IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT IP UNLIMITED COMPANY, MALLINCKRODT HOSPITAL PRODUCTS INC., and SCR PHARMATOP	:	
Plaintiffs,	:	
v.	:	C.A. No. 17-365-LPS
B. BRAUN MEDICAL INC.,	:	
Defendant.	:	

MALLINCKRODT IP UNLIMITED COMPANY AND MALLINCKRODT HOSPITAL PRODUCTS INC.,	:	
Plaintiff,	:	
v.	:	C.A. No. 17-660-LPS
B. BRAUN MEDICAL INC.,	:	
Defendant.	:	

Thomas C. Grimm, Jeremy A. Tigan, Stephen J. Kraftschik, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE

Kenneth G. Schuler, Marc N. Zubick, Sarah W. Wang, LATHAM & WATKINS LLP, Chicago, IL

Daniel G. Brown, Michelle Ernst, LATHAM & WATKINS LLP, New York, NY

Attorneys for Plaintiffs Mallinckrodt IP Unlimited Company and Mallinckrodt Hospital Products Inc.

Thomas C. Grimm, Jeremy A. Tigan, Stephen J. Kraftschik, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE

Charles A. Weiss, Merri C. Moken, HOLLAND & KNIGHT LLP, New York, NY

Attorneys for Plaintiff SCR Pharmatop

Benjamin J. Schladweiler, GREENBERG TRAURIG, LLP, Wilmington, DE

Richard C. Pettus, Scott J. Bornstein, GREENBERG TRAURIG, New York, NY

Attorneys for Defendant B. Braun Medical Inc.

MEMORANDUM OPINION

June 5, 2018
Wilmington, Delaware

STARK, U.S. District Judge:

On April 3, 2017, in response to a Paragraph IV certification to U.S. Patent No. 6,992,218 from Defendant B. Braun Medical Inc. ("Defendant" or "Braun"), Plaintiffs Mallinckrodt IP Unlimited Company, Mallinckrodt Hospital Products Inc., and SCR Pharmatop (collectively, "Plaintiffs") sued Braun, alleging infringement of the '218 patent and U.S. Patent No. 9,399,012. On May 31, 2017, in response to a second Paragraph IV letter from Braun with a certification to the '012 patent, Plaintiffs Mallinckrodt IP Unlimited Company and Mallinckrodt Hospital Products Inc. (collectively, "Mallinckrodt") filed a second lawsuit, alleging infringement of the '012 patent and U.S. Patent No. 9,610,265 (collectively with the '012 and '218 patents, the "asserted patents"). The '218 patent is directed to the manufacture of aqueous formulations of acetaminophen products with a reduced oxygen content below 2 parts per million ("ppm") that are stable over a prolonged period. The '012 and '265 patents are directed to methods of treatment utilizing intravenous administration of acetaminophen at reduced doses.

Presently before the Court is the issue of claim construction. The parties submitted briefs (*see* C.A. No. D.I. 128, 129, 146, 147) and the Court held a claim construction hearing on May 18, 2018 (*see* Tr.).[1]

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview*

[1]During the hearing, the parties agreed that there is no material dispute about the identification of a person of ordinary skill in the art in connection with any of the asserted patents. (*See* Tr. at 72, 76, 90-91) All references to the docket index ("D.I.") are to C.A. No. 17-365, unless otherwise noted.

Instruments, Inc., 517 U.S. 370, 388-91 (1996)). "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). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* 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 must also 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." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). 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.*

In some cases, "the district court will need to look beyond the patent's intrinsic evidence

and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "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 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. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

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) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERMS[2]

A. The '218 Patent

1. "inert gas"[3]

Plaintiffs No construction is necessary beyond plain and ordinary meaning, which is "a nonreactive gas under particular conditions"
Defendant A gas that is "inert," i.e., nonreactive under ordinary conditions (e.g., argon, carbon dioxide, neon, nitrogen, xenon - but does not include steam)
Court "a nonreactive gas under particular conditions (e.g., argon, carbon dioxide, neon, nitrogen, xenon)"

The parties agree that an inert gas is a nonreactive gas, but dispute whether: (1) the gas must be nonreactive under "ordinary" conditions, as Defendant proposes, or under "particular" conditions, as Plaintiffs propose; and (2) steam is an inert gas in the context of the patent.

Plaintiffs contend the '218 patent and prosecution history provide no definition for inert

---

[2]The parties have agreed that the preambles of the asserted claims of the '012 and '265 patents are limiting. (*See* D.I. 114 Ex. A at 12 n.5) The Court will, therefore, construe those preambles as limiting.

The parties also identified indefiniteness disputes regarding certain claim language – "an active principle of phenolic nature susceptible to oxidation, which is paracetamol," appearing in all asserted claims, and "colorless," appearing in claim 24 of the '218 patent – but agreed that these issues need not be addressed in connection with the instant claim construction proceedings. (*Id.* at 1 n.1)

[3]This term appears in claim 1 of the '218 patent.

gas, so they rely on a specialized technical dictionary, the International Union of Pure and Applied Chemistry ("IUPAC") Gold Book. (D.I. 128 at 5) The IUPAC defines "inert gas" as "[a] non-reactive gas under particular conditions." (*Id.* at 5-6) The term "particular conditions," Plaintiffs contend, adds clarity because a POSA "would readily understand that whether a gas is non-reactive depends on the ***particular conditions*** to which it is subjected; *i.e.*, specific gases may or may not be non-reactive under various conditions." (D.I. 146 at 3) Plaintiffs also contend that Defendant's proposal improperly narrows the claims by "adding the litigation-driven negative limitation that claimed 'inert gas' excludes steam." (D.I. 128 at 6; *see also* D.I. 146 at 4)

Defendant contends that the patent describes and claims "three uses of 'inert gas': 1) inert gas is bubbled through the aqueous solution (which includes an oxidation sensitive active ingredient) to deoxygenate the solution; 2) inert gas is used to clear glass bottles of air before adding the aqueous solution; and 3) inert gas is used as a 'topping gas which is heavier than air' to create an 'inert gas atmosphere' in the bottle after the aqueous solution is added." (D.I. 129 at 5) According to Defendant, because steam is reactive "in several ways that are antithetical to the alleged invention's goal of avoiding degradation of acetaminophen," it should be excluded from the construction of inert gas. (D.I. 147 at 3)

The Court agrees with Plaintiffs that defining an inert gas in terms of "particular" conditions is accurate and provides clarity. As both parties recognize, the intrinsic record does not resolve this dispute. (*See* D.I. 128 at 5; D.I. 147 at 4) Looking to the extrinsic evidence, the technical dictionaries cited by Plaintiffs explain that examples of inert gases are "nitrogen at ordinary temperatures and the noble gases." (D.I. 128 Ex. 5 at 1; *see also id.* Ex 6 ("examples

are the noble gases, and nitrogen at ordinary temperatures"); *id.* Ex 7 ("An inert gas is a gas which does not undergo chemical reactions under a set of given conditions. The noble gases and nitrogen often do not react with many substances.")) By calling out nitrogen separately from the noble gases, the dictionaries imply that different gases may have different reactivity levels at different conditions. Moreover, the Court is not persuaded a POSA would know what "ordinary conditions" are in this context.[4]

With respect to the dispute about steam, the Court agrees with Plaintiffs that this is not an issue of claim construction but should instead be decided on a full record in the context of infringement. (*See* Tr. at 70-71 (Plaintiffs' counsel acknowledging that time to decide if steam is within scope of "inert gas" is when evidentiary record is complete); *id.* at 88-89 (Plaintiffs' counsel stating "whether steam is an inert gas in the scope of claim 1 is better for the infringement phase when you have a more wholesome record")) Defendant has not pointed to any clear and unmistakable disavowal of steam by the patentees.[5]

Finally, the Court agrees with Defendant's proposed examples of inert gases. Contrary to Plaintiffs' suggestion, Defendant's construction does not limit the inert gases solely to one of the

---

[4]While Defendant criticizes Plaintiffs for relying on dictionaries that post-date the '218 patent priority date, the IUPAC Gold Book cites a 1990 reference for the definition of "inert gas," which pre-dates the patent priority date. Defendant has not shown that the definition has changed significantly over time. *See Lake Cherokee Hard Drive Techs., LLC v. Bass Computers, Inc.*, 2012 WL 3230973, at *17 (E.D. Tex. Aug. 6, 2012) ("Defendants challenged the dates of publication of Plaintiff's dictionaries as being too long after the priority date of the patents-in-suit, but Defendants have not submitted evidence of any relevant change in definition."); *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008) ("We note that the definitions of the word partially did not change depending on the version of the dictionary utilized."); *see also* Tr. at 66-68.

[5]The Court is not at this point deciding that steam is or is not an "inert gas" within the meaning of the claims.

five identified gases. *See, e.g.,* '218 patent at 2:39-40 ("an inert gas such as nitrogen, carbon dioxide or argon . . ."); *see also* D.I. 147 at 5 ("Braun's construction does not limit 'inert gas' to the five disclosed gases – but allows for use of other gases that are inert . . . .").

2. "residual oxygen content"[6]

Plaintiffs No construction is necessary beyond plain and ordinary meaning, which is "remaining oxygen content"
Defendant The oxygen content of the aqueous solution for the "prolonged period" of stability
Court The oxygen content of the aqueous solution for the "prolonged period" of stability

The parties dispute whether "residual oxygen content" refers to the oxygen content remaining after deoxygenation, as Plaintiffs contend, or to the oxygen content that is maintained throughout the "prolonged period" of stability, as Defendant contends. The Court agrees with Defendant.

This term appears in claims 3, 4, 20, and 21 of the '218 patent, which are all dependent on claim 1. Independent claim 1 recites:

> **1.** A method for preparing an aqueous solution with an active nature susceptible to oxidation, which is paracetamol, while preserving for a prolonged period, comprising 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 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, and optionally the deoxygenation of the solution is completed by addition of an antioxidant.

[6]This term appears in claims 3, 4, 20, and 21 of the '218 patent.

Representative dependent claim 4 recites:

> **4.** The method for preparing a formulation of claim **1** wherein the residual oxygen content in the aqueous solution is equal to 0.5 ppm or below.

As Defendant describes, "the goal/purpose of the alleged invention is to manufacture a ***final*** acetaminophen solution with below 2 ppm of oxygen using ***extreme deoxygenation*** and to ***maintain*** that oxygen level below 2 ppm for the claimed prolonged period in order to achieve the required preservation/stability." (D.I. 129 at 7; *see also* '218 patent at 2:56-60 ("[O]xygen shows a very great facility to dissolve in water, making it necessary to ensure that the solution, once deoxygenated, ***does not subsequently come into contact with atmospheric air***, otherwise the ***advantage of having previously eliminated the oxygen will be lost***.") (emphasis added); *id.* at 3:66-4:14 ("The object of the invention is specifically a method for producing aqueous formulations . . . , which are ***stable over a long period of time***, . . . , characterized in that they are obtained by ***submitting them to extreme deoxygenation*** either by bubbling of an inert gas, or by placing under vacuum, ***then protecting them from possible resorption of oxygen*** during the course of production . . . .") (emphasis added))

The patent contains no examples that expressly refer to the oxygen content of the aqueous solution during the prolonged period (e.g., 6-24 months). (*See, e.g.,* '218 patent at 7:9-18, 8:3-17 (examples noting oxygen content at certain points in deoxygenation process, but never addressing oxygen content after process is done); *see also* Tr. at 28-29 (Plaintiffs' counsel acknowledging this point); *id.* at 75 (Defendant's counsel agreeing)) In the Court's view, the patent's silence on this point supports a finding that a POSA would understand, in the context of the entirety of the patent specification and the remainder of the intrinsic record

(which now includes the history of the reexamination), that the "residual oxygen content" has to remain under 2 ppm for the entirety of the prolonged period. A POSA would expect that if the purpose of the patent could be achieved without maintaining the required deoxygenation level, that the patent or prosecution history would have given at least a hint of this reality (which they do not).

As just noted, this conclusion is supported by the evidence provided by the '218 patent inventor, Dr. François Dietlin, who is also an expert for Plaintiffs. Dr. Dietlin explained in a declaration submitted during reexamination that the '218 patent resulted from accidental testing in which acetaminophen solutions that had been deoxygenated to an oxygen content of 2 ppm or greater ***and were exposed to oxygen*** during sterilization were contaminated, while solutions that had an oxygen content of below 2 ppm and ***were not contaminated with oxygen*** during sterilization achieved the desired stability of greater than 6 months. (*See* D.I. 128 Ex. 13 at 13-14; *see also id.* at 16 (Dr. Dietlin stating, "at least 5 of our competitors have not only copied our formulation, but also our process of ***maintaining*** oxygen below 2 ppm. They must, ***otherwise prolonged stability is impossible.***") (emphasis added); *id.* (Dr. Dietlin concluding, "through the extreme deoxygenation process, we were able to realize our goal as we developed a commercial, IV acetaminophen solution . . . which has an oxygen content of below 2 ppm and is stable for at least 2 years"))[7]

[7]*See also generally* D.I. 136 (Plaintiffs' Motion for Issuance of Letters Rogatory at 1) ("The '218 Patent teaches that, absent deoxygenation, acetaminophen solutions become unstable in a matter of days."). Further, the Court does not view the parties' dispute through the lens of "disclaimer" of claim scope, which – to be found – would have to be clear and unambiguous. Instead, the Court is assessing the totality of the intrinsic evidence – including, most especially, the specification and the prosecution history, including the reexamination declaration of Dr. Dietlin – and, doing so, concludes that a POSA would understand the patentees to be using the terms in the

3. Previously Construed Terms[8]

a. "aqueous solution(s)"

Prior Construction "a composition containing water as a solvent and an active ingredient susceptible to oxidation"
Plaintiffs "a composition containing water as a solvent and an active ingredient susceptible to oxidation"
Defendant "It is the final 'aqueous solution' which must have the claimed oxygen content of below 2 ppm (not some intermediate)"
Court "a composition containing water as a solvent and an active ingredient susceptible to oxidation"

b. "while preserving for a prolonged period"

Prior Construction "the aqueous solution does not decompose substantially such that the formulation has a prolonged pharmaceutically acceptable shelf life"
Plaintiffs "the aqueous solution does not decompose substantially such that the formulation has a prolonged pharmaceutically acceptable shelf life of greater than six (6) months"
Defendant "The stability of the final aqueous solution is preserved by extreme deoxygenation to an oxygen concentration below 2 ppm, and ensuring the deoxygenated final aqueous solution does not subsequently come into contact with atmospheric air, so that the aqueous solution does not decompose substantially such that the formulation has a prolonged pharmaceutically acceptable shelf life for a period of greater than six (6) months"

---

manner in which the Court has construed them.

[8]Each of these terms appears in all asserted claims of the '218 patent.

Court "the final aqueous solution does not subsequently come into contact with atmospheric air, so that it does not decompose substantially, such that the formulation has a prolonged pharmaceutically acceptable shelf life of greater than six (6) months"

c. "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"

Prior Construction "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"
Plaintiffs "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"
Defendant "Either bubbling with at least one inert gas or placing under vacuum or both is carried out until the oxygen content of the final aqueous solution is less than 2 ppm prior to optional addition of an antioxidant"
Court "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"

This Court as well as the Southern District of California have previously construed these terms. *See Cadence Pharm., Inc. v. Paddock Labs. Inc.*, 886 F. Supp. 2d 445, 459-60 (D. Del. 2012); *Cadence Pharm., Inc. v. Agila Specialties Inc.*, 2016 WL 4524171, at *4 (D. Del. Aug. 29, 2016); *Cadence Pharm., Inc. v. Fresenius Kabi USA, LLC*, 2013 WL 12123854, at *9-15 (S.D. Cal. Dec. 2, 2013). Plaintiffs propose the Court adopt the prior constructions with only minor modifications. Defendant asks the Court to adjust the prior constructions to clarify that: (1) it is the ***final*** aqueous solution that, through extreme deoxygenation, has the claimed oxygen content of below 2 ppm; and (2) the stability of that final solution is maintained by

preventing re-oxygenation. (D.I. 147 at 8-9; D.I. 129 at 12-13)[9]

As discussed at the hearing, the parties agree that the "solution" proceeds through three stages during the claimed method: (1) an initial, pre-deoxygenation stage, (2) an extreme deoxygenation stage, during which the solution is deoxygenated until it reaches an oxygen content below 2 ppm, and (3) a post-deoxygenation stage, in which the solution is packaged and shelved and must remain stable for a prolonged period. (*See* Tr. at 22-24 (differentiating "mixing process" of "bubbling/vacuuming step" from "what happened once [the solution] got into the container" after bubbling/vacuuming step); *id.* at 44-45 (same)) The third stage – the stage involving what the Court will call the "final" aqueous solution – is the center of the parties' disputes here.[10]

Defendant contends the purpose of the invention is to "manufacture a ***final*** acetaminophen solution with below 2 ppm of oxygen using ***extreme deoxygenation***, and to ***maintain*** that oxygen level below 2 ppm for the claimed prolonged period in order to achieve the required preservation/stability." (D.I. 129 at 7; Tr. at 47) Defendant relies on Dr. Dietlin's statements during reexamination, in which he explained that "only solutions having below 2 ppm would have prolonged stability of more than 6 months" and "prolonged stability is

---

[9]To the extent Plaintiffs contend Defendant lacks credibility by now seeking modifications despite accepting the Court's prior constructions in its Paragraph IV notice letter, the Court disagrees. (*See* Tr. at 11-12, 20, 50-51)

[10]The issues raised by Defendant – specifically, what the "final" aqueous solution is and how that implicates these various claim construction disputes – were not presented to the prior courts construing these terms. *See Cadence*, 886 F. Supp. 2d at 459-60; *Cadence*, 2013 WL 12123854, at *9; *see also* Tr. at 23-24, 38, 44-47, 58-59. Even if they had been, the Defendant now before the Court has the right to ask the Court to resolve the pending claim construction disputes based on the record developed here, in accordance with the governing law.

impossible" if the solution does not maintain an oxygen content of below 2 ppm. (D.I. 147 at 8-10)

Plaintiffs insist that the doctrine of claim differentiation forecloses including a requirement in claim 1 that the oxygen content of the solution in a closed container – i.e., the final aqueous solution – be below 2 ppm. (D.I. 128 at 17; Tr. at 20-21) Specifically, Plaintiffs assert that claim 11 of the '218 patent "has a different scope" than claim 1 because claim 11 does not merely address "the oxygen content of the solution while it is being prepared," but rather, goes to "the oxygen content in the closed containers." (Tr. at 24) Plaintiffs contend the PTO Examiner similarly understood this to be a key difference between claims 1 and 11 during reexamination, as the Examiner found claim 11 to require "the dissolved oxygen content [be] minimized and maintained at th[e] reduced level," while finding claim 1 to only involve the formulation itself and not maintaining the oxygen level. (*Id.* at 36-37; *see also* '218 Patent Reexamination *Non-Final Office Action* dated July 30, 2014, pp. 11-15)

However, as Plaintiffs concede, claim 11 contains various other differences from claim 1. (*See* Tr. at 39-41, 56-57) Hence, here, as may often be the case, claim differentiation is not dispositive. *See Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed. Cir. 2001) ("Claim differentiation, while often argued to be controlling when it does not apply, is clearly applicable when there is a dispute over whether a limitation found in a dependent claim should be read into an independent claim, and that limitation is the only meaningful difference between the two claims."); *SunRace*, 336 F.3d at 1303 ("That 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.").

The Court agrees with Defendant that it is the ***final*** aqueous solution that must have and preserve an oxygen content of below 2 ppm. As stated above in connection with the term "residual oxygen content," the patent clearly calls out the advantages of preventing re-oxygenation. *See, e.g.,* '218 patent at 2:56-60 ("[O]xygen shows a very great facility to dissolve in water, making it necessary to ensure that the solution, once deoxygenated, does not subsequently come into contact with atmospheric air, otherwise the advantage of having previously eliminated the oxygen will be lost."); *id.* at 3:66-4:14 ("The object of the invention is specifically a method for producing aqueous formulations . . . , which are stable over a long period of time, . . . , characterized in that they are obtained by submitting them to extreme deoxygenation either by bubbling of an inert gas, or by placing under vacuum, then protecting them from possible resorption of oxygen during the course of production . . . ."). Dr. Dietlin similarly recognized the problem of re-oxygenation after extreme deoxygenation. (*See* D.I. 128 Ex. 13 at 13-14) ("[I]mmediately after sterilization, we learned that several of our manufactured vials were contaminated with oxygen during the sterilization process. This resulted in discolored solutions after just a few days.")

Despite agreeing with Defendant on this point, the Court finds it unnecessary to adjust its prior construction (other than adding the agreed reference to 6 months). The term "aqueous solution" is used in the patent to refer to times throughout the deoxygenation process, so the term does not ***always*** signify a final aqueous solution. *See, e.g., id.* at 2:29-40 ("[M]ethods [that] have been used for this purpose [of improving the stability of such medicinal active principles which are susceptible to oxidation include]: elimination of the oxygen by raising the

temperature of the aqueous solution, by putting the aqueous solution under vacuum or by bubbling an inert gas . . . through the solution."); *id.* at 4:18-20 ("an aqueous solution with at least one active principle is subjected to extreme, and possibly complete, deoxygenation"); *id.* at 4:34-37 ("The aqueous solution is introduced into the container under an inert gas atmosphere, such as nitrogen. Before the aqueous solution with active principle is introduced into the container, the latter is cleared of the air contained therein . . . ."). The patent's reference to residual oxygen content is what signifies that the solution has been deoxygenated and has entered the third, "final" stage. As the Court's construction of "residual oxygen content" already clarifies that the aqueous solution for which oxygen content is being measured is the final, post-deoxygenation solution, Defendant's proposed modification of "aqueous solution" is unnecessary. Together, the Court's constructions of "residual oxygen content" and "aqueous solution" are consistent with the inventor's position during reexamination – that is, the final aqueous solution must have and maintain an oxygen content below 2 ppm. Thus, while the Court is not modifying its prior construction of the term "aqueous solution," it agrees with Defendant that the final aqueous solution must have and maintain the claimed oxygen content of below 2 ppm.

Regarding the term "while preserving for a prolonged period," the parties agree that the Court's prior construction should be modified to clarify that the "prolonged period" must be greater than six (6) months. (D.I. 128 at 11 n.2; D.I. 129 at 11) Unlike the term "aqueous solution," this term only arises in claim 1, a claim that does not mention the "residual oxygen content." Therefore, the Court finds it necessary to clarify that the solution being "preserved for a prolonged period" is the final deoxygenated solution. As the patent specification

teaches, "it is necessary to ensure that the solution, ***once deoxygenated***, does not subsequently come into contact with atmospheric air, otherwise the advantage of having previously eliminated the oxygen will be lost." '218 patent at 2:55-60 (emphasis added). Dr. Dietlin also clarified during reexamination that, "at least 5 of our competitors have not only copied our formulation but also our process of ***maintaining*** oxygen below 2 ppm. They must, otherwise prolonged stability is impossible." (D.I. 128 Ex. 13 at 16) (emphasis added) The Court, therefore, finds it necessary to clarify that the final solution must not come into contact with atmospheric air after deoxygenation, so that its oxygen content is maintained.

However, as the claims specifically recite how preservation is accomplished and that the concentration must be below 2 ppm, the Court finds Defendant's recitation of "preserved by extreme deoxygenation to an oxygen concentration below 2 ppm" redundant. *See* '218 patent at cl. 1 ("A method for preparing an aqueous solution with an active nature susceptible to oxidation . . . while preserving for a prolonged period, comprising ***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 aforementioned aqueous solution . . . is topped with an inert gas atmosphere . . . and placed in a closed container . . . , and ***the oxygen content of the aqueous solution is below 2 ppm***, ...") (emphases added). Therefore, the Court will adopt its prior construction, adding the agreed-upon six month modification and the additional limitations as outlined above.[11]

---

[11]While the Court has narrowed its prior construction, it has formed no opinion at this time as to the viability of a doctrine of equivalents argument similar to that asserted in *Cadence Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, 2013 WL 11083853, at *21-22 (D. Del. Nov. 14, 2013).

Finally, regarding 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 2ppm," as the parties agree that bubbling "with at least one inert gas" is implicit in the Court's prior construction, the Court sees no reason to modify its construction here. In the context of this term, the solution is in a period of transition, and thus, the Court finds Defendant's added limitation improper. Accordingly, the Court will adopt its prior construction.

B. The '012 and '265 Patents

1. The "about" terms[12]

a. "about 550 mg" and/or "about 600 mg"

Plaintiffs No construction is necessary beyond plain and ordinary meaning, which is "approximately"
Defendant "about 550 mg" does not include "about 500 mg" within its literal scope and meaning" "about 600 mg" does not include "about 500 mg" within its literal scope and meaning"
Court "about 550 mg" does not include "about 500 mg" within its literal scope and meaning" "about 600 mg" does not include "about 500 mg" within its literal scope and meaning"

b. "about 800 mg" and/or "about 700 mg" and/or "about 750 mg"

[12] These terms appear in claims 1, 12, 38, and 39 of the '012 patent and claims 1 and 6 of the '265 patent. The "about" terms include: "about 550 mg," "about 600 mg," "about 700 mg," "about 750 mg," "about 800 mg," and "about 3 to about 5 hours."

Plaintiffs No construction is necessary beyond plain and ordinary meaning, which is "approximately 800 mg, which is less than about 1000 mg" No construction is necessary beyond plain and ordinary meaning, which is "approximately 800 mg, which is less than about 1000 mg" No construction is necessary beyond plain and ordinary meaning, which is "approximately 800 mg, which is less than about 1000 mg"
Defendant "about 700 mg" does not include "about 1000 mg" within its literal scope and meaning" "about 750 mg" does not include "about 1000 mg" within its literal scope and meaning" "about 800 mg" does not include "about 1000 mg" within its literal scope and meaning"
Court "about 700 mg" does not include "about 1000 mg" within its literal scope and meaning" "about 750 mg" does not include "about 1000 mg" within its literal scope and meaning" "about 800 mg" does not include "about 1000 mg" within its literal scope and meaning"

c. "about 3 [hours] to about 5 hours"

Plaintiffs No construction is necessary beyond plain and ordinary meaning, which is "approximately 3 to approximately 5 hours"
Defendant "about 3 to about 5 hours" does not include "about 6 hours" within its literal scope and meaning"
Court "about 3 to about 5 hours" does not include "about 6 hours" within its literal scope and meaning"

Plaintiffs contend the term "about" needs no construction and alternatively propose construing "about" as "approximately." (D.I. 128 at 18) Defendant counters that the patentee clearly and unambiguously disavowed claim scope and, therefore, the "about" terms need to be construed accordingly. (D.I. 147 at 13-14)

The Court agrees with Defendant. Plaintiffs offered no reason in their briefing or during the hearing as to why the Court should not adopt Defendant's constructions. In fact, Plaintiffs

conceded that they narrowed the claim scope during prosecution, consistent with Defendant's proposals. (*See* Tr. at 93-94)

2. "pharmaceutical composition"[13] / "first pharmaceutical composition"[14]

Plaintiffs No construction is necessary beyond plain and ordinary meaning, which is "one or more pharmaceutical compositions" / No construction is necessary beyond plain and ordinary meaning, which is "one or more pharmaceutical compositions of acetaminophen"
Defendant A "single dose formulation" / A "first single dose formulation"
Court "one or more pharmaceutical compositions" / "one or more pharmaceutical compositions of acetaminophen"

Defendant contends the claims' recitation of "'***a*** pharmaceutical composition' (singular), followed immediately thereafter by the claimed composition's dosage of acetaminophen" signifies that the term is singular and must only encompass a single dose formulation. (D.I. 129 at 20) (emphasis added) Plaintiffs counter that the indefinite article "a" should not be construed so narrowly and should, instead, encompass compositions that may include "one or more" doses.

The Court agrees with Plaintiffs. The Federal Circuit "has repeatedly emphasized that an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.'" *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000). Further, the '012 and '265

---

[13]This term appears in claims 1, 3, 4, and 9-13 of the '012 patent.

[14] This term appears in claims 1, 2, 6, and 7 of the '265 patent.

patent specifications state that "use of the singular includes the plural unless specifically stated otherwise." '012 patent at 3:63-67; '265 patent at 4:4-9. Moreover, dependent claim 12 of the '265 patent recites: "The method of claim 1, wherein the second pharmaceutical composition is administered as a single dose ***or in multiple doses***." (Emphasis added) With respect to these pharmaceutical composition terms, the patents do not "state otherwise."

III. CONCLUSION

The Court will construe the disputed terms as explained above. An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT IP UNLIMITED COMPANY, MALLINCKRODT HOSPITAL PRODUCTS INC., and SCR PHARMATOP	:	
Plaintiffs,	:	
v.	:	C.A. No. 17-365-LPS
B. BRAUN MEDICAL INC.,	:	
Defendant.	:	

MALLINCKRODT IP UNLIMITED COMPANY and MALLINCKRODT HOSPITAL PRODUCTS INC.	:	
Plaintiffs,	:	
v.	:	C.A. No. 17-660-LPS
B. BRAUN MEDICAL INC.,	:	
Defendant.	:	

ORDER

At Wilmington, this **5th** day of **June, 2018**:

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that the disputed claim terms of U.S. Patent Nos. 6,992,218, 9,399,012, and 9,610,265 are construed as follows:

Claim Term	**Court's Construction**
inert gas [claim 1 of the '218 patent]	a nonreactive gas under particular conditions (e.g., argon, carbon dioxide, neon, nitrogen, xenon)

residual oxygen content [claims 3, 4, 20, and 21 of the '218 patent]	the oxygen content of the aqueous solution for the "prolonged period" of stability
aqueous solution(s) [all asserted claims of the '218 patent]	a composition containing water as a solvent and an active ingredient susceptible to oxidation
while preserving for a prolonged period [all asserted claims of the '218 patent]	the final aqueous solution does not subsequently come into contact with atmospheric air, so that it does not decompose substantially, such that the formulation has a prolonged pharmaceutically acceptable shelf life of greater than six (6) months
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 [all asserted claims of the '218 patent]	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
"about 550 mg" and/or "about 600 mg" [claims 1, 12, and 38 of the '012 patent; claims 1 and 6 of the '265 patent]	"about 550 mg" does not include "about 500 mg" within its literal scope and meaning "about 600 mg" does not include "about 500 mg" within its literal scope and meaning
"about 800 mg" and/or "about 700 mg" and/or "about 750 mg" [claims 1, 12, and 38 of the '012 patent; claims 1 and 6 of the '265 patent]	"about 800 mg" does not include "about 1000 mg" within its literal scope and meaning "about 700 mg" does not include "about 1000 mg" within its literal scope and meaning "about 750 mg" does not include "about 1000 mg" within its literal scope and meaning
"about 3 to about 5 hours" [claims 1, 38, and 39 of the '012 patent]	"about 3 to about 5 hours" does not include "about 6 hours" within its literal scope and meaning"

pharmaceutical composition / first pharmaceutical composition [claims 1, 3, 4, and 9-13 of the '012 patent / claims 1, 2, 6, and 7 of the '265 patent]	"one or more pharmaceutical compositions" / "one or more pharmaceutical compositions of acetaminophen"

IT IS FURTHER ORDERED that the parties shall file, no later than June 7, 2018, a joint status report.

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE