id.* col. 7, lines 6–9. The Detailed Description goes on to describe the various modes of parenteral administration that are contemplated, all of which involve injection. *Id.* col. 7, lines 23–28. Finally, the five examples disclosed are all clevidipine emulsions. *Id.* col. 9, line 40 – col. 14, line 10.

Defendants claim that such isolated statements to "the present invention" in the specification are not sufficient to limit the term "pharmaceutical formulation." Def. Resp. Br., at 8 (citing *LMT Mercer Group, Inc. v. Maine Ornamental, LLC*, Civ. No. 10-4615, 2014 WL 183823 (D.N.J. Jan. 16, 2014)). The Court disagrees. The inventors' repeated characterizations of their invention far exceed isolated statements and the Court therefore finds *LMT Mercer* readily distinguishable. Despite Defendants' arguments to the contrary, the Court finds that the specification, when read as a whole, identifies the invention as an emulsion formulation for parenteral administration. It therefore strongly suggests the disavowal of other types of pharmaceutical formulations. *See Regents of U. of Minn. v. AGA Medical Group*, 717 F.3d 929,

936 (Fed. Cir. 2020) ("When a patent thus describes 'the present invention' as a whole, this description limits the scope of the invention.") (citation omitted); *AstraZeneca AB v. Hanmi USA, Inc.*, 554 Fed. Appx. 912, 914–6 (Fed. Cir. 2013). The Court next considers the prosecution history of the patents in suit.

3. The Prosecution History

According to Plaintiffs, the prosecution history supports their position because the inventors "relied on the emulsion and parenteral attributes of the claimed pharmaceutical formulations." Pl. Op. Br., at 7; Pl. Resp. Br., at 6. Defendants contend that the scope of what was argued during prosecution is far more limited than Plaintiffs' proposed construction and therefore cannot support it. Def. Resp. Br., at 9–11.

The Court has reviewed the two portions of the prosecution history provided by the parties: the inventors' response on July 11, 2013 to an Office Action from the USPTO ("2013 Response," attached as Exhibit 4 to the Pl. Op. Br., ECF No. 47-6) and the inventors' response on September 11, 2015 to an Office Action from the USPTO ("2015 Response," attached as Exhibit 5 to the Pl. Op. Br., ECF No. 47-7). In both Office Actions, a patent examiner cited Chaudry as part of the basis for an obviousness rejection. In their Responses to the Office Actions, the inventors briefly characterize their invention as follows: "the formulation is an oil-in-water emulsion composition which is administered intravenously." 2013 Response at 8; 2015 Response at 12. In both instances, the inventors later repeat their characterization to distinguish their invention from the composition disclosed by Chaudry: "The inhalable formulation of Chaudry is a liquid solution that is administered through the respiratory tract. This is in sharp contrast to the [inventors'] *oil-in-water emulsion composition that must be intravenously injected* into the blood stream." 2013 Response at 10; 2015 Response at 14. Defendants emphasize the differences in the inventors' articulation of their invention and Plaintiffs' proffered construction. That is, the inventors more

narrowly describe their invention as (1) "an oil-in-water emulsion," rather than simply any emulsion. They also describe it as one (2) not generally for parenteral administration, but more specifically to be intravenously injected. The Court agrees that the prosecution statements do vary from the characterizations made in the specification, but the prosecution statements do not wholly conflict with the specification's characterizations. Having considered both, the Court finds that the statements made during prosecution do not overcome the weight of the specification's repeated descriptions of the invention as an emulsion formulation for parenteral administration. *See also Phillips*, 415 F.3d at 1317 ("[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.")[7]

4. Extrinsic Evidence

Both parties offer extrinsic evidence in the form of expert testimony to interpret the term "pharmaceutical formulation." Defendants' experts, Dr. Crowley and Dr. Tarantino, assert that a person of ordinary skill in the art "would not find the phrase 'pharmaceutical formulation' as essential to understanding the limitations or terms in the [body of Claim 1]." Def. Op. Br. at 12; *see also* Tarantino Decl. ¶ 51; Crowley Decl. ¶ 61. They also assert that the "Summary of Invention makes clear that the phrase 'pharmaceutical formulation' does not require an emulsion." Def. Op. Br. at 12; *see also* Tarantino Decl., ¶ 55; Crowley Decl., ¶¶ 62–64). And they do not believe that the term "itself implies a parenteral drug." Def. Op. Br. at 12; *see also* Tarantino Decl.

[7] The Court notes that while it does not find these statements from the prosecution history persuasive in the context of claim construction, this does not foreclose later revisiting them should the need arise when considering any prosecution history estoppel arguments that might be made as part of an infringement analysis. *See Biodex Corp. v. Loredan Biomedical, Inc.*, 946 F.2d 850, 862 (Fed. Cir. 1991) ("There is a clear line of distinction between using the contents of the prosecution history to reach an understanding about disputed claim language, and the doctrine of prosecution history estoppel which estops or limits later expansion of the protection accorded by the claim to the patent owner under the doctrine of equivalents when the claims have been purposefully amended or distinguished over relevant prior art to give up scope.")

¶ 56; Crowley Decl. ¶ 64. Plaintiffs' expert, Dr. Little, disagrees with these conclusions. *See* Pl. Resp. Br. 2–5, 7–9, 11; Little Decl. ¶¶ 23–27.

Courts may consider extrinsic evidence, including expert testimony, if they deem it helpful to discern the meaning of claim terms. *Phillips*, 415 F3.d at 1319; *Markman*, 52 F.3d at 980. But extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) (*quoting Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n*, 366 F.3d 1311, 1318 (Fed. Cir. 2004)).

Because the Court has concluded, based on the intrinsic evidence, that "pharmaceutical formulation" refers unambiguously to an "emulsion for parenteral administration," its analysis can end. *Vitronics*, 90 F.3d at 1584. The Court notes that, were it inclined to consider expert testimony, it would find Defendants' expert evidence is inconsistent with the intrinsic evidence. *Id.* As such, the Court would "accord it no weight." *Id.*; *see also Markman*, 52 F.3d at 983. In other words, even if it were appropriate to look to extrinsic evidence to construe "pharmaceutical formulation," the Court would discount Defendants' expert testimony because it is "clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history." *Key Pharms.*, 161 F.3d at 716. *See Vitronics*, 90 F.3d at 1585 (stating that extrinsic evidence may not "contradict the import of other parts of the specification" or "be used to vary . . . the claim language").

Accordingly, the Court ultimately holds that "pharmaceutical formulation" means "an emulsion formulation for parenteral administration."

B. "Resistant to Microbial Growth"

The other term whose construction the parties dispute is "resistant to microbial growth." Here the parties essentially reverse positions, with Defendants arguing for a narrower construction

based on the specification while Plaintiffs seek a broader one.

Plaintiffs contend "microbial growth" should mean "having a reduced propensity for microbial contamination." Pl. Op. Br. at 12. In support of their construction, Plaintiffs point to the specification and prosecution history, and argue that Defendants' interpretation impermissibly renders Claim 8 of the '676 Patent redundant. *See* Pl. Op. Br. at 13. Defendants advance a far more limited definition: "a delay in onset or retardation of growth such that there was a less than 10-fold (1 log) increase in the viable colonies over a 24-hour period." Def. Op. Br. at 1. Defendants assert that the specification supports their construction, that Claim 1 and Claim 8 are not coextensive under their construction because they emphasize growth *onset* whereas Claim 8 emphasizes growth *rate*, and that, in any event, "surplusage may exist in some claims." *See* Def. Op. Br. at 15–16.

1. The Claim Language

Unlike the previous term, "resistant to microbial growth" is recited in its entirety in the '676 Patent only at Claim 1. It appears there as part of the concluding "wherein" clause.

> 1. A pharmaceutical formulation comprising
> (a) an effective amount of clevidipine, or a pharmaceutically acceptable salt or ester,
> (b) an antimicrobial agent, EDTA, present at about 0.001 to about 1.5% w/v,
> (c) a lipid,
> (d) an emulsifier,
> (e) a tonicity modifier, and
> (f) water
> wherein the formulation is ***resistant to microbial growth***.

Dependent Claim 8 touches on a portion of the disputed term by reciting a further limitation of "microbial growth":

> 8. The formulation of claim 1 wherein ***microbial growth*** is delayed or retarded such that there is less than 10-fold (1 log) increase in viable colonies over a 24-hour period.

One point of contention between the parties is the interaction between Claims 1 and 8 if, as Defendants argue, "resistant to microbial growth" were to mean "a delay in onset or retardation of growth such that there was a less than 10-fold (1 log) increase in the viable colonies over a 24-hour period." Grammatical issues aside[8], the wherein clause of Claim 1 would essentially read:

> 1. A pharmaceutical formulation comprising
> . . .
> wherein the formulation is ***a delay in onset or retardation of growth such that there was a less than 10-fold (1 log) increase in the viable colonies over a 24-hour period.***

This comes close to the limitation already explicitly recited by Claim 8:

> 8. The formulation of claim 1 wherein microbial growth is delayed or retarded such that there is less than 10-fold (1 log) increase in viable colonies over a 24-hour period.

Given the substantial overlap of the claims, as Plaintiffs point out, there is some tension created by Defendants' proposed meaning. This is because the doctrine of claim differentiation imposes a presumption that two claims of a patent are of different scope. *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1366 (Fed. Cir. 2000) ("Under the doctrine of claim differentiation, two claims of a patent are presumptively of different scope."); *see also Promos Techs., Inc. v. Samsung Elecs. Co.*, 809 F. App'x 825, 834 (Fed. Cir. 2020) ("[W]e have determined that it is generally improper to construe a patent claim so that express claim limitations or elements are rendered superfluous.")

Defendants first argue that claim differentiation does not apply because the claims are, in their view, different: Claim 8 recites a delay in microbial growth, whereas Claim 1 should be construed to claim a delay in the *onset* of that growth. Def. Op. Br., at 14–15. This is because the term "[a] delay in growth" in Claim 8 means "a delay in the *rate* of growth," whereas they cast Claim 1 in terms of growth *onset* only. Markman Tr., at 45:12–15 (emphasis added).

[8] There are any number of ways to resolve the grammatical dissonance in the wherein clause, but the Court declines to elect one in order to avoid introducing more confusion.

Plaintiffs criticize this as a manufactured distinction in the context of the claims, asserting that there is no meaningful difference between the "delay" of Claim 8 and the "delay in onset" of Claim 1. Second, to the extent there would be any difference between the two claims, Claim 8 would be rendered broader than Claim 1 despite Claim 8 depending from Claim 1, a result also disfavored in claim construction jurisprudence.

Having compared the language of the two claims, the Court is inclined to agree that there is no meaningful distinction between Claim 8 and Claim 1, if the latter was interpreted as Defendants propose. The language of each of the claims already encompasses the feature of "retarding" the rate of growth, *i.e.,* slowing it. (Claim 1: "or retardation of growth") (Claim 8: "growth is . . . or retarded"). What is left is the feature of delaying, in the sense of impeding initiation, and there is no meaningful distinction between the "delay" of Claim 8 and the "delay of onset" of Claim 1. Put another way, Defendants' proposal to construe "delay" of Claim 8 to mean a "delay in the *rate* of growth" would effectively read the claim feature of "retarded" out of Claim 8. This is counter to logic, as well as "the well-established rule that 'claims are interpreted with an eye toward giving effect to all terms in [the same] claim.'" *In re Certain Consolidated Roflumilast Cases*, Civ. No. 15-3375, 2016 WL 6089716, at *5 (D.N.J. Oct. 18, 2016) (quoting *Digital Vending Serv. Intern., LLC v. University of Phoenix, Inc.*, 672 F.3d 1270, 1275 (Fed. Cir. 2012)). Pursuant to this rule, courts "construe claim terms in light of the surrounding claim language, such that words in a claim are not rendered superfluous." *Digital Vending*, 672 F.3d at 1275.

Accordingly, the Court rejects Defendants' argument that there is a difference in the scope of Claim 8 and Claim 1, if the Court were to construe Claim 1 as they propose. Therefore, the Court finds that the doctrine of claim differentiation applies and that there is a presumption against

Defendants' proposed construction of "resistant to microbial growth." The presumption, however, is "not a hard and fast rule and will be overcome by a contrary construction dictated by the written description or prosecution history." *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005) (citing *Kraft,* 203 F.3d at 1368. Insofar as Plaintiffs' proposed construction for "resistant to microbial growth" raises no claim differentiation issues, there is no presumption against its adoption. With this in mind, the Court turns to the intrinsic record.

2. The Specification

As set forth above, the general rule is that a claim term is given its ordinary and customary meaning, with two exceptions: (1) when a patentee acts as its own lexicographer, and (2) when a patentee surrenders the full scope of a claim term in the specification or during prosecution. Consistent with the first exception, Defendants contend the inventors acted as their own lexicographers.

An inventor acts as its own lexicographer by providing an explicit definition for a claim term in the specification. *Level Sleep LLC v. Sleep Number Corp.*, App. No. 2020-1718, 2021 WL 2934816, at *4 (Fed. Cir. July 13, 2021) (citing *Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1242, 1249 (Fed. Cir. 1998)). To successfully define its own term in this way, the inventor must "clearly express that intent in the written description" and do so "with sufficient clarity to put one reasonably skilled in the art on notice that the [it] intended to redefine the claim term." *Merck & Co. v. Teva Pharm.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005). "It is not enough . . . to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must 'clearly express an intent' to redefine the term." *Thorner*, 669 F.3d at 1362 (citation omitted).

As evidence of lexicography, Defendants cite language from Example 1 of the specification, which includes a statement that "[m]icrobial inhibition was considered resistant to

microbial growth if there was *a delay in onset or retardation of growth such that there was less than 10-fold (1 log) increase in viable colonies over a 24-hour period.*" '676 Patent col. 9, lines 60–63. Defendants emphasize the significance of this sentence because it was part of some new matter added to the '676 Patent specification.[9] "Resistant to microbial growth" replaced the word "acceptable" in the original disclosure. Given this purposeful change and the unique language used, Defendants contend it constitutes lexicography by the inventors. Def. Op. Br. at 14; Def. Resp. Br. at 13–14. They point to no other support in the specification for their claim construction.

The Court finds a number of flaws in Defendants' position. First, the specification of the '676 Patent is replete with far clearer examples of the inventors' manifest intent to define their own terms, *e.g.*, "[a]s used herein, the term 'antimicrobial agent means'. . ." (col. 5, line 9); "[i]n general the term 'EDTA' means . . ." (col. 5, line 32); "[a]s used herein, the term 'lipid' in the formulations is . . ." (col. 6, lines 1–2); "[a]s used herein, the term 'emulsifier' represents . . ." (col. 6, lines 17–18); "[a]s used herein, the term 'co-emulsifier' represents . . " (col. 6, lines 32–33). *See* Markman Tr. 35:8–20. From this, the Court can reasonably infer that the inventors were capable of invoking language sufficiently clear to constitute lexicography when they so intended. The sentence from Example 1 cited by Defendants is devoid of similar clarity.

Second, as Plaintiffs point out, Defendants' construction adopts language appearing solely in Example 1 of the specification and would therefore run afoul of the general rule against "reading limitations from an embodiment [in the specification], a single embodiment, into the claims." Markman Tr., at 34:24-35:7, 37:8-21. The Federal Circuit has specifically urged caution with respect to reading limitations from the examples into the claims. *See Phillips*, 415 F.3d at 1323 ("To avoid importing limitations from the specification into the claims, it is important to keep in

[9] The '676 Patent is a continuation-in-part application to which new matter was added by the inventors.

mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so. One of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case. Much of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive.") (citation omitted). Defendants' focus on the 24-hour time period would exclude other embodiments of the invention that demonstrated inhibition of microbial growth, to different degrees, at 12, 30, and 48 hours. Pl. Op. Br. at 16 (citing '676 Patent Examples 1, 2, 4, and 5).

For these reasons the Court finds that the specification, on its own, does not support Defendants' narrow construction for "resistant to microbial growth," particularly given the presumption against it by virtue of the doctrine of claim differentiation.

The Court turns next to Plaintiffs' claim construction to assess its support in the specification. Plaintiffs propose that "resistant to microbial growth" means "having a reduced propensity for microbial contamination." Plaintiffs concede that their position lacks an express definition for "resistant to microbial growth" in the specification of the '676 Patent. They resort instead to a statement from the specification that sets forth an overall object of the invention as being "to provide a clevidipine emulsion formulation that is not only stable against the formation of impurities but *having a reduced propensity for microbial contamination*." '676 Patent col. 1, lines 59–62[10], Markman Tr., at 33:14–16. Plaintiffs also argue that the inventors differentiated the

[10] Plaintiffs similarly contend that the Court "can construe 'resistant to microbial growth' based on the parallel language in the '537 Patent in the abstract, which [states that the purpose of the invention] is 'reduced propensity for microbial growth.'" Markman Tr., at 34:12–15.

invention from the prior art by adding an antimicrobial agent to "inhibit microbial growth." Markman Tr., at 38:8–22.

Generally, it is permissible to rely on the "object of the invention" to support a claim construction. *See Praxair*, 543 F.3d at 1324 (defining a term to be consistent with the purpose of the invention, which was to "prevent a hazardous situation from the uncontrolled discharge of gas"); *Howmedica*, 401 F.3d at 1372. The abstract for each patent also uses the term "resistant to microbial growth" interchangeably with "reduced propensity for microbial contamination." *See* Compl. Ex. A–B. While these references are not "overriding" or "extensive," *Howmedica*, 401 F.3d at 1372, they do tend to support to Plaintiffs' claim construction.

3. The Prosecution History

In 2013, the USPTO rejected one or more of the inventors' proposed claims based on obviousness under 35 U.S.C. § 103. *See* 2013 Response. The inventors responded in part by emphasizing that their invention was designed to address "the problem of increase[d] microbial contamination risks if [the prior art clevidipine formulation] is not changed *after 4 hours*." *See* 2013 Response at 7 (emphasis added). They described the "risks of microbial growth," the need to "avoid microbial contamination," and the need to avoid the risk of "microbial contamination associated with multiple handlings." *Id.* According to the inventors, it was this search that "led to the invention described in the present application," including that "EDTA performed the best in achieving a stable and effective clevidipine composition that is resistant to microbial growth." *Id.* at 7–8. The inventors made similar statements in the course of their 2015 Response to the USPTO. *See* 2015 Response.

Based on the Court's review of the portions of the prosecution history provided by the parties, it finds that the prosecution history also supports Plaintiffs' proposed claim construction. Moreover, the Court finds no evidence that the inventors "limited the invention in the course of

the prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317; *Vitronics*, 90 F.3d at 1582–83; *Chimie*, 402 F.3d at 1384. Accordingly, the Court finds that, together with its reading of the specification, the intrinsic evidence supports Plaintiffs' position that "resistant to microbial growth" means "having a reduced propensity for microbial contamination."

4. Extrinsic Evidence

As set forth above, because the Court has concluded, based on the intrinsic evidence, that "resistant to microbial growth" means "having a reduced propensity for microbial contamination." its analysis can end. *Vitronics*, 90 F.3d at 1584. The Court notes that, were it inclined to consider expert testimony, it would find Defendants' expert evidence is inconsistent with the intrinsic evidence. *Id.* As such, the Court would "accord it no weight." *Id.*; *see also Markman*, 52 F.3d at 983. In other words, even if it were appropriate to look to extrinsic evidence to construe "resistant to microbial growth," the Court would discount Defendants' expert testimony because it is "clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history." *Key Pharms.*, 161 F.3d at 716. *See Vitronics*, 90 F.3d at 1585 (stating that extrinsic evidence may not "contradict the import of other parts of the specification" or "be used to vary . . . the claim language").

Accordingly, the Court will adopt Plaintiffs' construction, and construe "resistant to microbial growth" to mean "having a reduced propensity for microbial contamination."

V. CONCLUSION

For the foregoing reasons, the Court will construe the disputed and stipulated terms of the patents in suit in accordance with the table below. An appropriate Order will follow.

TERM	COURT'S CONSTRUCTION

"pharmaceutical formulation"	"emulsion formulation for parenteral administration"
"resistant to microbial growth"	"having a reduced propensity for microbial contamination"
"about" (stipulated)	"approximately"
"emulsifier" (stipulated)	"suitable pharmaceutically acceptable surfactant that used in the formulations"
"co-emulsifier" (stipulated)	"a second suitable pharmaceutically acceptable surfactant that may be included in the formulations of the invention"

DATED: October 19, 2021

ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE