IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAXTER HEALTHCARE CORPORATION, Plaintiff, v. NEVAKAR INJECTABLES, INC., Defendant.	)	Civil Action No. 21-1184-CJB
NEVAKAR INJECTABLES, INC., Plaintiff, v. BAXTER HEALTHCARE CORPORATION, Defendant.	)	Civil Action No. 21-1186-CJB

MEMORANDUM ORDER

In these two related actions between Baxter Healthcare Corporation ("Baxter") and Nevakar Injectables, Inc. ("Nevakar"), the parties request various relief from the Court. In Civil Action No. 21-1184-CJB, Baxter currently seeks, *inter alia*, a declaratory judgment that its Norepinephrine Bitartrate in 5% Dextrose Injection, 0.016 mg/mL and 0.032 mg/mL products do not infringe U.S. Patent Nos. 10,420,735 (the "'735 patent"), 10,471,026 (the "'026 patent"), 10,568,850 (the "'850 patent"), 10,646,458 (the "'458 patent") and 11,602,508 (the "'508 patent," and collectively, the "patents-in-suit"). (Civil Action No. 21-1184-CJB , D.I. 99) In Civil Action No. 21-1186-CJB, Nevakar, the patentee,[1] alleges infringement of the '735 patent, the

[1] Par Sterile Products, LLC ("Par") and Endo Ventures Ltd. ("Endo") were originally Plaintiffs in Civil Action No. 21-1186-CJB and Defendants in Civil Action No. 21-

'026 patent, the '850 patent, the '458 patent and the '508 patent. (Civil Action No. 21-1186-CJB, D.I. 97)[2] Presently before the Court is the matter of claim construction. (Civil Action No. 21-1184-CJB, D.I. 47; D.I. 48; Civil Action No. 21-1186-CJB, D.I. 45; D.I. 46) The Court hereby adopts the constructions as set forth below.

I. BACKGROUND

The parties commenced the respective actions on August 18, 2021. (Civil Action No. 21-1184-CJB, D.I. 1; Civil Action No. 21-1186-CJB, D.I. 1) In both actions, the parties consented to the Court's jurisdiction on April 7, 2022. (Civil Action No. 21-1184-CJB, D.I. 39; Civil Action No. 21-1186-CJB, D.I. 37)

As the common specification of the patents-in-suit describes,[3] the patents-in-suit are generally directed to "compositions and methods for ready-to-inject norepinephrine compositions with improved stability." ('735 patent, Abstract) The patents-in-suit addressed the "need for improved stable, low concentration, ready-to-inject and antioxidant free norepinephrine formulations, and methods of manufacturing and storing the same." (*Id.*, col. 3:45-48) Further details regarding the asserted patents will be provided below in Section III.

1184-CJB, along with Nevakar. For reasons the Court need not get into here, Baxter and Nevakar eventually stipulated in these actions to voluntarily dismiss Endo and Par and to maintain the two actions as between Baxter and Nevakar. (Civil Action No. 21-1184-CJB, D.I. 90 at 3-4; Civil Action No. 21-1186-CJB, D.I. 88 at 3-4)

[2] The respective suits initially included claims regarding one or both of two additional patents—U.S. Patent Nos. 10,159,657 (the "'657 patent") and 10,226,436 (the "'436 patent"); however, the '657 and '436 patents were subsequently dismissed without prejudice. (Civil Action No. 21-1184-CJB, D.I. 1; Civil Action No. 21-1186-CJB, D.I. 56)

[3] Since the patents-in-suit share a common specification, the Court will follow the parties' lead and cite to the specification in the '735 patent. It should be understood that the cited portions of the '735 patent are also found in the other patents-in-suit and related patents as well.

On August 15, 2022, the parties filed their joint claim construction brief. (D.I. 67)[4] The Court conducted a *Markman* hearing on November 16, 2022. (D.I. 86, hereinafter, "Tr.")

II. STANDARD OF REVIEW

The Court has often set out the relevant legal standard for claim construction, including in *Vytacera Bio LLC v. CytomX Therapeutics, Inc.*, Civil Action No. 20-333-LPS-CJB, 2021 WL 4621866, at *2-3 (D. Del. Oct. 7, 2021). The Court hereby incorporates by reference its discussion in *Vytacera Bio* of these legal standards and will follow them herein. To the extent consideration of the disputed terms necessitates discussion of other, related legal principles, the Court will discuss those principles in Section III below.

III. DISCUSSION

The parties set out five disputed terms or term sets ("terms") for the Court's review.[5] The Court takes up the terms in the order in which they were argued.

A. "chelating agent"

The first disputed term, "chelating agent[,]" appears in many claims, including claims 1, 7-8, and 14 of the '735 patent; claims 1 and 11-15 of the '026 patent; claims 1 and 14-15 of the '850 patent; and claims 1 and 17-18 of the '458 patent.

Exemplary claim 1 of the '735 patent recites:

---

[4] For ease of reference, from here on out the Court will cite to the docket entries in Civil Action No. 21-1184-CJB, unless otherwise noted.

[5] At the time of the parties' briefing, there were six disputed terms: the five terms mentioned herein and "large volume polymeric, semi-permeable infusion container." (D.I. 67 at 55-58) At the *Markman* hearing, it became clear that the only dispute with respect to this term was whether it was indefinite or not, (Tr. at 141-43); the parties did not dispute the construction of the term itself, (*id.*). Given the minimal briefing devoted to whether this sixth term was indefinite, the Court and the parties agreed that a ruling on indefiniteness should be deferred until a more fulsome record was before the Court. (*Id.* at 142-43) This leaves the five disputed terms at issue.

> **1**. A method of treating hypotension, comprising:
> administering a ready-to-administer norepinephrine composition at an initial dose per minute;
>
> administering the norepinephrine composition at a maintenance dose per minute, wherein the initial dose per minute is greater than the maintenance dose per minute;
>
> wherein the initial dose per minute is a dose of between 8 and 12 μg/min, and wherein the maintenance dose per minute is a dose of between 2 and 4 μg/min;
>
> wherein the norepinephrine composition comprises norepinephrine or a salt thereof at a concentration of between 10 μg/ml and 100 μg/ml in an aqueous acidic solution having a pH range of between 3.7 and 4.3, wherein the aqueous acidic solution further comprises a *chelating agent* at a concentration of between 1 μg/ml and 100 μg/ml and a tonicity agent;
>
> wherein the norepinephrine composition is substantially free of antioxidants; and
>
> wherein the norepinephrine or a salt thereof in the norepinephrine composition comprises at least about 90% R-isomer of norepinephrine after storage at 25±2° C. and 60±5% relative humidity, over at least three months as determined by HPLC.

('735 patent, col. 21:35-58 (emphasis added)) The parties proposed the following constructions:

Term	**Nevakar's Proposed Construction**	**Baxter's Proposed Construction**
"chelating agent"	"includes various bicarboxylic acids, tricarboxylic acids, and aminopolycarboxylic acids such as ethylenediaminetetraacetic acid (EDTA), ethylene glycol-bis(β-aminoethyl ether)-N,N,N',N'-tetraacetic acid (EGTA), and penta(carboxymethyl)diethylenetriamine (DTPA), and salts and hydrates thereof"	"a separate chemical compound, added to the composition, with at least two donor groups that form a ring structure with a metal ion"

(D.I. 67 at 5)

The parties' dispute as to this term primarily relates to whether a chelating agent has to be a *separate* chemical compound from the other compounds in the composition, when added to the

composition.[6] In Nevakar's view, "chelating agents" should be construed to include *both* those compounds that are separate at the time of addition into the aqueous solution and those that become separate chemical compounds when in the solution. (*Id.* at 21; *see also id.* at 6) For instance, according to Nevakar, the claimed norepinephrine (i.e., the active ingredient) can be norepinephrine bitartrate salt—and when that norepinephrine bitartrate salt is placed in the claimed aqueous solution, its bitartrate anion separates from the active ingredient. And Nevakar asserts that that now-separated bitartrate anion can then serve as the claimed chelating agent. (*Id.* at 6 ("[U]nder Baxter's proposed construction, the anion of the claimed 'norepinephrine or a

[6] In addition to requiring that the chelating agent be "a separate chemical compound, added to the composition," Baxter's proposed construction also requires that the chelating agent should have "at least two donor groups that form a ring structure with a metal ion." (D.I. 67 at 8-9) In its briefing, Nevakar appeared to indicate that it had no dispute with this second portion of Baxter's construction. (*Id.* at 20 (noting that the "dispute [between the parties] boils down to a single issue: whether the chelating agent must be a '*separate* chemical compound' as Baxter proposes") (emphasis in original)) In light of this, going into the *Markman* hearing, both the Court and Baxter believed that the second portion of Baxter's proposed construction was unchallenged. (Tr. at 78, 96-97) During the *Markman* hearing, however, Nevakar offered new arguments, suggesting that Baxter's "at least two donor groups" construction is incorrect. (*Id.* at 40-43) More specifically, Nevakar argued, among other things, that this portion of Baxter's construction might sweep in compounds with at least two donor groups that form a ring structure with a metal ion but that do not actually act as chelating agents. (*Id.* at 42)

On the one hand, it is not fair for Nevakar to make an argument about claim scope for the first time during the *Markman* hearing. And it is Nevakar's fault that we do not have a better back-and-forth in the briefing as to this issue. Yet on the other hand, the Court is hesitant to simply conclude that because Nevakar failed to make an argument about the "at least two donor groups" language in its briefing, the Court should simply adopt Baxter's proposed language (without hearing more about why that language is or is not on point). That is because the Court has an obligation (not only to these parties, but also to others who might encounter these patents) to construe the claim term at issue correctly. And that task is not well-fulfilled if the Court does not have a good adversarial presentation from the parties about a disputed issue regarding claim scope before it makes a decision on the issue. Therefore, for now the Court will not address this proposed addition by Baxter. If the dispute over this suggested limitation lingers, the parties can jointly advise the Court of this by no later than the deadline for submission of summary judgment briefing.

salt thereof' could not serve as the 'chelating agent' because it is not a 'separate chemical compound' from the norepinephrine salt."); Tr. at 10-13)[7] Baxter, meanwhile, disagrees that the chelating agent can have originally been a portion of one of the other referenced compounds in the claim (i.e., norepinephrine or a salt thereof); it argues that the chelating agent must be a separately added chemical composition. (D.I. 67 at 10-20) For the reasons that follow, the Court agrees with Baxter.

The Court begins its analysis by looking to the claim language itself. Multiple aspects of that language favor Baxter's proposal.

For one thing, "chelating agent" is a separate claim term from "norepinephrine." Claim 1 of the '735 patent, for example, recites a norepinephrine composition that is, *inter alia*, comprised of certain separately-named chemical components or compounds (in distinct concentration ranges), namely: (1) "norepinephrine or a salt thereof" that is in "an aqueous acidic solution[;]" (2) "a chelating agent" that is also a part of that solution; and (3) "a tonicity agent" that is additionally in the solution. ('735 patent, col. 21:35-58) The United States Court of Appeals for the Federal Circuit has stated that "[w]here a claim lists elements separately, the clear implication of the claim language is that those elements are distinct component[s] of the patented invention." *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (internal quotation marks and citations omitted); *see also Willis Elec. Co., Ltd. v. Polygroup Macau Ltd.*, 777 F. App'x 495, 498 (Fed. Cir. 2019) (same); *cf. HTC Corp. v. Cellular Commcn's Equip., LLC*, 701 F. App'x 978, 982 (Fed. Cir. 2017) ("The separate naming

[7] Nevakar's counsel further explained that "[n]orepinephrine is the active ingredient that[is] its own molecule, and then . . . when in the salt form, it can have a counterion, another molecule that is temporarily affixed to it, and the counterion . . . can be a bicarboxylic acid, for example, tartrate, which [in Nevakar's view] is a synonym for bitartrate." (Tr. at 11)

of two structures in the claim strongly implies that the named entities are not one and the same structure."). And so claim 1's use of the distinct terms "chelating agent" and "norepinephrine or a salt thereof" is at least an indicator that those are two distinct, separate components.[8]

Moreover, in claim 1 the term "chelating agent" is immediately preceded by the phrase "further comprises[,]" such that the claim reads: "wherein the norepinephrine composition comprises norepinephrine or a salt thereof . . . in an aqueous acidic solution" and "wherein the aqueous acidic solution *further comprises* a chelating agent[.]" ('735 patent, col. 21:45-51 (emphasis added)) Federal courts have noted that the addition of "further comprises" before an additional term (like the "chelating agent" term here) can also signal that the additional term is something separate and apart from what came before it.[9] *See, e.g.*, *Purdue Pharm. Prods. L.P. v. Actavis Elizabeth LLC*, No. 12-5311 (JLL)(JAD), 2015 WL 5032650, at *14 (D.N.J. Aug. 25, 2015) ("The phrase 'further comprising' signals that these claimed elements ('zolpidem or a pharmaceutically acceptable salt thereof,' on the one hand, and 'a buffer' on the other) are distinct components of the solid pharmaceutical composition."); *see also David Netzer*

[8] Surely, this initial indication or presumption could be overcome, such as if other intrinsic evidence (i.e., evidence from the specification) demonstrated that the two terms at issue could be satisfied by one structure. *See Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1231-32 (Fed. Cir. 2011); *Wasica Fin. GmbH v. Schrader Int'l, Inc*., C.A. No. 13-1353-LPS, 2019 WL 1011321, at *4 (D. Del. Mar. 4, 2019). But as will be set out below, the remaining intrinsic evidence does not suggest this at all.

[9] Nevakar responds to this point in part by arguing that Baxter's position (i.e., that the phrase "further comprises" means that the "norepinephrine or a salt thereof" must be a separate chemical compound distinct from the "chelating agent") is an "improper and premature attempt[] to argue noninfringement under the guise of claim construction[.]" (D.I. 67 at 22 (citing *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1339-40 (Fed. Cir. 2005)) But the Court does not see why this is so. And Nevakar provided no further explanation. The dispute here is over the scope of the claim term. That is, it relates to what a "chelating agent" is (and what it is not), based in part on the language of the claims.

Consulting Eng'r LLC v. Shell Oil Co., 824 F.3d 989, 996 (Fed. Cir. 2016) (noting that a process "further comprising" "a hydrotreating step" was not a part of a previously-referenced "fractionating step"); *HTC Corp. v. IPCom GmbH & Co.*, 667 F.3d 1270, 1275 (Fed. Cir. 2012) (finding that "further comprising" signals something "additional") (emphasis omitted).[10]

Lastly, certain claims of other patents-in-suit further support Baxter's take. For instance, the claims of the '026 patent require "*admixing* an R-isomer of norepinephrine or salt thereof, a chelating agent and a tonicity agent into an aqueous acidic solution[,]" while the claims of the '458 patent require "*combining* norepinephrine or a salt thereof, a chelating agent, a tonicity adjusting agent, and an aqueous acidic solution[.]" ('026 patent, col. 20:31-33 (emphasis added); '458 patent, col. 20:44-46 (emphasis added)) Using terms like "admixing" and "combining" in this way signals that the "chelating agent" is an entirely separate chemical compound as compared to the other ingredients with which it is being "admix[ed]" or "combin[ed]" into the solution—including "norepinephrine or a salt thereof." (D.I. 61, Constantinides Decl. at ¶ 35 (noting that a person of skill in the art, or a "POSITA," would understand from the use of "admix" and "combine" that the chelating agent is separate from the norepinephrine or a salt thereof); *see also* Tr. at 75)

[10] At the *Markman* hearing, Nevakar's counsel seemed to acknowledge that this "further comprises" language can be a "strong clue" that two claim terms like these are fully separate entities. (Tr. at 24-25) But it argued that here, this "implication" is overcome by the fact that the patentees purportedly provided their own special definition of "chelating agent" in the patents. (*Id*. at 25 ("And a critical distinction of all those cases to the situation here, none of them involve a circumstance where the patentee is provid[ing] a special definition. That is why those courts went down those rabbit holes, engaged in claim construction to see, in the context of intrinsic and extrinsic evidence, a [person of skill in the art's] views [as to] what those claim terms have to require[.]")) The Court will discuss Nevakar's lexicography argument in more detail below (and explain why it is unavailing).

While the patents' claim language is helpful to Baxter, so too is the shared specification. It is undisputed that every embodiment of the invention listed in the specification involves a separate chelating agent added to the composition; none of those embodiments describe a scenario where a chelating agent was liberated in solution from the norepinephrine or norepinephrine salt. (Tr. at 27, 35, 48, 71) By way of example, Baxter points to the specification's Table 6, which discloses an exemplary formulation. (D.I. 67 at 14) In that formulation, under the "Ingredient" column, "[n]orepinephrine [b]itartrate[,]" the active ingredient, is listed separately from "[e]detate [s]odium[,]" the chelating agent. ('735 patent, Table 6; *see also id.*, Table 11 (listing "[n]orepinephrine [b]itartrate" as a separate ingredient from the chelating agent, "[e]detate [s]odium")) Table 4 is similar, as it identifies "[n]orepinephrine [b]itartrate" as a separate ingredient from the chelating agent, "[c]itric acid[.]" (*Id.*, Table 4) Although the Federal Circuit has cautioned "against limiting the claimed invention to preferred embodiments or specific examples in the specification[,]" *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1328 (Fed. Cir. 2002) (internal quotation marks and citations omitted), the specifics of preferred embodiments are also not irrelevant to a determination of the correct meaning of claim terms, *see Phonometrics, Inc. v. Northern Telecom Inc.*, 133 F.3d 1459, 1466 (Fed. Cir. 1998). Here, when considered together with the clear language of the claims themselves, the fact that every single embodiment in the specification illustrates the use of separate chelating agents certainly supports Baxter's proposed construction. *See ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1374-75 (Fed. Cir. 2009) (affirming a construction of the term "spike" as requiring "'an elongated structure having a pointed tip for piercing the seal, which tip may be sharp or slightly rounded[,]'" rejecting the patentee's broad construction of "'an upward projection[,]'" and concluding that the district court correctly included the concept

of being able to pierce a seal in the construction, since (1) all the embodiments shown in the specification described the spike as being pointed; (2) nothing in the intrinsic evidence suggested that the spike could be non-pointed; and (3) including the functional aspect of being able to pierce a seal in the construction helped to define further how "pointed" the spike had to be).[11] The Court therefore concludes that Baxter's proposed construction is well-supported by the intrinsic evidence.

Moreover, Nevakar's criticisms of Baxter's construction seem off-base. The Court will address some of those criticisms here.

First, Nevakar argues that the specification does in fact contemplate a scenario in which the bitartrate anion, which could form when norepinephrine bitartrate is in solution, serves as the claimed chelating agent. Specifically, Nevakar posits as follows:

> [T]he Specification recites numerous examples of chelating agents, including "bicarboxylic acids . . . and salts and hydrates thereof." . . . A POS[IT]A would have known that one example of a bicarboxylic acid (i.e., an acid having two carboxyl groups) is tartaric acid[.] . . . A POS[IT]A would have also known that bitartrate salts are salts of tartaric acid, and are understood to function as chelating agents. . . . The [s]pecification expressly discloses tartrate as an example of a bicarboxylic acid that can serve as the claimed chelating agent . . . and further recites that norepinephrine "may be a salt of any suitable and pharmaceutically acceptable form, including . . . organic salts (e.g., bitartrate)." . . .

---

[11] It is also worth noting that, just as the claims do, the specification uses language highlighting how the chelating agent is a separate compound from the active ingredient. (*See* '735 patent, col. 4:26-37 ("[T]he inventors also contemplate a method of preparing a ready-to-inject norepinephrine composition that includes a step of formulating a liquid parenteral composition that contains in an aqueous acidic buffer norepinephrine as an R-isomer. . . . [T]he aqueous buffer *will further comprise a chelating agent*[.]") (emphasis added); *see also id.*, col. 3:56-60 ("In one aspect of the inventive subject matter, the inventors contemplate a [] ready-to-inject norepinephrine composition that comprises an aqueous acidic buffer having a pH range of between 3.7 and 4.3, wherein the aqueous buffer *further comprises a chelating agent*[.]") (emphasis added); *id.*, col. 4:43-48 ("[T]he aqueous buffer *also includes a chelating agent*[.]") (emphasis added); *id.*, col. 9:13-14 ("*Citric acid was added* and the solution was stirred until a homogenous solution was obtained.") (emphasis added))

> Thus, the claimed norepinephrine can be "provided as the norepinephrine bitartrate salt," . . . with the bitartrate anion serving as the claimed chelating agent.

(D.I. 67 at 6-7 (citations omitted)) So, to sum up Nevakar's position, it argues that because "tartrate" can be a chelating agent, and since you can find "bitartrate" in the norepinephrine active ingredient, then the specification contemplates the use of a chelating agent that is liberated from the active ingredient in solution.[12]

The Court agrees with Nevakar that tartrate can act as a chelating agent. But the key point here is that *the claim language itself otherwise requires* that if tartrate (or anything else that qualifies) is to be used as a chelating agent, then it must be separately added into the composition. Nowhere does the claim language (or the specification) suggest otherwise. In fact, as Baxter points out, the specification appears to note that when a chelating agent is not separately added, the result is ineffective. Specifically, Baxter pointed to Tables 1 and 3 in the specification, which disclose stability data for prior art formulations including norepinephrine bitartrate but no additional chelating agent. (D.I. 67 at 15) In the listed examples where a chelating agent is not separately added, the specification notes that "the norepinephrine at ready-to-inject concentrations underwent significant degradation." (*Id.* (quoting '735 patent, col. 3:15-17; *see also* '735 patent, Tables 1 & 3)) This is partly so, according to Baxter, because the "bitartrate anion [was] insufficient to provide the purportedly stable formulation claimed." (*Id.*) This example, although not determinative, further indicates that the patents do not seem to

[12] Here, Nevakar seemed to be asserting that "tartrate" and "bitartrate" amount to the same thing. Baxter disagrees with this assertion. (*But see* Tr. at 68) However, the Court need not resolve that dispute in order to dispose of Nevakar's argument.

contemplate a scenario where a substance that may be released from the active ingredient when in solution can amount to the "chelating agent."[13] (Tr. at 61-63)

Nevakar also faults Baxter's proposed construction for failing to sufficiently explain what it is that the chelating agent needs to be separate *from*. Nevakar argues that Baxter's construction could mean that the chelating agent is "separate from norepinephrine, or separate from all other ingredients in the composition, or something else." (D.I. 67 at 21 (citing D.I. 62, Second Buckton Decl. at ¶ 32)) But as Baxter responded, it is clear that the chelating agent simply needs to be separate from the other separately-listed ingredients in the claims (e.g., norepinephrine or a salt thereof and the tonicity agent). (*Id.* at 13-16, 28; *see also* Tr. at 79-80) And as noted above, this position is supported by both the claim language and the specification.

Having concluded that the chelating agent must be a separate chemical compound added to the composition (as Baxter suggests), the Court will next address some of the issues with Nevakar's proposed construction.

In support of its construction, Nevakar argued that the Court need not look to intrinsic and extrinsic evidence because the patentees acted as a lexicographer, providing a specific definition of "chelating agents[.]"[14] (Tr. at 10, 25-26, 38-39) Nevakar pointed to the following

---

[13] Nevakar responded to this point by arguing that "the extent to which the bitartrate anion chelates metal ions in the claimed solution is beside the point[because] the claims simply require that a 'chelating agent' be present in the recited concentration, but the claims do not recite a threshold level of functionality that the chelating agent itself must achieve in the composition." (D.I. 67 at 23; *see also* Tr. at 90-93) But if Nevakar's assertion (i.e., that the bitartrate anion that is part of norepinephrine bitartrate can serve as a chelating agent in the claimed composition) was correct, then it would seem strange that the specification would describe a composition that includes norepinephrine bitartrate and no separate chelator as one that was insufficient to meet the goals of the patent.

[14] During the *Markman* hearing, there was a dispute over whether Nevakar had raised this "lexicographer" argument in its briefing. Baxter asserted that Nevakar had not, (Tr. at

passage in the specification as the special definition on which its construction is based: "For example, suitable chelators include various bicarboxylic acids, tricarboxylic acids, and aminopolycarboxylic acids such as ethylenediaminetetraacetic acid (EDTA), ethylene glycol-bis(β-aminoethyl ether)-N,N,N',N'-tetraacetic acid (EGTA), and penta(carboxymethyl)diethylenetriamine (DTPA), and salts and hydrates thereof[.]" ('735 patent, col. 6:57-63) Nevakar's position seemed to be that (1) since this passage is purportedly definitional as to "chelating agent," and (2) since nowhere in the passage did the patentees suggest that the chelating agent need be a separate compound from the other components referenced in the claims, then (3) Baxter's proposal must be incorrect. (Tr. at 38-39)

The Court is not persuaded that, with this passage, the patentees meant to assign a special definition to "chelating agents."[15] To act as a lexicographer, a patentee must "clearly express" an intent to redefine the meaning of a particular claim term away from the ordinary meaning. *Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005). Examples of clear lexicography include saying "[this term] means" or "[the term is] defined [as]." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012). In other words, it is an "exacting" standard that requires "clearly set[ting] forth a definition" and "clearly express[ing] an intent to define the term." *GE Lighting Sols. LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014) (internal quotation marks and citations omitted). Here, the patentees expressed

---

49), which Nevakar disputed, (*id.* at 93-94). Without deciding this issue, the Court will address the argument for the sake of completeness.

[15] Of course, even if Nevakar were right and this passage did serve as a special definition of "chelating agent," that would not necessarily mean that Baxter's "a separate chemical compound, added to the composition" proposal is incorrect. As noted above, that requirement is drawn directly, *inter alia*, from particular additional language found *in the claims*. And the meaning of that claim language must be respected here.

no such intent. Rather than defining the term "chelating agents," in this passage, the patentees instead were simply focused on providing some examples of such agents. This is evidenced by the fact that the sentence begins with "[*f*]*or example*, suitable chelators *include*[,]" and that it introduces additional subcategories of chelators with the phrase "such as[.]" The use of this type of exemplary language does not clearly demonstrate that the patentees intended to assign some all-encompassing, specific meaning to "chelating agents." *See Aventis Pharm., Inc. v. Impax Labs., Inc.*, No. 02-1322 (GEB), 2011 WL 94188, at *3 (D.N.J. Jan. 11, 2011) (concluding that the inventor did not act as a lexicographer to define the term "suitable antiadherent[,]" where the specification stated only that the "suitable antiadherent *includes*" certain compounds listed as examples, and where there was no indication from the specification that the list of examples was meant to be exhaustive) (emphasis added); *Pelican Int'l, Inc. v. Hobie Cat Co.*, Case No. 20-cv-2390-BAS-MSB, 2022 WL 298959, at *14-15 (S.D. Cal. Feb. 1, 2022) (finding that the patentee's use of "i.e.," in the specification did not show that the patentee was acting as a lexicographer, because the surrounding language indicated that the patentee was merely offering an example, rather than defining the term at issue).[16]

[16] During the *Markman* hearing, Nevakar's counsel stated that the intended effect of Nevakar's proposed construction was to create a "closed set"—such that the only compounds that could act as chelating agents were those molecules and salts and hydrates thereof that were explicitly listed in the specification passage at issue. (Tr. at 43-44) In other words, Nevakar was suggesting that one could simply drop the word "includes" from its construction, so that the construction would simply list as chelating agents "bicarboxylic acids, tricarboxylic acids, and aminopolycarboxylic acids such as ethylenediaminetetraacetic acid (EDTA), ethylene glycol-bis(β-aminoethyl ether)-N,N,N',N'-tetraacetic acid (EGTA), and penta(carboxymethyl)diethylenetriamine (DTPA), and salts and hydrates thereof[.]" (*Id.*) Yet such a construction would not be supported by the intrinsic evidence. That is because the language in this passage (which uses the words "[f]or example" and "include[s]") makes clear that the list provided is intended to be exemplary—i.e., *not* a closed set. ('735 patent, col. 6:57-63) From this, it is clear that the patentees did not intend on limiting chelators to only those agents listed in the passage at issue. *See Blue Spike LLC v. Grande Commc'ns, Inc.*, CIVIL ACTION NO. 4:20-CV-671, 2021 WL 5094911, at *18-19 (E.D. Tex. Nov. 2, 2021) ("The word

Nevakar's proposed construction is also unhelpful because it does not attempt to define what a "chelating agent" is or what it does, or even how a chelating agent functions along with the rest of the claimed components. Instead, its construction simply lists examples of what a chelating agent could be. While reference to certain examples might sometimes be helpful to include in a claim construction for a disputed term, *see Purdue Pharma L.P. v. Al Vogen Pine Brook, LLC*, C.A. No. 15-687-GMS(consolidated), 2017 WL 1943957, at *1 (D. Del. May 10, 2017), ideally, the final construction would also tell interested observers (including jurors) something more about what the term is and/or what its function is.[17]

With Baxter having provided significant support for the key disputed portion of its proposed construction, and with Nevakar's alternative construction being problematic, the Court will construe "chelating agents" to mean "a separate chemical compound, added to the composition." The Court acknowledges that an optimal construction would also contain additional wording that better describes what a "chelating agent" actually is, *see supra* n.6, but that can be addressed prior to trial if necessary.

B. "antioxidants"

'example' and the phrases 'can be used' and '[o]ne possible use' demonstrate that the patentee disclosed using 28 bits as an example, not a definition.") (citation omitted).

[17] *See, e.g.*, *Bracco Diagnostics, Inc. v. Maia Pharm., Inc.*, 839 F. App'x 479, 486-87 (Fed. Cir. 2020) ("Listing numerous compounds that meet the language of a functional term in a claim confuses construing what the function is with what compounds perform that function. The latter is not the task of claim construction, which is to provide definitional meaning to claim language."); *see also Eli Lilly & Co. v. Eagle Pharm., Inc.*, Civ. No. 17-1293-MSG, 2019 WL 1299212, at *4-5 (D. Del. Mar. 21, 2019) (excluding an example from the defendant's proposed construction where the example "[was] not definitional but only exemplary" and was merely "one example, out of many possible examples, demonstrating how the definition 'effective amount' can operate").

The next disputed term, "antioxidants," appears, *inter alia*, in claims 1 and 14 of the '735 patent, claim 1 of the '026 patent, claim 1 of the '850 patent, and claim 1 of the '458 patent. Its use in claim 1 of the '735 patent, which was previously set out above, is exemplary. As part of that claimed method, claim 1 states "wherein the norepinephrine composition is *substantially free of antioxidants*[.]" ('735 patent, cols. 21:52-53 (emphasis added))

The parties proposed the following constructions:

Term	**Nevakar's Proposed Construction**	**Baxter's Proposed Construction**
"antioxidants"	"excipients whose function is commonly understood by a person of ordinary skill in the art to be antioxidants, as listed in the Handbook of Pharmaceutical Excipients (7th ed.)"	"agents that inhibit oxidation of another agent"

(D.I. 67 at 32)

The parties have two disputes with regard to this term. The Court will address them in turn.

The first dispute has to do with whether the construction should include Baxter's proposal that antioxidants are "agents that inhibit oxidation." The Court agrees with Baxter that this should be a part of the construction, for a few reasons.

For one thing, this terminology is well-grounded in the specification. More specifically, the specification identifies Levophed® as a prior art concentrated injectable norepinephrine bitartrate formulation that is diluted prior to intravenous infusion. ('735 patent, col. 2:1-5) The patent then notes that Levophed "contains sodium metabisulphite as an antioxidant[,]" (*id*., col. 2:15-16), and goes on to state:

> Stability of Levophed® and Norepinephrine bitartrate injection (Baxter), in normal saline solutions is presented in Table 2 and Table 3 where norepinephrine was diluted to a concentration of 16 µg/ml. Stability was assessed in 250 ml saline at accelerated (i.e.,

> 40±2° C. and 75±5% relative humidity, duration as indicated) and long term stability (i.e., 25±2° C. and 60±5% relative humidity, duration as indicated) storage conditions. . . .
>
> As can be seen from the results, the norepinephrine at ready-to-inject concentrations underwent significant degradation. *Oxidative degradation could possibly be reduced or even prevented by addition of effective amounts of sodium metabisulphite* to the ready-to-inject norepinephrine solution.

(*Id.*, cols. 2:37-3:21 (emphasis added)) Here, then, the antioxidant (sodium metabisulphite) is functioning as an "agent[] that inhibit[s] oxidation[,]" in that the specification contemplates using sodium metabisulphite to reduce or prevent "[o]xidative degradation" of the active ingredient (i.e., the norepinephrine bitartrate).[18]

Additionally, extrinsic evidence supports Baxter's proposed construction. Specifically, Baxter cites to various treatises, which all agree that antioxidants inhibit oxidation. (*See, e.g.*, D.I. 61, ex. 18 at 24 ("Antioxidants are materials added to a product to prevent oxidation of the active ingredient(s)."); *id.*, ex. 8 at 112 (stating that "[a]ntioxidant" refers to "[a]n agent which inhibits oxidation and thus is used to prevent the deterioration of preparations by the oxidative process"))

Moreover, Nevakar's criticisms of this portion of Baxter's proposal seem off the mark. For example, Nevakar faults this language because it "would improperly include agents that 'inhibit oxidation of another agent' only to some incidental, de minimis extent." (D.I. 67 at 35) This is problematic, according to Nevakar, because "[t]he inclusion of such agents has no support in the intrinsic evidence, and a POS[IT]A would not consider an agent that only trivially

[18] Indeed, even Nevakar's expert, Dr. Graham Buckton, agrees that antioxidants inhibit oxidation. (D.I. 60, Buckton Decl. at ¶ 33 ("An antioxidant is an excipient which is both safe and effective in limiting oxidation of an active in a formulation, and in this case one which is suitable for administration into the bloodstream."))

inhibits oxidation of another agent to be within the ordinary meaning of the term 'antioxidant.'" (*Id.*) Yet Nevakar cites to no authority to support its assertion that a POSITA would take this view. (*Id*.) And as Baxter noted during the *Markman* hearing, the patents never suggest that there is some minimum oxidation inhibition threshold that an agent must meet in order to qualify as an antioxidant. (Tr. at 114-18)[19] In light of that, the Court does not see why this aspect of Baxter's proposal is problematic.

Another problem with Nevakar's position is that its competing proposal, which does not mention the concept of inhibiting oxidation, otherwise fails to imbue the claim term with clear meaning. Indeed, it would cause confusion. Functionally, Nevakar's proposal reads as though an antioxidant *has to be in* the *Handbook of Pharmaceutical Excipients* (7th ed.) ("Handbook") in order to qualify. (*See also* D.I. 67 at 34 ("[T]he Handbook is a codification of the understanding of a POS[IT]A.")) In other words, the proposal facially suggests that if an agent is not listed in the Handbook, then it could not count as an antioxidant. (*Id.* at 45) In its briefing, Baxter explained that this was problematic, because in its view, certain substances that are undeniably antioxidants are not listed as such in in the Handbook. (*Id.* at 40 (Baxter asserting that reducing sugars, which are not in the Handbook, can act as an antioxidant)) But then, during the *Markman* hearing, Nevakar's counsel stated that its proposal was not so limited. (Tr. at 99-100) Instead, Nevakar's counsel explained that while "the Handbook is . . . the first source that a POS[IT]A would turn to in seeking to understand" what is an antioxidant, Nevakar's construction was actually meant to allow that if a sufficient number of POSITAs consider an

[19] Indeed, if Nevakar was correct and there was some minimal threshold that an agent had to meet in terms of inhibiting oxidation in order to qualify as an antioxidant, that would just beg the question: "Well, what is that threshold?" Or "How much oxidation inhibition is enough?" When asked what was the answer to those questions, Nevakar's counsel did not seem to have a ready answer. (Tr. at 103)

agent to be an antioxidant (such that the agent is "commonly understood" to be one), it can qualify, even if it is not listed in the Handbook. (*Id.* at 100; *see also id.* at 122-23) But this clarification raises more questions than it answers. What does it mean to be "commonly understood" to be an antioxidant? How many POSITAs would have to agree to reach the "commonly understood" threshold? What if an agent is listed as an antioxidant in the Handbook, but many POSITAs would disagree that it fits that bill? Nevakar's proposal provides no answers to these questions. And so, in that sense, it is not so much a construction as it is a black box—one that would essentially punt on obtaining clarity as to claim scope until expert discovery is completed. (*Id.* at 101-02, 119, 122-23) That is sub-optimal. The Court will therefore reject Nevakar's construction for failing to assign a "fixed, unambiguous . . . meaning to the claim[.]" *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 355 F.3d 1361, 1367 (Fed. Cir. 2004); *see also Magna-Mug, LLC v. Novelty, Inc.*, No. 1:13-cv-304, 2014 WL 3895237, at *6 (S.D. Ohio Aug. 8, 2014). And it will adopt Baxter's proposal as to the "agents that inhibit oxidation" portion of its construction.

The Court now considers the parties' second dispute about the term. This stems from the final portion of Baxter's proposal, which raises the question: must antioxidants simply be "agents that inhibit oxidation *of another agent*"? Nevakar agrees that an antioxidant must inhibit oxidation of the *active ingredient* of the composition, but it criticizes this portion of Baxter's construction for allowing an agent to be an antioxidant if it were to inhibit oxidation not of the active ingredient, but instead simply of another excipient. (D.I. 67 at 40; Tr. at 106) Baxter responds that an antioxidant can, in fact, prevent oxidation of other parts of the formulation other than the active ingredient (such as a tonicity agent). (Tr. at 111-14)

On this dispute, the Court sides with Nevakar. As an initial matter, Baxter has pointed to little in the intrinsic or extrinsic record to support this portion of its construction. And in fact, Baxter's cited extrinsic evidence provides some support for *the opposite* position. Specifically, the *Parenteral Technology Manual* by Michael J. Groves—one of the treatises relied on by Baxter for its proposed construction, (D.I. 67 at 36)—states that antioxidants are "materials added to a product to prevent oxidation of the *active ingredient(s)*." (D.I. 61, ex. 18 at 24 (emphasis added)).[20]

Moreover, the patents' specification supports Nevakar's view here. In multiple places, it appears to discuss the concept of inhibiting oxidation as to the active ingredient. ('735 patent, cols. 3:15-20, 7:26-31)

Lastly, the parties' own agreed-upon construction of another claim term—substantially free of antioxidants"—further supports Nevakar's position. That is because the construction states that "substantially free of antioxidants" means "does not include antioxidants in an amount effective to reduce degradation of total *norepinephrine*[. . . .]" (D.I. 67 at 4 (emphasis added)) In other words, when it came time to define what it meant to be "substantially free" of antioxidants, Baxter too was focused on the degradation effect on the active ingredient alone, and not on other aspects of the formulation. (Tr. at 124-25) To adopt Baxter's "another agent" phraseology here would seem to lead to inconsistent constructions of the "substantially free" term and the "antioxidants" term.

For all of the above reasons, "antioxidants" should be construed to mean "agents that inhibit oxidation of the active ingredient."

---

[20] Similarly, Nevakar's expert, Dr. Buckton, explains that an antioxidant "limit[s] oxidation of an active [ingredient] in a formulation[.]" (D.I. 60, Buckton Decl. at ¶ 33; *see also* D.I. 62, Second Buckton Decl. at ¶¶ 9, 11)

C. "tonicity agent" / "tonicity adjusting agent"

The next disputed term, "tonicity agent" / "tonicity adjusting agent[,]" appears, *inter alia*, in claims 1, 9, 14, and 19 of the '735 patent, claim 1 of the '026 patent, claims 1 and 16 of the '850 patent, and claims 1 and 19 of the '458 patent. Representative claim 1 of the '735 patent recites in part: "wherein the norepinephrine composition comprises norepinephrine or a salt thereof at a concentration of between 10 μg/ml and 100 μg/ml in an aqueous acidic solution having a pH range of between 3.7 and 4.3, wherein the aqueous acidic solution further comprises a chelating agent at a concentration of between 1 μg/ml and 100 μg/ml and a *tonicity agent*[.]" ('735 patent, col. 21:45-51 (emphasis added)) The parties proposed the following constructions:

Term	**Nevakar's Proposed Construction**	**Baxter's Proposed Construction**
"tonicity agent" / "tonicity adjusting agent"	"excipient whose function is commonly understood by a person of ordinary skill in the art to be a tonicity agent, as listed in the Handbook of Pharmaceutical Excipients (7th ed.)"	"a separate chemical compound, added to the composition, that increases osmolality of the composition"

(D.I. 67 at 46)

The first dispute with respect to this term is whether (similar to the discussion above regarding "chelating agent") a "tonicity agent" or "tonicity adjusting agent" must be a separate chemical compound from the other compounds described in the claims. For similar reasons, the Court agrees with Baxter that it must.

First, the claim language of the patent supports Baxter's position. Claim 1 of the '735 patent clearly delineates "tonicity agent" from the other distinct elements of the norepinephrine composition. Having listed these elements separately, the implication is that the patentees meant for the tonicity agent to be a "separate chemical compound." *Becton*, 616 F.3d at 1254. Second, as with "chelating agent," the term "tonicity agent" is preceded by the phrase "further

comprises," which indicates that tonicity agents are separately added compounds. Third, the '735 patent specification provides further support for this conclusion. It states, for example, that the tonicity agent, "[s]odium chloride[,] *was added* and the solution was stirred until a homogenous solution was obtained." ('735 patent, col. 9:10-12 (emphasis added); *see also id.*, col. 7:17-18 ("[A]dditional tonicity agents *may be added*[.]") (emphasis added)) As with chelating agents, the examples in the specification all contemplate separately added tonicity agents; Tables 4, 6, and 11 all separately list "[n]orepinephrine [b]itartrate[,]" the active ingredient, from "[s]odium chloride[,]" the tonicity agent. (*Id*., Tables 4, 6, 11) And fourth, claims of other of the patents-in-suit indicate the same. For example, the '026 patent recites "admixing" the "tonicity agent" with other components of the aqueous solution, including norepinephrine or a salt thereof. ('026 patent, col. 20:30-33) For all of these reasons, the Court agrees with Baxter that a tonicity agent must be "a separate chemical compound, added to the composition."[21]

Having concluded that tonicity agents are separate chemical compounds from the other components of the solution, the Court addresses the remainder of Baxter's proposed construction (i.e., whether a tonicity agent is one "that increases osmolality of the composition").[22] At the *Markman* hearing, it became clear that the parties dispute whether a tonicity agent *increases* or simply adjusts *in either direction* the osmolality of the composition. At the hearing, Nevakar

---

[21] In opposing Baxter's construction, Nevakar asserted that "nothing in the intrinsic evidence supports Baxter's proposal that the tonicity agent must be a 'separate chemical compound.'" (D.I. 67 at 47-48) That is demonstrably incorrect, as the Court has explained above. Moreover, Nevakar did not cite to any contrary intrinsic evidence, nor did it substantively respond to the wealth of intrinsic evidence cited by Baxter.

[22] Osmolality is the function of the total number (concentration) of dissolved molecular particles that are present in the solution. (D.I. 61, Constantinides Decl. at ¶ 47)

suggested—again, for the very first time—that a tonicity agent could adjust the osmolality upwards or downwards depending on what is needed. This is purportedly because the "end goal of adjusting osmolality is so it matches the natural physiological conditions[.]" (Tr. at 129-30) So, according to Nevakar's counsel, "if the composition being injected into the person is too low of an osmolality . . . you would adjust it upward by adding something to the solution. If it is too high, then you delete the solution to lower the osmolality." (*Id.* at 130)

Nevakar's belated argument, however, is not supported by the specification, which indicates only that tonicity agents operate to *increase* osmolality. Specifically, the specification states that:

> With respect to suitable salts it is contemplated that the salt is a pharmaceutically acceptable salt that can be used to *increase tonicity*. . . .
>
> Depending on the particular salt concentration, additional tonicity agents may be added. . . . *The amount of tonicity adjusting agent used can be adjusted to obtain osmolality of the formulations in the range of 260 to 340 mOsm/kg*. An osmometer can be used to check and adjust the amount of tonicity adjusting agent to be added to obtain the desired osmolality.

('735 patent, col. 7:9-23 (emphasis added)) Thus, the specification provides support for Baxter's proposal that tonicity agents act to "increase osmolality of the composition."[23] (Tr. at 132-33) Baxter's expert, Dr. Panayiotis Constantinides, also opines that a POSITA would commonly understand that the purpose of a tonicity agent is to increase the osmolality of a composition.

[23] Nevakar faults Baxter's proposed construction for potentially allowing compounds to be classified as tonicity agents or tonicity adjusting agents even if they only increase the osmolality of a composition by some incidental, de minimis amount. (D.I. 67 at 47) What Nevakar has not cited to, however, is any indication from the patents-in-suit that tonicity agents are required to meet some minimum threshold for an osmolality increase. In other words, Nevakar does not explain why the patents contemplate that a compound that only incidentally increases osmolality would not count as a tonicity agent.

(D.I. 61, Constantinides Decl. at ¶¶ 46-47) And Nevakar provided absolutely no intrinsic or extrinsic backing for its suggestion that the claimed tonicity agent may be used to decrease osmolality.[24]

Therefore, the Court will construe "tonicity agent" / "tonicity adjusting agent" to mean "a separate chemical compound, added to the composition, that increases osmolality of the composition."

D. "norepinephrine" / "norpepinephrine"[25]

The next disputed term, "norepinephrine" / "norpepinephrine[,]" appears in numerous claims of the asserted patents, including representative claim 1 of the '735 patent. The parties proposed the following constructions:

Term	Nevakar's Proposed Construction	Baxter's Proposed Construction
"norepinephrine" / "norpepinephrine"	"norepinephrine or a salt thereof"	"norepinephrine and pharmaceutically acceptable salts (e.g., norepinephrine bitartrate) and prodrugs thereof"

(D.I. 67 at 58)

The parties' dispute as to the term is singular: whether "norepinephrine" should include "prodrugs thereof" in addition to "norepinephrine or a salt thereof[.]"[26] Nevakar contends that

[24] Nevakar's proposed construction is also unhelpful for the same reasons as was its proposal for "antioxidants."

[25] The parties do not dispute that the term "norpepinephrine" in the patents-in-suit, (*see, e.g.*, '735 patent, col. 23:17-22), is a typographical error that should be understood to mean "norepinephrine[,]" (D.I. 67 at 58 n.26; *id.* at 61).

[26] During the *Markman* hearing, Nevakar's counsel said that Nevakar understood Baxter's proposed construction to mean that whenever "norepinephrine" was used in the claims, all three of the listed components (i.e., norepinephrine, norepinephrine salts, and norepinephrine prodrugs), must be present in the composition in order to meet that claim limitation. (Tr. at 144-46) Baxter's counsel confirmed during the hearing, however, that this was not Baxter's intent.

the addition of "prodrugs thereof" is improper. More specifically, although the specification states in column 4 that "[a]s used herein, reference to the term norepinephrine should be interpreted broadly to include pharmaceutically acceptable salts *and prodrugs thereof*[,]" ('735 patent, col. 4:22-25 (emphasis added)), Nevakar points out that certain of the asserted claims of the '735, '026, '850, and '458 patents "each recite 'norepinephrine *or* a salt thereof[,]'" (D.I. 67 at 59 (emphasis in original)).[27] This claim language, according to Nevakar, signals that the patentees intended for the scope of "norepinephrine" in those claims to include either norepinephrine *or* salts of norepinephrine, but not prodrugs of norepinephrine. (*Id.* ("[I]f the patentees had intended for the scope of a claim to include norepinephrine *and* pharmaceutically acceptable salts *and* prodrugs thereof, they could have claimed simply 'norepinephrine[.]'") (emphasis in original)) Nevakar concludes that "[a] POS[IT]A would recognize that the wording of the claims, including the use of 'or' in the disjunctive sense, serves to narrow the 'broad[]' interpretation of 'norepinephrine' discussed in the [s]pecification." (*Id.* (citation omitted))

In response, Baxter argues that its construction tracks the clear definition provided in column 4 of the specification, which includes both pharmaceutically acceptable salts *and* prodrugs thereof in defining norepinephrine. (*Id.* at 61 (citing '735 patent, col. 4:22-25)) Indeed,

---

Rather, Baxter's proposed construction was only meant to require the presence of *one* of these three components. (*Id.* at 146-47) To that end, Baxter confirmed during the *Markman* hearing that it would be willing to replace the "and" in its proposed construction with "or[,]" such that the construction would read "norepinephrine *or* pharmaceutically acceptable salts (e.g., norepinephrine bitartrate) *or* prodrugs thereof." (*Id.* at 147) Thus, the Court will consider Baxter's proposed construction as amended.

[27] For instance, claim 1 of the '735 patent recites a method of treating hypotension "wherein the *norepinephrine or a salt thereof* in the norepinephrine composition comprises at least about 90% R-isomer of norepinephrine after storage at 25±2° C. and 60±5% relative humidity, over at least three months as determined by HPLC." ('735 patent, col. 21:54-58 (emphasis added))

beyond this language in column 4, Baxter notes that the patent otherwise emphasizes that "norepinephrine" includes prodrugs thereof. ('735 patent, col. 6:24-29 ("Of course, it should also be appreciated that the norepinephrine may be a salt of any suitable and pharmaceutically acceptable form, including mineral salts (e.g., HCl salt) and organic salts (e.g., bitartrate). Similarly, where desired, the *norepinephrine may also be used in any suitable prodrug form*[.]") (emphasis added)) As a result, Baxter argues that Nevakar's construction ignores the patentees' lexicography to arrive at a construction inconsistent with what the patentees intended. (D.I. 67 at 62)

Both sides make good arguments here, but on balance, the Court believes Baxter's proposed construction is the better one. The parties agree that column 4's sentence amounts to an explicit definition for this term. And it surely does. The specification's use of the phrase "[a]s used herein" at the start of that sentence indicates as much.[28] And the sentence's statement to the effect that "the term norepinephrine should be *interpreted broadly* to include pharmaceutically acceptable salts and *prodrugs thereof*" could not be clearer: "norepinephrine" does in fact include prodrugs thereof. Where as here, the patentees have provided a clear definition for a term, "the inventor's lexicography governs." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005); *see also Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1356 (Fed. Cir. 2014) ("Under our precedent, the patentee's lexicography must govern the claim construction analysis.").

[28] *See Abbott Labs. v. Andrx Pharm., Inc.*, 473 F.3d 1196, 1210 (Fed. Cir. 2007) (noting that the phrase "as used herein" serves to "unambiguously provide[] definitions") (internal quotation marks and citations omitted); *see also Intellectual Ventures I LLC v. AT&T Mobility LLC*, C.A. No. 12-193-LPS, 2015 WL 1393386, at *8 (D. Del. Mar. 24, 2015).

In opposing Baxter's construction, Nevakar argues that the construction would result in redundancy. (Tr. at 149-50) And Nevakar's argument is understandable. Nevakar's point is that according to the express definition for "norepinephrine" set out in column 4, "a salt thereof" would already be an example of "norepinephrine." And if this definition was meant to carry over to the claims, Nevakar asserts, then it would be strange for the patentees to have written out "norepinephrine or a salt thereof" in certain claims (as they do in several instances)—since the "a salt thereof" portion should already have been incorporated into the claim by virtue of the claim's use of the word "norepinephrine." In order to avoid redundancy in these claims, Nevakar argues, the Court should assume that despite the clear definition in the patent to the contrary, "norepinephrine" means *only* "norepinephrine" (and does not include salts or prodrugs thereof, unless additional wording is used in a claim to signify the same).

The Court acknowledges that this argument has some force. It is true that if Baxter's proposal were adopted, certain claims would include some redundant language. (Tr. at 152)

But ultimately, the Court sides with Baxter here. In part, that is because it seems to the Court that when a patentee explicitly defines a term in a patent, it is pretty clearly announcing to the world its view that the term, as used throughout the patent, should have exactly the meaning that the patentee said that it should. Otherwise, what was the point of defining the term in the first place? Moreover, the presumption is that the same claim term should be understood to have the same meaning across related patents. *See, e.g.*, *Omega Eng'g, Inc. v. Raytek Corp*., 334 F.3d 1314, 1334 (Fed. Cir. 2003).

Additionally, it is worth noting that certain claims of a related patent that was once a part of this case do simply use the term "norepinephrine." For instance, one of the limitations of claim 1 of the '436 patent recites "norepinephrine dissolved at a concentration suitable for

administration to a patient in need thereof[.]" ('436 patent, col. 21:52-53; Tr. at 166) As to the use of "norepinephrine" in that claim and in further dependent claims in that patent, it seems hard to deny that the patentees meant for the explicit definition of "norepinephrine" that they included in column 4 to control.

And so even though in a number of claims, there may be a bit of redundancy in light of the adoption of Baxter's construction, the Court does not see this as an absolute barrier here. *Cf. Plastic Omnium Advanced Innovation & Research v. Donghee Am., Inc.*387 F. Supp. 3d 404, 420 (D. Del. 2018); *Robocast, Inc. v. Microsoft Corp.*, C.A. 10-1055-RGA, C.A. 11-235-RGA, 2013 WL 3294862, at *9 (D. Del. June 28, 2013) Therefore, the Court will construe "norepinephrine" / "norpepinephrine" to mean "norepinephrine or pharmaceutically acceptable salts (e.g., norepinephrine bitartrate) or prodrugs thereof."

E. Range Terms

The parties' final disputed term is a series of range terms relating to ranges of amounts and concentrations (the "Range Terms"). The Range Terms, relevant claims, and parties' proposed constructions are as follows:

Term	**Nevakar's Proposed Construction**	**Baxter's Proposed Construction**
"an amount of between 0.6 wt % and 1.2 wt %" ('735 patent, claims 9, 19; '026 patent, claim 1; '850 patent, claim 1; '458 patent, claim 1)	Plain and ordinary meaning, i.e., "an amount of between 0.6 wt % and 1.2 wt %"	"an amount of between exactly 0.6 wt % and exactly 1.2 wt %"
"in an amount of between 1 µg/ml and 100 µg/ml" ('735 patent, claim 14; '026 patent, claim 1; '850 patent, claim 1)	Plain and ordinary meaning, i.e., "in an amount of between 1 µg/ml and 100 µg/ml"	"in an amount of between exactly 1 µg/ml and exactly 100 µg/ml"

"at a concentration of between 10 μg/ml and 100 μg/ml" ('735 patent, claims 1, 8, 14; '026 patent, claim 15)	Plain and ordinary meaning, i.e., "at a concentration of between 10 μg/ml and 100 μg/ml"	"at a concentration of between exactly 10 μg/ml and exactly 100 μg/ml"
"at a concentration of between 1 μg/ml and 100 μg/ml" ('735 patent, claim 1)	Plain and ordinary meaning, i.e., "at a concentration of between 1 μg/ml and 100 μg/ml"	"at a concentration of between exactly 1 μg/ml and exactly 100 μg/ml"
"between 10 μg/ml and 100 μg/ml" ('026 patent, claim 1)	Plain and ordinary meaning, i.e., "between 10 μg/ml and 100 μg/ml"	"between exactly 10 μg/ml and exactly 100 μg/ml"
"at a concentration of between 1 μg/ml and 10 μg/ml" ('026 patent, claim 1)	Plain and ordinary meaning, i.e., "at a concentration of between 1 μg/ml and 10 μg/ml"	"at a concentration of between exactly 1 μg/ml and exactly 10 μg/ml"
"in an amount of between 10 μg/ml and 100 μg/ml" ('850 patent, claim 1)	Plain and ordinary meaning, i.e., "in an amount of between 10 μg/ml and 100 μg/ml"	"in an amount of between exactly 10 μg/ml and exactly 100 μg/ml"
"in an amount of between 10 μg/ml and 100 μm/ml" ('458 patent, claim 1)	Plain and ordinary meaning, i.e., "in an amount of between 10 μg/ml and 100 μg/ml"	"in an amount of between exactly 10 μg/ml and exactly 100 μg/ml"
"in an amount of between 1 μg/ml and 100 μm/ml" ('458 patent, claim 1)	Plain and ordinary meaning, i.e., "in an amount of between 1 μg/ml and 100 μg/ml"	"in an amount of between exactly 1 μg/ml and exactly 100 μg/ml"

(D.I. 67 at 64-65)

With respect to the Range Terms, the parties' dispute is over whether the numerical endpoints in each Range Term are approximations or whether they refer to exact amounts. Nevakar argues that the Range Terms refer to approximations because this interpretation aligns

with how a POSITA would read the intrinsic evidence. (*Id.* at 65) In support, Nevakar cites to the following passage from column 20 in the specification:

> In some embodiments, the numbers expressing quantities of ingredients, properties such as *concentration*, reaction conditions, and so forth, used to describe and claim certain embodiments of the invention *are to be understood as being modified in some instances by the term "about." Accordingly, in some embodiments, the numerical parameters set forth in the written description and attached claims are approximations that can vary depending upon the desired properties sought to be obtained by a particular embodiment.* In some embodiments, the numerical parameters should be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of some embodiments of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as practicable. The numerical values presented in some embodiments of the invention may contain certain errors necessarily resulting from the standard deviation found in their respective testing measurements.

(*Id.* at 65-66 (quoting '735 patent, cols. 20:62-21:14) (emphasis added)) Relying on this excerpt, Nevakar asserts that there is nothing in the intrinsic evidence to suggest that the Range Terms would not amount to the type of "numerical parameters" discussed in this portion of the specification. Indeed, Nevakar says that a POSITA would understand that "absolute precision is simply not possible, for example, due to issues such as 'the number of reported significant digits,' 'ordinary rounding techniques,' and 'errors necessarily resulting from the standard deviation found in . . . testing measurements.'" (*Id.* at 66 (quoting D.I. 60, Buckton Decl. at ¶ 56))

The Court, however, agrees with Baxter's contrary position. As Baxter noted in its briefing, the Federal Circuit has made clear that when a patent includes qualifying language for certain claim limitations but omits it from others, the claims without such approximation language should be construed with numerical precision. *See Jeneric/Pentron, Inc. v. Dillon Co.,*

Inc., 205 F.3d 1377, 1381 (Fed. Cir. 2000) ("This construction, assigning numerical precision to composition ranges, is particularly appropriate when other variables in the same claims explicitly use qualifying language."); *see also TwinStrand Biosciences, Inc. v. Guardant Health, Inc.*, Civil Action No. 21-1126-GBW-SRF, 2022 WL 17986012, at *11 (D. Del. Dec. 9, 2022). This is because a POSITA would understand that the patentees knew how to express ambiguity in claim language when they so desired. *See Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1365 (Fed. Cir. 2014) ("[H]ad the inventors desired the average particle diameter to include a margin of error, they could easily have included the word 'about' in the claim language. In the absence of their decision to do so, however, we will not take it upon ourselves to rewrite the claim in that way.").

Here, the patentees did just that; each of the patents-in-suit includes claims that use approximation language. (*See, e.g.*, '735 patent, cols. 21:55, 21:64-65, 22:15, 22:20, 22:26, 22:30, 22:55, 22:60, 23:7, 23:13, 23:19; '026 patent, cols. 20:57, 20:62, 21:1, 21:6, 21:10, 21:15, 21:20, 21:27, 22:9; '850 patent, cols. 20:49, 21:28, 22:19, 22:24; '458 patent, cols. 20:66, 21:32, 22:6, 22:20) The use of such language confirms that the patentees intended to make some numerical values approximations, while the Range Terms, which do not include such language, are to be construed as exact amounts. (*Compare* '850 patent, col. 20:40-41 ("an amount of between 0.6 wt % and 1.2 wt %") *with id.*, col. 20:48-52 ("wherein the sterile, ready-to-administer, packaged norepinephrine composition comprises at least *about* 90% of R-isomer of norepinephrine" (emphasis added)))

Not only is Baxter's position supported by Federal Circuit law, but it also jibes with the specification. This is because the exact passage from column 20 relied on by Nevakar explicitly states that it is only *in some cases* that numerical values are to be construed as approximations.

('735 patent, col. 20:62-66 ("[T]he numbers expressing . . . properties such as concentration . . . used to . . . claim certain embodiments of the invention are to be understood as being modified *in some instances* by the term 'about.'") (emphasis added)) Nevakar's proposed construction would moot this language to require that the Range Terms be interpreted as approximations in every single instance, even when the claims do not use the word "about" or something like it.

In opposing Baxter's proposed construction, Nevakar faults Baxter for failing to identify a concentration *range* claim that incorporated qualifying language. (D.I. 67 at 71) Instead, Nevakar asserts that Baxter only pointed to language of approximation existing in claims relating to "*single values* of concentrations, or to entirely different measurements such as relative humidity and isomer content." (*Id.* (emphasis added)) This is problematic, according to Nevakar, because Baxter has not demonstrated that the patentees intended to imbue the *Range Terms specifically* with precise meaning (as opposed to other, non-concentration range terms). (*Id.* at 72; *see also* Tr. at 159-61)

But the Court can easily dispense with this argument. This is because the portion of the specification relied on by Nevakar is not limited to "concentration *ranges*." Rather, it discusses simply "concentration[.]" ('735 patent, col. 20:62-66) Thus, Baxter need not cite to *concentration range* claims in the related patents that include approximation language; it is enough for Baxter to have cited to *concentration* claims in those patents with approximation language, which it did. (D.I. 67 at 69 (citing '657 patent, col. 21:9-17 ("wherein the norepinephrine is present at a concentration of about 16 μg/ml, about 32 μg/ml, or about 64 μg/ml")); *see also* Tr. at 164-65)

Therefore, the Court will construe the "Range Terms" to include "exactly[.]"

IV. CONCLUSION

For the foregoing reasons, the Court adopts the following construction:

1. "chelating agent" should be construed to mean "a separate chemical compound, added to the composition"

2. "antioxidant" should be construed to mean "agents that inhibit oxidation of the active ingredient"

3. "tonicity agent" / "tonicity adjusting agent" should be construed to mean "a separate chemical compound, added to the composition, that increases osmolality of the composition"

4. "norepinephrine" / "norpepinephrine" should be construed to mean "norepinephrine or pharmaceutically acceptable salts (e.g., norepinephrine bitartrate) or prodrugs thereof"

5. "Range Terms" should be construed to include "exactly[.]"

Dated: June 26, 2023

Christopher J. Burke
Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE