IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CADENCE PHARMACEUTICALS, INC. and SCR PHARMATOP	:	
Plaintiffs,	:	
v.	:	C.A. No. 11-733-LPS
PADDOCK LABORATORIES INC.; PERRIGO COMPANY; PADDOCK LABORATORIES, LLC; EXELA PHARMA SCIENCES, LLC; EXELA PHARMSCI, INC.; and EXELA HOLDINGS, INC.	:	

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MEMORANDUM OPINION

August 22, 2012
Wilmington, Delaware

STARK, U.S. District Judge:

Pending before the Court is the issue of claim construction of various disputed terms found in U.S. Patent Nos. 6,028,222 (the "'222 patent") and 6,992,218 (the "'218 patent") (collectively, the "patents-in-suit").

I. BACKGROUND

Plaintiffs Cadence Pharmaceuticals, Inc. and SCR Pharmatop (collectively, "Plaintiffs") filed this patent infringement action against defendants Paddock Laboratories, Inc., Perrigo Company, Paddock Laboratories, LLC, Exela Pharma Sciences, LLC, Exela Pharmsci, Inc., and Exela Holdings, Inc. (collectively, "Defendants") on August 18, 2011, alleging infringement of the patents-in-suit. (D.I. 1) The patents-in-suit relate to formulations and methods for making liquid acetaminophen compositions. The '222 patent claims to address an oxygenation problem by including "a buffering agent" and a free radical scavenger/antagonist in the chemical composition of liquid acetaminophen. (*See* '222 patent col.18 ll.50-55) The '218 patent relates to an "extreme, and possibly complete" deoxygenation process, which reduces the oxygen content of the drug during the manufacturing process and potentially removes all oxygen from the chemical formulation. (*See* '218 patent col.4 ll.18-20; *id.* at col.6 ll.50-53)

The parties completed briefing on claim construction on July 10, 2012. (*See* D.I. 165) The Court held a *Markman* hearing on August 10, 2012. *See Markman* Hr'g Tr., Aug. 10, 2012 (D.I. 187) (hereinafter "Tr.").

II. LEGAL STANDARDS

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312

(Fed. Cir. 2005) (internal quotation marks omitted). Construing the claims of a patent presents a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-

15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

A court also may rely on "extrinsic evidence," which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and

learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of ordinary skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19.

Finally, "[t]he construction that stays true to the claim language and most naturally aligns 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). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007).

III. CONSTRUCTION OF DISPUTED TERMS

A. "stable"[1]

Plaintiffs' Proposed Construction: "The active pharmaceutical ingredient does not decompose substantially such that the formulation has a pharmaceutically acceptable shelf life."

Defendants' Proposed Construction: Indefinite under 35 U.S.C. § 112, ¶ 2 and, therefore, not amenable to construction.

Court's Construction: "The active pharmaceutical ingredient does not decompose substantially such that the formulation has a pharmaceutically acceptable shelf life."

Defendants' contention that "stable" is indefinite is unavailing.[2] Even assuming the Court should consider indefiniteness as part of the claim construction process, *see generally Personalized User Model LLP v. Google, Inc.*, 2012 WL 295048, at *22 (D. Del. Jan. 25, 2012) ("[T]he Court does not permit summary judgment arguments, including indefiniteness arguments, during the claim construction phase of the litigation."), proof of indefiniteness is an "exacting standard" that requires a determination that the claim term is "insolubly ambiguous,"

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[1]This disputed term appears in claim 1 of the '222 patent. All parties agree that "stable" is a claim limitation even though it appears in the preamble of claim 1. (*See* Tr. at 76)

[2]Specifically, Defendants contend that the term "stable" is indefinite because: (1) the patent fails to identify the experimental conditions under which any of the disclosed methods should be used, (2) the patent fails to specify which results would indicate acceptable stability, (3) the patent fails to distinguish the claimed invention, in stability terms, over the prior art, and (4) the patent fails to instruct what methods to use to determine or measure stability. (*See* D.I. 146 at 6) However, 35 U.S.C. § 112 does not require that the patent address these issues in order to be definite. *See generally Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1367 (Fed. Cir. 2011) ("[A]n inventor need not explain every detail because a patent is read by those of skill in the art. Well known industry standards need not be repeated in a patent.") (internal citations omitted); *see also generally In re Omeprazole Patent Litig.*, 222 F. Supp. 2d 423, 569 (S.D.N.Y. 2002) ("[T]here is no requirement that the . . . patent include any examples of stability data, as long as the disclosure enables one of ordinary skill in the art to make and use the invention.").

see Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008). "[A] claim is not indefinite merely because it poses a difficult issue of claim construction. Rather if the meaning of the claim is discernible, even though the task may be formidable and the conclusions may be one over which reasonable persons will disagree . . . the claim [is] sufficiently clear to avoid invalidity on indefiniteness grounds." *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1350 (Fed. Cir. 2010) (internal citations and quotation marks omitted). At this stage of the proceeding, Defendants fall short of demonstrating by clear and convincing evidence that the term "stable" is insolubly ambiguous, such that it is incapable of construction.[3]

Defendants' contention that the '222 patent does not teach a method for determining stability is unpersuasive. The '222 patent specification provides two measures by which one of ordinary skill in the art could assess stability – color change and the existence of secondary peaks by high pressure liquid chromatography. (*See* '222 patent col.6 ll.46-col.10 ll.67) Further, Defendants' reliance on *Honeywell Int'l Inc. v. Int'l Trade Comm'n,* 341 F.3d 1332 (Fed. Cir. 2003), to argue that the claim term "stable" is indefinite because one of ordinary skill in the art would not be able to determine how to measure stability, is misplaced. In *Honeywell*, a person of ordinary skill in the art had to choose among four different sample preparation methods, with each method influencing whether the accused products fell within the scope of the asserted claims; thus, the Court concluded that the claims were indefinite because no intrinsic or extrinsic

[3]With respect to this disputed term, the Court finds it is able to provide a construction. *See generally Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 2003 WL 124149, at *1 n.1 (D. Del. Jan 13, 2003) (stating that when court chooses to construe term that is alleged to be indefinite, "the court is merely holding that the claim is sufficiently definite to survive claim construction").

evidence indicated a single preferred method of sample preparation and the results obtained by the methods "vari[ed] greatly." *See id.* at 1340-41. The present case is distinguishable. While the '222 patent does not specify the precise test that must used to determine stability, there is no evidence that multiple methods for evaluating stability exist that lead to results that vary significantly; rather, the evidence indicates that a person of ordinary skill in the art[4] would understand that there are multiple accepted methods to assess stability, each leading to measurable results.[5] (*See* D.I. 166 ¶ 10 (Plaintiffs' expert, Stephen R. Byrn, Ph.D., stating that one of ordinary skill in the art would understand that color and secondary peaks are common tests that both yield measurable results for assessing stability))

Other support for the Court's construction is found elsewhere in the specification. The specification identifies a problem in the pharmaceutical industry:

> [I]n view of the quality control requirements specific to pharmaceutical practice regulations, the stability of paracetamol in aqueous solutions is . . . insufficient and does not allow the formulation of liquid pharmaceutical compositions for injection . . . . [I]t has not been possible to prepare aqueous liquid solutions of paracetamol . . . [f]or injection, having a guaranteed stability.

('222 patent col.1 ll.53-60; *id.* at col.2 ll.14-16; *see also id.* at col.1 ll.37-40 ("[T]he time needed to observe a 5% decrease in paracetamol concentration of an aqueous solution stored at 25° C. at the optimal pH has been predicted to be 19 months.")) The '222 patent then offers a solution:

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[4]For purposes of this case, a person of ordinary skill in the art would have a Bachelor's Degree in chemistry, pharmacy, or a related field, and two to five years of experience in formulating pharmaceuticals, or equivalent experience. (*See* D.I. 145 ¶ 8)

[5]For this same reason, *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1341 (Fed. Cir. 2003), is inapposite, as the court in *Amgen* found a claim that failed to specify a method for preparing human urinary EPOs invalid because "the glycosylation of human urinary EPO was . . . a moving target" depending on which method of preparation was selected.

stable pharmaceutical compositions of paracetamol. (*See id.* at col.2 ll.19-22)

The examples in the specification demonstrate the importance of stability to the claimed invention by first characterizing acetaminophen's instability in an aqueous solution and then discussing and illustrating various factors which improve stability. (*See id.* at col.10 ll.22-32 (Example II) (stating that paracetamol in water rapidly turns pink upon exposure to light or storage at high temperature); *id.* at col.11 ll.64-67 (Example III) (determining that paracetamol solutions are most stable at pH 5.0 and 6.0); *id.* at col.12 ll.23-50 (Example IV) (concluding that paracetamol solutions are more stable when bubbled with nitrogen and/or placed under nitrogen); *id.* at col.12 l.54-col.14 l.40 (Example V) (demonstrating that paracetamol solutions are more stable when free radical antagonist is added); *id.* at col.14 l.44-col.16 l.37 (Example VI) (same))

The prosecution history is also supportive. (*See* D.I. 113, Ex. 3 at JA104-116) During prosecution of the '222 patent, the applicant explicitly relied on the stability characteristics of the present invention in order to distinguish prior art. (*See* D.I. 113, Ex. 3 at JA104-116 (wherein applicant states that present invention involves "novel stable liquid formulations" of aqueous solutions of paracetamol and states that prior art "teaches that aqueous solutions of paracetamol are unstable in contrast to Applicant['s] stable compositions" and directs examiner's attention to the examples illustrated in '222 patent – all of which demonstrate how present invention improves stability of pharmaceutical compositions)) Of note is the fact that, in its reasons for allowance, the PTO examiner explicitly indicated that the claims of '222 patent were allowed, in part, because the "[i]nstant claims are directed to a ***stable***, liquid formulation." (*See id.*, Ex. 3 at JA125) (emphasis added); *see also* Tr. at 90 (wherein Defendants' counsel acknowledged that applicant distinguished present invention from prior art on basis of stability and agreed that PTO

examiner specifically listed "stability" as reason for allowance))

Extrinsic evidence further supports the Court's determination that the term "stable" is amenable to construction. Plaintiffs' expert, Dr. Byrn, opined that a person of ordinary skill in the art would have understood stable in the context of the '222 patent and would have been able to determine stability based on the guidance provided in the specification and accepted industry standards. (*See* D.I. 145 ¶¶ 10-12; D.I. 166 ¶¶ 3-10) Defendants' expert, Anthony Palmieri III, PhD., did not refute Dr. Byrn's opinion that one of ordinary skill in the art would understand the meaning of the term "stable." (*See* D.I. 174; *see also* D.I. 166 ¶ 3; D.I. 181 ¶ 3 (wherein Plaintiffs' expert opines that it is "well-understood that a particular drug would be 'stable' if it remains fit for a period of time that is adequate for the intended use – that is, long enough to have a reasonably acceptable shelf-life in the pharmaceutical industry for the specific drug")) Additionally, Defendants' Abbreviated New Drug Applications (ANDAs) repeatedly refer to "stability" characteristics of their aqueous acetaminophen formulations, which further illustrates that the meaning of the term "stable" is understood in the pharmaceutical industry. (*See* D.I. 165, Ex. 3 at 12 (Exela's ANDA for OFIRMEV, which states that "all monitoring attributes fall well within the proposed stability specifications"); *id.*, Ex 4 at 3 (Paddock's ANDA for acetametophen injectable, which includes "long-term stability study," objective of which "is to establish the shelf life of [the drug]"))

B. "liquid formulation consisting essentially of acetaminophen dispersed in an aqueous medium"[6]

Plaintiffs' Proposed Construction: "A solution of acetaminophen dissolved primarily in water."

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[6]This disputed term appears in claim 1 of the '222 patent.

Defendants' Proposed Construction: The term "consisting essentially of" should be construed as "formulation is limited to claimed elements and those that do not affect the 'basic and novel' characteristics, i.e., the stability characteristics." The term "aqueous medium" should be construed as "medium containing water or aqueous mixtures of water and a polyhydric compound and/or a water soluble alcohol."

Court's Construction: "A solution of acetaminophen dissolved in a medium containing water or aqueous mixtures of water and a polyhydric compound and/or a water soluble alcohol."

The parties raise two disputes with respect to this claim term: (1) what specific language the Court should construe and (2) how the patent uses the term "aqueous medium." The Court concludes that it should construe the entire claim phrase – "liquid formulation consisting essentially of acetaminophen dispersed in an aqueous medium" – as one term as this comports with the way the phrase is used in the '222 patent and will preserve the internal coherence of the patent. *See Versa Corp. v. Ag-Bag Int'l Ltd.*, 392 F.3d 1325, 1336 (Fed. Cir. 2004) ("[C]laims must be construed in a way that comports with the instrument as a whole and preserves the patent's internal coherence.") (internal quotation marks omitted); *SourceOne Global Partners, LLC v. KGK Synergize, Inc.*, 2010 WL 2232944, at *4 n.5 (N.D. Ill. June 3, 2010) ("Construing the disputed phrase in pieces would be more likely to lead to inconsistent or erroneous constructions."). Additionally, the Court concludes the term "aqueous medium" as used in the '222 patent means "a medium containing water or aqueous mixtures of water and a polyhydric compound and/or a water soluble alcohol."

The Court's construction is supported by the specification, which discloses acetaminophen "in an aqueous solvent having added thereto a free radical antagonist." ('222 patent col.2 ll.20-22) The specification goes on to state:

> The aqueous solvent may be water or else aqueous mixtures containing water and a polyhydric compound such as polyethylene-glycol (PEG) 300, 400, 1000, 1540, 4000, or 8000, propylene glycol or tetraglycol. A water-soluble alcanol such as for example ethanol may also be used.

(*Id.* at col.2 ll.22-27)[7]

Contrary to Plaintiffs' contention, the patent does not draw a distinction between liquid mediums containing water and those containing a mixture of water and a polyhydric compound and/or water soluble alcohol; rather, the examples in the '222 patent illustrate that the patented invention covers all of these solutions. (*See id.* at col.10 l.23 (Example 2.1, describing two liquid formulations both containing acetaminophen – "solution in water" and "solution no. 20"); *id.* at col.11 ll.18-54 (Example 3.1, discussing two formulations containing acetaminophen – "Solution 20," consisting of mixture of propyleneglycol and PEG 400, and "[t]he aqueous solution" containing water as solvent); *see also id.* at col.2 l.31 (referring to various solutions listed in examples as "aqueous solutions mentioned above"))

Plaintiffs' proposed construction appears to exclude several preferred embodiments, *see Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1276-77 (Fed. Cir. 2008) ("We normally do not interpret claim terms in a way that excludes embodiments disclosed in the specification."), i.e., embodiments which permit less than 50% water and greater than 50% of another element.[8] (*See* '222 patent col.4 ll.48-51; *id.* at col.5 ll.1-3 (preferred water content ranges from 5%-65% and

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[7]The '222 patent uses the term "aqueous medium" and "aqueous solvent" interchangeably. (*See* Tr. at 102)

[8]When Plaintiffs use the word "primarily" in their proposed construction, they intend to limit the "aqueous medium" to a medium which contains more than fifty percent water. (*See* Tr. at 50 (stating primary means that water must compose "more than 50 percent of the solution"); *see also id.* at 32-33)

25%-100% respectively); *id.* at col.4 ll.58-59 (preferred water content ranges from 20%-60%))

Plaintiffs' prosecution history disclaimer argument (*see* D.I. 144 at 13-14) is unavailing. The patentee did not distinguish the present invention on the basis of the content of the aqueous solution. Rather, the patentee distinguished the prior art by relying on the complete language of claim 1. *See* D.I. 113, Ex. 3 at JA121-22; *see also 01 Communique Laboratory, Inc. v. LogMeIn, Inc.*, __ F.3d ___, 2012 WL 3089367, at *4 (Fed. Cir. July 31, 2012) ("There is no 'clear and unmistakable' disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent with a proffered meaning of the disputed term."). There was no unambiguous disavowal of claim scope. *See generally Grober v. Mako Prods., Inc.*, __ F.3d ___, 2012 WL 3065278, at *3 (Fed. Cir. 2012) ("[W]hile the prosecution history can inform whether the inventor limited the scope in the course of prosecution, it often produces ambiguities created by ongoing negotiations between the inventor and the PTO. Therefore, the doctrine of prosecution disclaimer only applies to unambiguous disavowals.") (internal citations omitted); *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003) (stating that disclaimer "requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable").

C. "a buffering agent"[9]

Plaintiffs' Proposed Construction: "An agent that helps the formulation resist change in pH."

Defendants' Proposed Construction: "A system comprising a weak acid and its conjugate base, or a weak base and its conjugate acid in an effective concentration to resist material changes in pH."

[9]This disputed claim term appears in claim 1 of the '222 patent.

Court's Construction: "An agent that helps the formulation resist change in pH."

The Court's construction is supported by the specification. (*See* '222 patent col.3 ll.24-26) ("The buffer used is a buffer compatible with parenteral administration in humans, the pH of which may be adjusted between 4 and 8."); *see also id.* at col.3 ll.26-32) Contrary to Defendants' assertion, the specification does not limit a buffer to a combination of a weak acid and conjugate base or a weak base and conjugate acid, but rather lists these combinations as examples.[10] (*See id.* at col.3 ll.26-28 ("***Preferred buffers*** are based on alkaline earth metals acetates or phosphates.") (emphasis added)) The Court declines to import limitations from the specification into the claim language. *See Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 865 (Fed. Cir. 1998) ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations."). Further, nothing in the patent limits the scope of the claimed buffering agent to an "effective concentration" or one that resists "material changes in pH."

D. "free radical scavenger/free radical antagonist"[11]

Plaintiffs' Proposed Construction: "Substance that functions in the formulation as an antioxidant by scavenging free radicals."

Defendants' Proposed Construction: "Substance that functions in the formulation as an antioxidant."

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[10]Defendants' reliance on extrinsic evidence to support this acid/base limitation is unpersuasive as none of the authorities cited requires a buffering agent to consist of a specific acid/base combination. (*See* D.I. 165 at 12-13 (discussing Defendants' extrinsic evidence and providing complete definitions))

[11]The disputed term "free radical scavenger" appears in claims 1, 8, and 9 of the '222 patent. The disputed term "free radical antagonist" appears in claim 5 of the '222 patent.

Court's Construction: "Substance that functions in the formulation as an antioxidant."

The parties propose similar constructions for this disputed term. Plaintiffs' construction adds the additional requirement that the antioxidant act by scavenging free radicals. The Court concludes that there is no requirement that the antioxidant function by scavenging free radicals and, consequently, adopts Defendants' proposed construction.

The Court's construction is supported by the intrinsic evidence, as the '222 patent interchangeably refers to glutahion, a thiol compound, as an antioxidant and free radical scavenger/antagonist. (*Compare* '222 patent col.2 l.52, *with id.* at col.3 ll.35-36) The Court's construction is also supported by the original French priority application for the patented invention, which referred to "antioxidants" but did not use the terms free radical scavenger or free radical antagonist. (*See* D.I. 113, Ex. 3 at JA171 ll.29-30)

E. "an isotonizing agent"[12]

Plaintiffs' Proposed Construction: "An agent that acts to adjust osmotic pressure of the formulation so that the formulation can be used for infusion."

Defendants' Proposed Construction: "A substance used to make the osmotic pressure of the formulation more similar to osmotic characteristics of physiological fluids."

Court's Construction: "A substance used to make the osmotic pressure of the formulation more similar to osmotic characteristics of physiological fluids."

The Court's construction is supported by the claim language. (*See* '222 patent col.18 ll.51-55; *id.* at col.20 ll.1-2) The disputed term "an isotonizing agent" appears in claim 17, which depends from claim 1. Claim 1 recites a "stable, liquid formulation" and does not limit

[12]This disputed term appears in claim 17 of the '222 patent.

the patented invention to formulations that are used for infusion only. (*See id.* at col.18 l.51)

The Court's construction is also supported by the specification, which indicates that "[t]he present invention relates to novel stable, liquid, analgesic formulations" containing acetaminophen. (*Id.* at col.1 ll.9-10) The specification does not limit the claimed invention to compositions intended for infusion.

In support of their construction, Plaintiffs point to instances in the specification that indicate acetaminophen formulations may be infused via injection. (*See* D.I. 144 at 17; *see also* '222 patent col.3 ll.45-46 ("Liquid compositions according to the invention are ***preferably*** compositions intended for injection.") (emphasis added)) However, these statements do not constitute an express disavowal or disclaimer of the claim scope and, so, do not support Plaintiffs' proposal. *See Cohesive Techs. Inc. v. Waters Corp.*, 543 F.3d 1351, 1360-61 (Fed. Cir. 2008); *see also Laitram Corp.*, 863 F.2d at 865.

F. "diluted to a concentration of 2 to 50 mg/ml"[13]

Plaintiffs' Proposed Construction: "The formulation has a concentration of 2 to 50 mg/ml of acetaminophen;" or, alternatively, "the formulation is prepared at a concentration of 2 to 50 mg/ml of acetaminophen as opposed to 2 to 350mg."

Defendants' Proposed Construction: The Court should construe the term "diluted" as "diluted after first having a paracetamol concentration as described in formulation 14."

Court's Construction: "The formulation has a concentration of 2 to 50 mg/ml of acetaminophen."

The parties dispute (1) what language the Court should construe, (2) whether this is a formulation or product-by-process claim, and (3) whether the formulation must be first formed

[13]This disputed term appears in claim 16 of the '222 patent.

at one concentration and then actively diluted to a second concentration.

The Court concludes that it is necessary to construe the entire claim phrase as one term in order to preserve the internal coherence of the patent. *See Versa*, 392 F.3d at 1336; *see also SourceOne*, 2010 WL 2232944, at *4 n.5. Additionally, the Court concludes that this is not a product-by-process claim in which the formulation must be first formed at one concentration and then diluted to a second concentration.

The Court's construction is supported by the language of the claims.[14] (*See* '222 patent col.20 ll.1-2; *see also id.* at col.19 ll.26-29) There is nothing in the claim language that indicates the patentee intended claim 16 to be a product-by-process claim. Claims 1, 14, and 16 all contain the word "formulation," discuss the characteristics of the formulation, and do not address the process through which the formulation is created. Thus, contrary to Defendants' contention, the mere presence of the verb "diluted" in claim 16 does not convert claim 16 to a product-by-process claim. *See 3M Innovative Prop. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371 (Fed. Cir. 2003) ("Even words of limitation that can connote with equal force a structural characteristic of the product or a process of manufacture are commonly and by default interpreted in their structural sense, unless the patentee has demonstrated otherwise."). Rather, the word

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[14]The use of the word "diluted" to describe the formulation in claim 16 versus the use of the word "wherein" in claims 14 and 15 creates a presumption of claim differentiation. *See Comark Commc'ns Inc. v. Harris Corp.*, 156 F.3d 1182, 1887 (Fed. Cir. 1998) ("There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims."). However, this presumption is overcome by the intrinsic evidence, which, as discussed above, indicates the patentee did not intend for claim 1 to be a product-by-process claim. In light of the Court's conclusion that the presumption of claim differentiation is defeated, Defendants' construction lacks support. (*See* Tr. at 110 (Defendants' counsel stating that presumption of claim differentiation is "the biggest reason" Court should adopt Defendants' construction))

diluted in claim 16 indicates that the concentration range of the formulation specified in claim 16 (2 to 50 mg/ml) is more dilute than the concentration range of the formulation of claim 14 (2 to 350 mg/ml).

The Court's construction is also supported by the specification. None of the patent's examples of a "diluted solution" indicate that it is necessary to first create a concentrated solution that is then diluted to achieve the diluted solution. (*See, e.g.*, '222 patent col.12 ll.6-34; *id.* at col.12 ll.35-51) Defendants' proposed construction mandates an order of steps – requiring the concentration of "formulation 14" to be achieve before dilution – which is unsupported by the patent.

Defendants' proposed construction is further undermined by the conceded fact that it is impossible to dilute a solution with a concentration of 2 mg/ml (at the low end of 2 to 350 mg/ml range) to a concentration of 2 mg/ml (at the low end of the 2 to 50 mg/ml range). *See* Tr. at 112-13 (Defendants' counsel admitting "[i]t would, in fact, not be possible to dilute 2 to make 2"); *see also generally Level 3 Commc'ns, LLC v. Limelight Networks*, 630 F. Supp. 2d 654, 662 (E.D. Va. 2008) (stating that adopting construction which renders claim "practically impossible [to practice] would make little sense"); *Neev v. Abbott Med. Optics, Inc.*, 2012 WL 1066797, at *12 (D. Del. Mar. 26, 2012) (rejecting construction that would make practicing patent claim impossible).

G. "an aqueous solution"[15]

Plaintiffs' Proposed Construction: "A composition containing water as the primary solvent and at least one other substance."

Defendants' Proposed Construction: "A composition containing water as a solvent and an active ingredient susceptible to oxidation."

Court's Construction: "A composition containing water as a solvent and an active ingredient susceptible to oxidation."

H. "an injectable aqueous solution"[16]

Plaintiffs' Proposed Construction: "A composition containing water as the primary solvent and at least one other substance that can be safely administered by parenteral injection to humans or animals."

Defendants' Proposed Construction: "An injectable composition containing water as a solvent."

Court's Construction: "An injectable composition containing water as a solvent and an active ingredient susceptible to oxidation."

The parties raise three disputes with respect to these related terms: (1) whether water must be the primary solvent (as Plaintiffs contend), (2) whether the aqueous solution must contain an active ingredient susceptible to oxidation (as Defendants contend), and (3) whether the term "injectable" requires construction (as Plaintiffs contend). The Court concludes (1) the aqueous solution is not limited to a solution in which water is the primary solvent, (2) the aqueous solution must contain an ingredient, besides water, that is susceptible to oxidation, and (3) the term "injectable" does not require construction.

The Court's constructions are supported by the intrinsic evidence. First, there is nothing

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[15]This disputed term appears in claims 1, 3, 4, 11, and 15 of the '218 patent.

[16]This disputed term appears in claim 19 of the '218 patent.

in the claim language or specification of the '218 patent mandating that water be the primary solvent. The intrinsic evidence discussed above in relation to the related '222 patent supports a similar conclusion here.

Second, the intrinsic evidence indicates that an aqueous solution must contain an active ingredient susceptible to oxidation. (*See* '218 patent, Abstract (indicating claimed method is one for "obtaining aqueous formulations with easily oxidizable active principles . . . comprising subjecting them to extreme deoxygenation by bubbling with inert gas and/or placing under vacuum"); *id.* at col.12 ll.53-54 (claiming "[a] method for preparing an aqueous solution with an active nature susceptible to oxidation, which is paracetamol"); *id.* at col.12 ll.56-57 (requiring "deoxygenation of the solution by bubbling with at least one inert gas and/or placing under vacuum")) Each example in the '218 patent that incorporates a bubbling step recites bubbling a "paracetamol solution," which indicates that the solution itself must contain an active ingredient susceptible to oxidation. (*See, e.g.*, *id.* at col.6 ll.50-54 (Example I) ("A paracetamol solution is prepared in water at a concentration ranging from 2 to 50 mg/ml. Extreme deoxygenation to less than 2 ppm was carried out by bubbling with inert gas."); *id.* at col.7 ll.6-32 (Example II) (preparing "paracetamol solution," adjusting pH and adding a buffer, then "[d]eoxygenation is carried out by bubbling with nitrogen"))

Finally, the term "injectable" does not require construction since the plain meaning of this term would be understood by a person of ordinary skill in the art. Indeed, Plaintiffs concede that a person of ordinary skill in the art would understand that the word "injectable," as used in the '218 patent, requires that the solution be safely administered by parenteral injection to humans or

animals. (*See* Tr. at 52)[17]

I. "while preserving for a prolonged period"[18]

Plaintiffs' Proposed Construction: "The aqueous solution with an active principle does not decompose substantially such that the formulation has a prolonged pharmaceutically acceptable shelf life."

Defendants' Proposed Construction: This term does not require construction as it is not an affirmative claim limitation.

Court's Construction: "The aqueous solution does not decompose substantially such that the formulation has a prolonged pharmaceutically acceptable shelf life."

As an initial matter, the parties dispute whether the phrase "while preserving for a prolonged period" as used in claims 1 and 28 of the '218 patent is an affirmative claim limitation that requires construction. Although generally the preamble does not limit the claims, *see Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002), language in a preamble is construed as limiting "if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim," *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (internal quotation marks omitted). A preamble term meets the *Catalina* test if it: (1) provides antecedent basis for a claim term, (2) is essential to help understand the claim terms,[19] (3) provides any additional steps or structure that is underscored as important by

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[17]The Court recognizes that its constructions render the words "active principle" redundant in claims 1 and 19 of the '218 patent. (*See* Tr. at 46-47, 121) In context, this redundancy is not problematic, but, instead, maintains consistency with the intrinsic evidence, which indicates that the aqueous solution must contain an active principle subject to oxidation.

[18]This disputed language appears in claim 1 of the '218 patent.

[19]An alternative way of describing such a situation is where a preamble term is "not merely a context in which the invention may be used, but the ***essence of the invention*** without which performance of the recited steps is nothing but an academic exercise." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2005)

the specification, or (4) was relied on during prosecution. *See Catalina*, 289 F.3d at 808.

Here, the preamble phrase "while preserving for a prolonged period" is necessary to give life, meaning, and vitality to the claimed method of the '218 patent, as it is essential to help understand the meaning of claim 1. The specification of the '218 patent explicitly states that the goal of the claimed method is to "obtain stability of longer duration" ('218 patent col.5 ll.23-25) and that "[t]he object of the present invention is therefore a procedure for preparation of formulations of aqueous solutions with phenolic active principles . . . making it possible to confer ***a high degree of stability over the course of time***" (*id.* at col.3 ll.54-59) (emphasis added).[20] Thus, the Court concludes that it must construe the preamble language "while preserving for a prolonged period."

The Court's construction is supported by the specification, which indicates that the goal of the invention is to produce stable aqueous solutions for injection which are "useful in therapeutics." (*See id.* at col.1 ll.7-12; *see also id.* at col.4 ll.58-61 ("The formulations according to the invention are utilized in the field of therapeutics.")) In order to be useful in therapeutics, the formulation needs to have an acceptable shelf-life. (*See* D.I. 145 ¶ 11 (Plaintiffs' expert stating that, in order to have stable solution that is useful in therapeutics, it is necessary that drug "remain[ ] fit for a period of time that is adequate for the intended use – that is, long enough to have a reasonably acceptable shelf-life in the pharmaceutical industry for the specific drug"))

(emphasis added); *see also* Tr. at 55.

[20]Also, during prosecution of the '218 patent, the patentee emphasized that extended stability was a key feature of the claimed method. (*See* D.I. 113, Ex. 2 at JA208-216 (in order to overcome obvious rejection, patentee emphasizing that '218 patent taught methods that "result[ ] in a stable solution as can be seen from the data in the examples"))

J. Nitrogen Bubbling and Vacuum Terms[21]

Plaintiffs' Alternative Proposed Constructions[22]	
Proposed Claim Term	Proposed Construction
"deoxygenation of the solution . . . until the oxygen content is below 2 ppm"	"Reducing the dissolved oxygen content of the solution to below 2 ppm by the combination of bubbling and/or vacuum alone or bubbling and/or vacuum plus one or more of the other recited steps."
"deoxygenation of the solution by bubbling with at least one inert gas and/or placing under vacuum, until the oxygen content is below 2 ppm . . ., and optionally the deoxygenation of the solution is completed by addition of an antioxidant"	"Alternatively, reducing the dissolved oxygen content of the solution to below 2 ppm by the combination of bubbling and/or vacuum and adding an antioxidant to the solution."

Defendants' Proposed Constructions[23]	
Proposed Claim Term	Proposed Construction
"deoxygenation of the solution"	"'The solution' that is deoxygenated contains an active agent susceptible to oxidation."
"by bubbling with at least one inert gas and/or placing under vacuum, until the oxygen content is below 2 ppm"	"Either bubbling or placing under vacuum or both is carried out until the oxygen content of the solution is less than 2 ppm prior to optional addition of an antioxidant."
"optionally the deoxygenation of the solution is completed by addition of an antioxidant"	"Either bubbling or placing under vacuum or both is carried out until the oxygen content of the solution is less than 2 ppm, and then an antioxidant is optionally added."

[21]These disputed terms appear in claim 1 of the '218 patent.

[22]Plaintiffs request that the Court construe either of these terms.

[23]Defendants request that the Court construe all of these terms.

Court's Constructions	
Claim Term	Construction
"deoxygenation of the solution by bubbling with at least one inert gas and/or placing under vacuum, until the oxygen content is below 2 ppm"	"Either bubbling or placing under vacuum or both is carried out until the oxygen content of the solution is less than 2 ppm prior to optional addition of an antioxidant."
"optionally the deoxygenation of the solution is completed by addition of an antioxidant"	"Either bubbling or placing under vacuum or both is carried out until the oxygen content of the solution is less than 2 ppm, and then an antioxidant is optionally added."

The parties dispute (1) what language the Court should construe and (2) after which step(s) the oxygen content of the solution must be below 2ppm. Defendants contend that the oxygen content must be below 2ppm after the bubbling/vacuuming step, whereas Plaintiffs contend that the oxygen content must be below 2ppm after the bubbling/vacuuming and addition of antioxidant steps.

The Court concludes that the proper terms for construction are "deoxygenation of the solution by bubbling with at least one inert gas and/or placing under vacuum, until the oxygen content is below 2 ppm" and "optionally the deoxygenation of the solution is completed by addition of an antioxidant." The claim terms the Court has selected to construe track the claim language and preserve the internal coherence of the patent. *See Versa*, 392 F.3d at 1336; *see also SourceOne*, 2010 WL 2232944, at *4 n.5. Additionally, the Court concludes that the oxygen content must be below 2ppm after the bubbling/vacuuming step.

The Court's constructions are supported by the claim language. (*See* '218 patent col.12 ll.53-64) Claim 1 contains two "optionally" clauses (*see id.* at col.12 ll.58-64), and, consistent with the plain meaning of the term "optionally," the steps recited in these clauses do not

necessarily have to be performed in order to practice the claimed method. However, the bubbling and/or vacuum step must be performed, and the language of claim 1 indicates that the solution resulting from either bubbling or placing under vacuum or both must have an oxygen content of less than 2 ppm. (*See id.* at col.12 ll.56-58 ("by bubbling with at least one inert gas and/or placing under vacuum, ***until the oxygen content is below 2 ppm***") (emphasis added))

The Court's constructions are also supported by the specification. (*See id.* at col.4 ll.27-31; *id.* at col.7 ll.30-31) The specification states that "[t]he bubbling process can be continued until a content of less than 2ppm is obtained." (*Id.* at col.4 ll.27-31) The specification also clarifies that the presence of an antioxidant does not replace the requirement that the solution have an oxygen level of below 2 ppm prior to the addition of the antioxidant. (*See id.* at col.7 ll.30-31 ("The possible presence of an antioxidant completes the effect of the deoxygenation but does not replace it."))[24]

The Court's constructions are further supported by the prosecution history. During prosecution of the '218 patent, the applicant distinguished the claimed method over prior art by stating that prior art demonstrates "[t]he residual oxygen concentration present in the solution after bubbling of the nitrogen is on the order of 2 ppm," whereas, "[i]n contrast thereto, [a]pplicant's bubbling with nitrogen is reduced to below 2 ppm." (D.I. 313, Ex. 3 at JA215) The PTO examiner agreed that the claimed method was distinguishable from the prior art due to the fact that after the bubbling step the nitrogen concentration is reduced to below 2 ppm. (*See* D.I.

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[24]In view of this guidance in the specification about the role of the antioxidant, the Court's construction is not inconsistent with the portion of claim 1 that recites "deoxygenation of the solution is completed by addition of an antioxidant" ('218 patent col.12 ll.63-65), as the antioxidant completes the effect of deoxygenation, but does not displace the requirement that the solution already have an oxygen level of below 2 ppm.

147, Ex. 15 at 2 ("The [prior art] reference teaches similar process of making stabilized paracetamol as claimed herein. However, in herein, after nitrogen is bubbled, the oxygen content is below 2 ppm."))

Consistent with the claim language and the specification, the process implicitly requires that the steps listed in claim 1 be performed in the stated order. Thus, the Court's constructions clarify that the first step must produce a solution with an oxygen content of 2 ppm prior to performing a later step. *See generally Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1342-43 (Fed. Cir. 2001) (stating performance of steps in particular order may be required when "the method steps implicitly require that they be performed in the order written").

K. Packaging Claim Limitations[25]

Plaintiffs' Proposed Construction	
Claim Term	Construction
"and optionally the aforementioned aqueous solution with an active principle is topped with an inert gas atmosphere heavier than air and placed in a closed container in which the prevailing pressure is 65,000 Pa maximum, and the oxygen content of the aqueous solution is below 2 ppm"	"May, but does not necessarily, include the steps of putting the solution with an active principle in a container under an inert, heavier than air gas and pressure of less than 65,000 Pa and wherein the final dissolved oxygen content of the solution is below 2 ppm."

[25]These related disputed terms appear in claim 1 of the '218 patent.

Defendants' Proposed Constructions	
Claim Term	Construction
"and optionally the aforementioned aqueous solution with an active principle is topped with an inert gas atmosphere heavier than air"	"Optionally filling takes place under an inert gas atmosphere that is heavier than air."
"and placed in a closed container in which the prevailing pressure is 65,000 Pa maximum"	"Stoppering takes place under vacuum of 65,000 Pa or less."

Court's Construction	
Claim Term	Construction
"and optionally the aforementioned aqueous solution with an active principle is topped with an inert gas atmosphere heavier than air and placed in a closed container in which the prevailing pressure is 65,000 Pa maximum, and the oxygen content of the aqueous solution is below 2 ppm"	"May, but does not necessarily, include the steps of putting the solution with an active principle in a container under an inert, heavier than air gas and pressure of less than 65,000 Pa and wherein the final dissolved oxygen content of the solution is below 2 ppm."

The parties generally agree on the meaning of the disputed claim language, although they propose different language. The parties dispute (1) what specific language the Court should construe and (2) whether placing the drug product "in a closed container in which the prevailing pressure is 65,000 Pa maximum" is a required step.

The Court concludes that the proper term for construction is "and optionally the aforementioned aqueous solution with an active principle is topped with an inert gas atmosphere heavier than air and placed in a closed container in which the prevailing pressure is 65,000 Pa maximum, and the oxygen content of the aqueous solution is below 2 ppm." Construing this

entire section of the claim as one cohesive term preserves the patent's internal coherence. *See Versa*, 392 F.3d at 1336; *see also SourceOne*, 2010 WL 2232944, at *4 n.5. Additionally, the Court concludes that placing the drug product in a closed container is not a required step.

The Court's construction is supported by the language of the claims. (*See* '218 patent col.12 ll.53-64; *id.* at col.13 l.26-col.14 l.10) Indeed, at the hearing, Defendants conceded that the claim language supports Plaintiffs' construction. (*See* Tr. at 128 (acknowledging "English language construction" would indicate that word "optionally" modified both clauses)) In relevant part, claim 1 recites:

> optionally the aforementioned aqueous solution with an active principle is topped with an inert gas atmosphere heavier than air and placed in a closed container in which the prevailing pressure is 65,000 Pa maximum . . . .

('218 patent col.12 58-62 ll.58-61) The language of claim 1 plainly indicates that the word "optionally" applies to both the first and second clauses, which are connected by the word "and." *See generally In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983) ("A claim must be read in accordance with the precepts of English grammar."); *Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A.*, 301 F. Supp. 2d 970, 977-78 (S.D. Iowa 2004) ("[T]he normal rules of grammar and syntax apply to interpreting the claim meaning.").

Defendants contend that their conclusion is not inconsistent with the specification and is essentially compelled by the prosecution history. (*See* Tr. at 128) To the contrary, Defendants' prosecution history argument is unavailing. The statements made during prosecution of the '222 patent do not rise to the level of an explicit disclaimer, as the patentee did not did not clearly and unmistakably indicate that the vacuum step was required. Thus, Defendants have failed to meet

their heavy burden of establishing a prosecution history disclaimer. *See Omega*, 334 F.3d at 1325-26.

IV. CONCLUSION

For the foregoing reasons, the Court will construe the disputed claim terms in the patents-in-suit consistent with this Memorandum Opinion. An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CADENCE PHARMACEUTICALS, INC. and SCR PHARMATOP	:	
Plaintiffs,	:	
v.	:	C.A. No. 11-733-LPS
PADDOCK LABORATORIES INC.; PERRIGO COMPANY; PADDOCK LABORATORIES, LLC; EXELA PHARMA SCIENCES, LLC; EXELA PHARMSCI, INC.; and EXELA HOLDINGS, INC.	:	

ORDER

At Wilmington this 22nd day of August, 2012, for the reasons set forth in the Memorandum Opinion issued this same date,

IT IS HEREBY ORDERED that the claim language of U.S. Patent Nos. 6,028,222 and 6,992,218 shall be construed as follows:

1. The term "stable" is construed to mean "the active pharmaceutical ingredient does not decompose substantially such that the formulation has a pharmaceutically acceptable shelf life."

2. The term "liquid formulation consisting essentially of acetaminophen dispersed in an aqueous medium" is construed to mean "a solution of acetaminophen dissolved in a medium containing water or aqueous mixtures of water and a polyhydric compound and/or a water soluble alcohol."

3. The term "a buffering agent" is construed to mean "an agent that helps the

formulation resist change in pH."

4. The terms "free radical scavenger" and "free radical antagonist" are construed to mean "substance that functions in the formulation as an antioxidant."

5. The term "an isotonizing agent" is construed to mean "a substance used to make the osmotic pressure of the formulation more similar to osmotic characteristics of physiological fluids."

6. The term "diluted to a concentration of 2 to 50 mg/ml" is construed to mean "the formulation has a concentration of 2 to 50 mg/ml of acetaminophen."

7. The term "an aqueous solution" is construed to mean "a composition containing water as a solvent and an active ingredient susceptible to oxidation."

8. The term "an injectable aqueous solution" is construed to mean "an injectable composition containing water as a solvent and an active ingredient susceptible to oxidation."

9. The term "while preserving for a prolonged period" is construed to mean "the aqueous solution does not decompose substantially such that the formulation has a prolonged pharmaceutically acceptable shelf life."

10. The term "deoxygenation of the solution by bubbling with at least one inert gas and/or placing under vacuum, until the oxygen content is below 2 ppm" is construed to mean "either bubbling or placing under vacuum or both is carried out until the oxygen content of the solution is less than 2 ppm prior to optional addition of an antioxidant."

11. The term "optionally the deoxygenation of the solution is completed by addition

of an antioxidant" is construed to mean "either bubbling or placing under vacuum or both is carried out until the oxygen content of the solution is less than 2 ppm, and then an antioxidant is optionally added."

12. The term "and optionally the aforementioned aqueous solution with an active principle is topped with an inert gas atmosphere heavier than air and placed in a closed container in which the prevailing pressure is 65,000 Pa maximum, and the oxygen content of the aqueous solution is below 2 ppm" is construed to mean "may, but does not necessarily, include the steps of putting the solution with an active principle in a container under an inert, heavier than air gas and pressure of less than 65,000 Pa and wherein the final dissolved oxygen content of the solution is below 2 ppm."

UNITED STATES DISTRICT JUDGE