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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA**

Rowpar Pharmaceuticals Incorporated, et al.,
Plaintiffs,
v.
Lornamead Incorporated,
Defendant.

No. CV-13-01071-PHX-DGC

ORDER

The Court held a *Markman* hearing on March 25, 2014. This order will set forth the Court’s constructions of the disputed terms and phrases.

I. Background.

Plaintiffs Rowpar Pharmaceuticals, Inc. (“Rowpar”) and Micropure, Inc. (“Micropure”) assert claims for misappropriation of trade secrets, breach of contract, and patent infringement by Defendant Lornamead, Inc. (“Lornamead”). Doc. 1.

The United States Patent and Trademark Office issued United States Patent No. 6,017,554 (“the ’554 Patent”) on January 25, 2000. Dr. Perry Ratcliff, the founder of Rowpar, is named as the inventor. Micropure is the assignee of the ’544 Patent. The ’544 Patent teaches the use of chlorine dioxide in conjunction with a phosphate compound. According to the specification, chlorine dioxide may be used to prevent and treat fungal and bacterial infections of the rectal, vaginal, urethral, oral, nasal, ocular, and auditory canal orifices, and other abnormal conditions of the epithelium. Chlorine dioxide is unstable in aqueous solutions at lower pH levels, which makes it difficult for

1 use on areas of the human body. The phosphate compound has a dual role: it inhibits the
2 escape of chlorine dioxide at lower pH levels, and it acts as a surface tension reducing
3 agent.

4 Rowpar's complaint alleges infringement of claims 2, 5, and 8-13 of the '544
5 Patent by making, selling, and offering for sale a sulfate-free stabilized chlorine dioxide
6 toothpaste that was marketed and sold at Walgreens. Doc. 1, ¶¶ 47, 49.

7 **II. Legal Standard.**

8 A patent includes two basic components: (1) a written description of the invention,
9 which is referred to as the "specification" of the patent, and (2) the patent claims. The
10 claims of a patent define the scope of the invention to which the patentee is entitled.
11 *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005); *see also Vitronics Corp. v.*
12 *Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Claim construction is a matter
13 of law exclusively within the province of the Court. *Markman v. Westview Instruments,*
14 *Inc.*, 517 U.S. 370, 372 (1996). When construing a patent's claims, the words of a claim
15 are generally given their ordinary and customary meaning. *Phillips*, 415 F.3d at 1312.
16 The ordinary and customary meaning of a claim term is the meaning that the term would
17 have to a person of ordinary skill in the art in question at the time of the invention, read
18 "not only in the context of the particular claim in which the disputed term appears, but in
19 the context of the entire patent, including the specification." *Id.* at 1313.

20 When construing the claims, the Court should first look to the intrinsic evidence of
21 the patent, which includes the specification, file history, and patent prosecution. *Id.* The
22 specification is the primary basis for claim construction and the best source for
23 understanding a technical term in the proper context. *Id.* at 1315. In addition to the
24 specification and the claims themselves, the Court should also consider the patent's
25 prosecution history. *Id.* at 1317; *see also Graham v. John Deere Co.*, 383 U.S. 1, 33
26 (1966) ("[A]n invention is construed not only in the light of the claims, but also with
27 reference to . . . the prosecution history[.]").

28 Extrinsic evidence may also be used to assist the Court's claim construction.

1 Extrinsic evidence consists of all evidence external to the patent and prosecution history,
2 including expert and inventor testimony, dictionaries, learned treatises, and other patents.
3 *Phillips*, 415 F.3d at 1317. Extrinsic evidence must not be used to vary or contradict
4 claim terms. *Vitronics*, 90 F.3d at 1584.

5 **III. Construction of Disputed Terms.**

6 **A. Preamble of the Asserted Claims.**

7 Rowpar originally disputed Lornamead's assertion that the preambles to the
8 independent claims are limiting. Doc. 75 at 6. Rowpar now agrees with Lornamead that
9 the preambles are limiting. *Id.*

10 **B. Epithelium.**

11 The term "epithelium" is found in the preamble of every independent claim of the
12 '544 Patent. Rowpar asserts that "epithelium" should be construed as "tissue covering
13 internal and external surfaces of the body, including gingival tissue (gums)." *Id.*
14 Lornamead asserts that "epithelium" should be construed as "tissue lining the surfaces of
15 body cavities." Doc. 74 at 19. The Court will adopt the general definition of "tissue
16 covering internal and external surfaces of the body."

17 The parties agree that neither the claims nor the specification provide a definition
18 of "epithelium." The claims and specification do, however, shed some light on the
19 proper construction. The preamble to each claim refers to the "epithelium of the rectal,
20 vaginal, urethral, oral, nasal, ocular, and auditory canal orifices." *See, e.g.*, U.S. Patent
21 No. 6,017,554 col.15 ll.41-42. Lornamead asserts that the construction of "epithelium"
22 should therefore be limited to tissue that is part of the orifices identified in the preamble.
23 Doc. 74 at 20. Lornamead also points to language at multiple locations in the '544 Patent
24 in which the term "epithelium" is used in connection with the body cavities identified in
25 the claim preambles. Doc. 74 at 20. For example, the '544 Patent indicates that the
26 composition treats "abnormal conditions of the epithelium of bodily orifices." U.S.
27 Patent No. 6,017,554 col.1 ll.14-15.

28 It is important to note that the term being construed consists of a single word:

1 “epithelium.” If that word, standing alone, was construed to mean “tissue lining the
2 surfaces of body cavities” as Lornamead suggests, then the remainder of the phrase in
3 which it appears repeatedly – “of the rectal, vaginal, urethral, oral, nasal, ocular, and
4 auditory canal orifices” – would be superfluous. Courts generally should avoid
5 constructions that render other terms superfluous. *See CAE Screenplates Inc. v. Heinrich*
6 *Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000) (“In the absence of any
7 evidence to the contrary, we must presume that the use of . . . different terms in the
8 claims connotes different meanings.”); *Primos, Inc. v. Hunter’s Specialties, Inc.*, 451
9 F.3d 841, 848 (Fed. Cir. 2006) (rejecting overlapping constructions that would render one
10 of several distinct claim terms superfluous).

11 The first part of Rowpar’s proposed construction is consistent with definitions of
12 “epithelium” in pertinent dictionaries. *See* Doc. 78-2 at 4 (defining “epithelium” as cells
13 constituting “the covering of internal and external surfaces of the body.”); Doc. 78-3 at 6
14 (defining “epithelium” as “[t]he nonvascular cellular layer that covers the internal and
15 external surfaces of the body.”); Doc. 78-4 at 5 (defining “epithelium” as “the covering of
16 the internal and the external organs of the body[.]”); Doc. 78-5 at 4 (defining
17 “epithelium” as “[t]he purely cellular avascular layer covering all the free surfaces[.]”).

18 The Court concludes that the proper construction of the single word “epithelium”
19 is “tissue covering internal and external surfaces of the body.” The Court need not
20 expressly state, as Rowpar suggests, that “epithelium” includes gingival (gum) tissue, as
21 that is inherent in this general meaning of “epithelium.”

22 **C. Topical Composition.**

23 The phrase “topical composition” is found in the preamble of every independent
24 claim in the ’544 Patent. Rowpar asserts that no construction is necessary. Doc. 75 at 7.
25 Lornamead asserts that “topical composition” should be construed as “a pharmaceutical
26 mixture of active and inactive ingredients for the treatment of ailments on the surface
27 tissues of the body.” Doc. 74 at 21.

28 Neither the claims nor the specification provides a definition of “topical

1 composition.” Lornamead points to uses of the phrase “topical composition” in the
2 preamble that are coupled with “[for] treating conditions of the epithelium” to argue that
3 “topical compositions” refers only to compositions for the treatment of ailments of the
4 surface tissues of the body. Doc. 74 at 22. Lornamead also argues that the term
5 “composition” refers to a pharmaceutical mixture for a therapeutic effect that contains
6 both active and inactive ingredients. *Id.*

7 The word “composition” is a general term in patent law that simply suggests a
8 mixture or combination. *See* 35 U.S.C. § 101 (“Whoever invents or discovers any new
9 and useful process, machine, manufacture, or composition of matter . . .”). Nothing in the
10 patent suggests that the single word “composition” is limited to a mixture of active and
11 inactive ingredients. Although some of the examples include such ingredients, the patent
12 never suggests that “composition” is intended to be limited by them. The Court agrees
13 with Rowpar that the patent’s use of the term “composition” imposes no limitations on
14 any of the claims and does not need to be construed. *See Abbot Laboratories v. Bayer*
15 *HealthCare LLC*, No. 09-40002-FDS, 2010 WL 4340565, at *4-5 (D. Mass. Oct. 25,
16 2010) (declining to construe “composition,” which “is a term of art in patent law, and is
17 not a term that normally requires interpretation.”).

18 Rowpar asserts that “topical” should be construed as “local application to part(s)
19 of the body” because in every instance where a “topical” composition or preparation is
20 used it is applied locally to a part of the body. Doc. 75 at 9-10. Lornamead argues that
21 “topical” means “for the treatment of ailments on the surface tissues of the body.”
22 Doc. 74 at 20. Lornamead’s definition does not require application of the composition
23 directly to the treated area of the body. An oral medication would satisfy its definition,
24 contrary to the descriptions contained throughout the patent. The Court largely adopts
25 Rowpar’s proposed construction of “topical.” The Court construes “topical” to mean “to
26 be applied locally to a part of the body.”

27 **D. Topical Preparation.**

28 The phrase “topical preparation” is found in every independent claim of the ’544

1 Patent. Rowpar asserts that the term should be construed as “a composition ready for
2 local application to part(s) of the body.” Doc. 75 at 8. Lornamead asserts that the term
3 should be construed as “a pharmaceutical mixture of active and inactive ingredients for
4 the treatment of ailments on the surface tissues of the body” – the same construction that
5 Lornamead proposes for “topical composition.” Doc. 74 at 25. Because the Court
6 construed the term “topical” above, it need only address “preparation.”

7 The parties agree that the claims provide a list of “preparation[s],” including
8 “liquid solutions, suspensions, semi-solids, salves, creams, and suppositories.” *See* U.S.
9 Patent No. 6,017,554 col.15 ll.48-50. Lornamead’s suggestion that “preparation” must be
10 construed to include active and inactive ingredients improperly attempts to impose
11 narrowing limitations on the claims that have no basis in the claim language. Nothing in
12 the patent suggests that “preparation” is limited to a mixture of active and inactive
13 ingredients. Although some of the examples include such ingredients, the patent does not
14 suggest that “preparation” is intended to be limited by such examples. The Court will not
15 impose narrowing constructions without support from the claim language. *See*
16 *Honeywell Int’l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 992-93 (Fed. Cir.
17 2007) (rejecting construction that imposed additional, narrowing limitations not found in
18 the claim language).

19 Rowpar’s proposed construction of “topical preparation” accords more naturally
20 with the intrinsic and extrinsic evidence. The ’544 Patent uses the term “preparation” to
21 refer to nine compositions that “may be prepared” for a particular use. *See, e.g.*, U.S.
22 Patent No. 6,017,554 col.12 l. 1 through col.14 l.62 (“Hypothetically, the following
23 composition may be prepared . . .); *see also Id.* at col. 7 ll.3-13 (detailing how a test
24 solution was “prepared.”). Pertinent dictionaries also define a “preparation” as
25 something ready for a particular use. *See* Doc. 78-2 at 6 (“[A] medicine made ready for
26 use[.]”); Doc. 78-3 at 7 (“A substance, such as medicine, prepared for a particular
27 purpose.”); Doc. 78-5 at 8 (“[S]omething made ready, as a medicinal or other
28 mixture[.]”). The Court concludes that “preparation” means “a composition for

1 treatment.” Thus, “topical preparation” means “a composition for treatment to be applied
2 locally to a part of the body.”

3 **E. Total Preparation.**

4 The phrase “total preparation” is found in claim 7 of the ’544 Patent. Rowpar
5 asserts that the phrase should be construed as “topical preparation” as construed above.
6 Lornamead asserts that the claim language and prosecution history provide “a strong
7 indication that ‘total preparation’ is a typographic error” and that the phrase should be
8 construed in the same manner as “topical preparation.” Doc. 74 at 36. Because the
9 parties agree that the phrase “total preparation” should be construed in the same manner
10 as “topical preparation,” the Court will adopt its construction of “topical” and
11 “preparation” above.

12 **F. Retard Escape.**

13 The phrase “retard escape” is found in every independent claim of the ’544 Patent.
14 Rowpar asserts that the phrase should be construed as “slow emission.” Doc. 75 at 11.
15 Lornamead asserts that it should be construed as “slow the production of chlorine dioxide
16 breakdown products during product storage.” Doc. 74 at 27. The Court prefers
17 Rowpar’s proposed construction for three reasons.

18 First, Lornamead’s proposed construction introduces a limitation – “during
19 product storage” – which does not follow from the phrase’s ordinary meaning. Nor does
20 it follow from the use of the phrase in the patent, which uses this language: “retard escape
21 of the chlorine dioxide from said topical preparation.” *See, e.g.*, U.S. Patent No.
22 6,017,554 col.15 ll.55-56. Nothing in this phrase suggests that “retard escape” is limited
23 to the storage of the topical preparation, and the Court declines to add an unnecessary
24 limitation. *See Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1300-01 (Fed.
25 Cir. 2013) (it is improper to introduce narrowing limitations not found in the claim
26 language).

27 Second, the specification mentions “retard escape” only once, stating that “[t]he
28 addition of activating inhibitor phosphates to the stabilized chlorine dioxide reduces

1 surface tension and retards the rapid escape of chlorine dioxide gas at the pH range of 6.5
2 to 7.0 typical of the orifices of the body.” U.S. Patent No. 6,017,554 col.15 ll.52-56.
3 Lornamead’s construction overlooks the fact that “retard escape” is used in connection
4 with retarding the escape of chlorine dioxide when the topical preparation is applied to
5 bodily orifices, not only when storing the preparation.

6 Third, after excluding the words “during product storage” from Lornamead’s
7 construction, it appears that the parties’ constructions are substantially the same. The
8 Court construes “retard escape” as “slow emission.”

9 **G. Liquid Solution.**

10 The phrase “liquid solution” is found in every independent claim of the ’544
11 Patent. Each of the independent claims requires that the claimed topical preparation be
12 “selected from the group consisting of liquid solutions, suspensions, semi-solids, salves,
13 creams, and suppositories.” *See, e.g.*, U.S. Patent No. 6,017,554 col.15 ll.48-50. Rowpar
14 asserts that the phrase should be given its plain and ordinary meaning or, if it must be
15 construed, should be defined as “a dissolved mixture in liquid form of a solute and
16 solvent.” Doc. 75 at 12. Lornamead asserts that the phrase should be construed as “a
17 mixture of liquid ingredients and solid ingredients dissolved in the liquid ingredients.”
18 Doc. 74 at 28.

19 Neither the claims nor specification shed much light on the meaning of “liquid
20 solution.” The only intrinsic evidence is that “liquid solution” is an embodiment of a
21 “topical preparation.” Pertinent dictionaries do provide definitions of the term “solution”
22 that aid the Court’s analysis. *See* Doc. 78-2 at 7 (defining “solution” as “a homogenous
23 mixture of one or more substances (solutes) dispersed molecularly in a sufficient quantity
24 of dissolving medium (solvent). The solute may be a gas, liquid, or solid; the solvent is
25 usually liquid, but may be solid[.]”); Doc. 78-5 at 9 (defining “solution” as “[t]he
26 incorporation of a solid, a liquid, or a gas in a liquid or noncrystalline solid resulting in a
27 homogenous single phase.”).

28 Lornamead’s proposed construction requires the solute to originate as a solid, but

1 none of the dictionaries consulted by the Court suggest that limited meaning. To the
2 contrary, some specifically state that the solute may be gas, liquid, or solid. In addition,
3 nothing in the claim language or specification suggests that the solute must be solid. *See*,
4 *e.g.*, U.S. Patent No. 6,017,554 col.5 ll.60-67 (describing liquid solution prepared by
5 combining liquid solute with liquid solvent). Because the phrase “liquid solution” has a
6 plain and ordinary meaning that accords with the intrinsic evidence and relevant
7 dictionary definitions, the Court will construe is as “a dissolved mixture in liquid form of
8 a solute and solvent.”

9 **H. Suspensions.**

10 The term “suspensions” is found in every independent claim of the ’544 Patent.
11 Rowpar asserts that the term should be given its plain and ordinary meaning or, if it must
12 be construed, should be defined as “a dispersed mixture of particles in a liquid medium.”
13 Doc. 75 at 13. Lornamead asserts that the term should be construed as “a mixture of
14 liquid ingredients and solid ingredients that are reversibly dispersed in a liquid.” Doc. 74
15 at 28. The Court will adopt Rowpar’s proposed construction.

16 The intrinsic record does not significantly inform the meaning of the term
17 “suspension.” Pertinent dictionaries do provide definitions of “suspension.” *See*
18 Doc. 78-5 at 10 (defining “suspension” as “[c]oarse dispersion; the dispersion through a
19 liquid of a solid in finely divided particles of a size large enough to be detected by purely
20 optical means[.]”); Doc. 78-8 at 4 (defining “suspension” as “[a] system in which very
21 small particles (solid, semi-solid, or liquid) are more or less uniformly dispersed in a
22 liquid or gaseous medium.”). The dictionary definitions differ from one another. The
23 Federal Circuit has instructed, however, that “consulting dictionary definitions is simply
24 a first step in the claim construction analysis and is another reason why resort must
25 always be made to [the intrinsic evidence].” *Brookhill-Wilk 1, LLC. v. Intuitive Surgical,*
26 *Inc.*, 334 F.3d 1294, 1300 (Fed. Cir. 2003).

27 The Court finds no basis in the intrinsic or extrinsic evidence for the portion of
28 Lornamead’s construction requiring that suspension components be “reversibly

1 dispersed.” The Court will adopt Rowpar’s construction because it is broader than
2 Lornamead’s and comports with both dictionary definitions.

3 **I. Semi-Solids.**

4 The term “semi-solids” is found in every independent claim of the ’544 Patent.
5 Rowpar asserts that the term should be given its plain and ordinary meaning or, if it must
6 be construed, should be defined as “forms used for topical application that are not fully
7 solid, such as creams, gels, pastes, and lotions.” Doc. 75 at 14. Lornamead asserts that
8 the term should be construed as “a mixture that is neither solid nor liquid.” Doc. 74 at
9 28. The Court will adopt Rowpar’s proposed construction.

10 Several dictionary definitions shed light on the meaning of the term “semi-solid.”
11 *See* Doc. 78-9 at 4 (defining “semi-solid” as “having the qualities of both a solid and a
12 liquid: highly viscous[.]”); Doc. 78-10 at 4 (defining “semi-solid” as “[i]ntermediate in
13 properties, esp. in rigidity, between solids and liquids” or “[a] semisolid substance, such
14 as a stiff dough or firm gel.”). The Court rejects Lornamead’s proposed construction
15 because it is ambiguous. It would include a gas since gases are neither “solid nor liquid,”
16 but gases clearly are not “semi-solid.” The Court will adopt Rowpar’s proposed
17 construction because it is consistent with the dictionary definitions and the specification
18 provides examples of semi-solid preparations including toothpaste, gels, gel mixtures,
19 and lotions. *See, e.g.*, U.S. Patent No. 6,017,554 col.11 ll.61-67 (describing a toothpaste
20 preparation).

21 **J. Salves.**

22 The term “salves” is found in every independent claim of the ’544 Patent. Rowpar
23 asserts that the term should be given its plain and ordinary meaning or, if it must be
24 construed, should be defined as “ointment.” Doc. 75 at 14. Lornamead asserts that the
25 term should be construed as “an ointment.” Doc. 74 at 28. The Court prefers Rowpar’s
26 construction only because it is not singular. Lornamead’s proposed construction of “an
27 ointment” is inconsistent with the plural “salves. The Court construes “salves” as
28 “ointment.”

1 **K. Creams.**

2 The term “creams” is found in every independent claim of the ’544 Patent.
3 Rowpar asserts that the term should be given its plain and ordinary meaning or, if it must
4 be construed, should be defined as “any fluid mixture of thick consistency.” Doc. 75 at
5 15. Lornamead asserts that the term should be construed more narrowly as “a
6 pharmaceutical emulsion, made of oil and water, for the treatment of body surfaces.”
7 Doc. 74 at 29. The Court will adopt Rowpar’s proposed construction.

8 Lornamead’s proposed construction would limit “creams” to “emulsions” made of
9 oil and water. Doc. 75 at 15. The specification and claims are silent as to the meaning of
10 the term “cream,” and the intrinsic record provides no reason to conclude that “creams”
11 are limited as Lornamead suggests. The Court will not impose narrowing constructions
12 without support from the claim language. *Honeywell Int’l Inc.*, 488 F.3d at 992-93.

13 **L. Suppositories.**

14 The term “suppositories” is found in every independent claim of the ’544 Patent.
15 Rowpar asserts that the term should be given its plain and ordinary meaning or, if it must
16 be construed, should be defined as “a medicated solid body intended for introduction into
17 an orifice of the body.” Doc. 75 at 15. Lornamead asserts that the term should be
18 construed more narrowly as “a solid pharmaceutical preparation designed for insertion
19 into the rectum, vagina or urethra.” Doc. 74 at 29. The Court will adopt Rowpar’s
20 proposed construction.

21 Both parties suggest that suppository means a solid body or preparation, but
22 Lornamead’s proposed construction would require that it be designed for insertion “into
23 the rectum, vagina, or urethra.” This limitation is not found in the intrinsic record.
24 Although Lornamead’s proffered dictionary definition lists the rectum, urethra, and
25 vagina as orifices suitable for suppositories, it does not suggest that the list is exhaustive.
26 Because the intrinsic evidence does not suggest Lornamead’s limitation, the Court will
27 not adopt it. *Honeywell Int’l Inc.*, 488 F.3d at 992-93.

28

1 **M. Shelf Life.**

2 The phrase “shelf life” is found in every independent claim of the ’544 Patent.
3 Rowpar asserts that the phrase should be construed as “stability over time of chlorine
4 dioxide at a pH in the range of about 6.0 to 7.4.” Doc. 75 at 16. Lornamead asserts that
5 the phrase should be construed as “the storage period of a product, during which it has
6 full pharmacological or cosmetic effect as defined by the manufacturer’s product
7 specifications.” Doc. 75 at 33. The Court will adopt Rowpar’s construction.

8 Lornamead asserts that its proposed construction is derived from the claim
9 language and specification. Doc. 74 at 33. As Lornamead indicates, the phrase “shelf
10 life” is embedded in each independent claim:

11 “. . . wherein the concentration of phosphate compound is in a
12 range . . . to retard escape of the chlorine dioxide from said
13 topical preparation, said topical preparation being at a pH in
14 the range of about 6.0 to about 7.4, thereby increasing the
 shelf life and efficacy of said topical preparation.”

15 *See, e.g.*, U.S. Patent No. 6,017,554 col.15 ll.54-59. Lornamead argues that “the claim
16 language clearly links the concentration of the phosphate compound with the pH range to
17 increase the product’s shelf life.” Doc. 74 at 33. Because the specification teaches that
18 the escape of chlorine dioxide can be inhibited by addition of a phosphate compound,
19 Lornamead argues that the construction of “shelf life” must reflect a measure of
20 continued potency. *Id.* But this definition would render unnecessary the word “efficacy”
21 which appears immediately after “shelf life” in the patent language quoted above. By
22 defining “shelf life” to include “full pharmacological or cosmetic effect,” Lornamead’s
23 definition would leave no need for the term “efficacy.”

24 Lornamead argues that Rowpar’s construction is “misleading because it relies
25 solely on the pH of the topical composition, whereas the specification clearly teaches that
26 it is the phosphate compounds that improve the stability of the chlorine dioxide” at a
27 given pH. Doc. 74 at 33-34. Lornamead also argues that Rowpar’s construction “implies
28 that ‘shelf life’ is solely related to chlorine dioxide and pH, when the specification and

1 claims indicate that it is also related to the ‘phosphate compound[.]’” *Id.* at 34. The
2 Court does not agree. When read within the context of the claim, Rowpar’s construction
3 of “shelf life” accounts for the central feature of the claim – improved stability of
4 chlorine dioxide at a lower pH – without disregarding the fact that the stability is
5 achieved by the addition of a phosphate compound.

6 **N. Efficacy.**

7 The term “efficacy” is found in every independent claim of the ’544 Patent.
8 Rowpar asserts that the proper construction of “efficacy” is “effectiveness in said
9 treatment of [conditions] of the epithelium.” Doc. 75 at 17. Lornamead asserts that the
10 proper construction is “product’s ability to produce the desired effect when used
11 topically.” Doc. 74 at 34.

12 Lornamead identifies evidence in the claim language and specification that links
13 the term “efficacy” to the “shelf life” of the topical preparation. Taken together, these
14 terms indicate that the term “efficacy” is intended to reflect the ability of stabilized
15 chlorine dioxide to produce a beneficial result. A dictionary definition buttresses
16 Lornamead’s proposed construction. Doc. 82-3 at 7 (defining “efficacy” as “[t]he extent
17 to which a specific intervention, procedure, regimen, or service produces a beneficial
18 result under ideal conditions.”).

19 Rowpar asserts that the “preamble explicitly identifies the specific effect by which
20 efficacy is to be judged.” Doc. 75 at 17. For example, the topical preparation in claim 11
21 must be effective “for treating the epithelium of the rectal, vaginal, oral, anal, ocular, and
22 auditory canal orifices by reducing the occurrence of leukoplakia in the orifices.” U.S.
23 Patent No. 6,017,554 col.17 ll.44-47. The specification also teaches that the claimed
24 compositions can be used to treat specific bodily orifice maladies “by reducing the
25 presence of fungal and bacterial infections and leukoplakia[.]” *Id.* at col.4 ll.14-21.
26 Rowpar asserts that the proper construction of “efficacy” must focus on the capacity of an
27 accused product to produce a particular result and not on its intended or actual use.
28 Doc. 75 at 17; *see Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358,

1 1369-70 (Fed. Cir. 2009) (finding that claim term required only that accused product had
2 a capacity to perform a function regardless of whether the accused product is actually
3 used to perform that function) (citing *Intel Corp. v. United States Int'l Trade Comm'n*,
4 946 F.2d 821 (Fed. Cir. 1991)).

5 The Court will adopt Rowpar's construction. The words "desired effect" in
6 Lornamead's proposed interpretation are ambiguous and appear to focus on the intent of
7 the manufacturer or users of the accused product, which is improper during claim
8 construction. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1353 (Fed.
9 Cir. 2001) ("We are not prepared to assign a meaning to a patent claim that depends on
10 the state of mind of the accused infringer."). Rowpar's proposed construction refers to
11 treatment of the specific conditions described in the patent. Contrary to Lornamead's
12 assertion, Rowpar's proposed construction is not misleading because it clearly ties
13 "efficacy" to "said treatment," which entails treatments involving chlorine dioxide.

14 **O. Chlorine Dioxide in a Concentration in the Range of About 0.005% to**
15 **About 2.0%.**

16 The phrase "chlorine dioxide in a concentration in the range of about .005% to
17 about 2.0%" is contained in independent claims 1, 2, 7, 8, 10, and 12 of the '544 Patent.
18 Rowpar asserts that the phrase should be construed consistent with its plain and ordinary
19 meaning. Doc. 75 at 18. Lornamead argues that it should be construed as "chlorine
20 dioxide is present in a concentration from exactly .005% to 2.0%." Doc. 75 at 14.

21 Lornamead asserts that because the claim language does not provide any guidance
22 on the amount of variability permitted in the claimed range, the range should be
23 construed "as being exact and non-variable." Doc. 74 at 14. Because nothing in the
24 specification, prosecution history, or claim language identifies a concentration outside
25 this range, Lornamead argues that its "exact and non-variable" proposed construction is
26 suitable notwithstanding the use of the word "about" in the patent. *See Pall Corp. v.*
27 *Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995) ("[T]he word 'about' does
28 not have a universal meaning in patent claims, and the meaning depends on the

1 technological facts of the particular case.”); *Conopco, Inc. v. May Dept. Stores Co.*, 46
2 F.3d 1556, 1561 (Fed. Cir. 1994) (finding that the term “about” provides less flexibility
3 for the boundaries of a claimed range where the patent teaches that a specific value is
4 critical to the invention). Lornamead notes that the specification’s examples include a
5 maximum concentration of 0.2%, and indicate that the preferred concentration for most
6 patients of chlorine dioxide is between 0.005% and 0.5%. U.S. Patent No. 6,017,554
7 col.4 ll.35-36. In extreme cases, the specification indicates that the concentration could be
8 increased to 1.0-2.0%. Given this intrinsic evidence, Lornamead argues, the phrase
9 “chlorine dioxide in a concentration range of about 0.005% to about 2.0%” should be
10 narrowly construed. Doc. 74 at 16.

11 In *Conopco*, the patent claimed a range of relative weight ratios from “about 40:1
12 to 1:1.” 46 F.3d at 1561. The patent taught that adherence to the range was responsible
13 for the efficacy of the patented composition. *Id.* The claimant also emphasized the
14 importance of adhering to the range in the prosecution history. *Id.* The trial court
15 considered a ratio of 162.9:1 to be within the literal scope of the range, in part because
16 “about” allows a range to extend as far as the prior art would allow. *Id.* The Federal
17 Circuit rejected this conclusion and held that a person of ordinary skill in the art would
18 not have read “about” to encompass a fourfold increase in the specified numerical range.

19 The Court will not adopt Lornamead’s rigid construction. *Conopco* rejected a
20 claim construction in which “about” meant a fourfold increase in the claimed numerical
21 range, but it did not hold that the term “about” should be effectively deleted and the
22 claimed range strictly enforced. The Court concludes that “about” should be given its
23 plain and ordinary meaning. “About” does not ordinarily mean “exactly,” and the Court
24 cannot conclude that Lornamead’s narrow construction is warranted when the patent
25 itself uses “about” and does not require strict adherence to the range. If the Court is
26 required to apply the patent to specific facts, it may need to make a determination as to
27 the reasonable scope of “about,” as was required in *Conopco*. But the Court cannot now
28 conclude that “about” means “exactly.”

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P. At Least 0.1% Chlorine Dioxide.

The phrase “at least 0.1% chlorine dioxide” is found in independent claims 5, 9, 11, and 13 of the ’544 Patent. Rowpar asserts that the term should be given its plain and ordinary meaning. Doc. 75 at 19. Lornamead asserts that it should be construed to mean that “chlorine dioxide is present in a concentration from 0.1% to no more than 2.0%.” Doc. 75 at 17. The Court will adopt Rowpar’s construction.

The phrase “at least” has been construed by the Federal Circuit to mean a range with a defined lower limit. See *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1582 (Fed. Cir. 1995). Lornamead asserts that because the examples in the specification teach a maximum concentration of 2.0% chlorine dioxide, the Court should impose an upper limit of 2.0%. Doc. 74 at 18. But Lornamead’s arguments for strictly limiting the top of the range to 2.0% have been rejected above. Moreover, the ordinary meaning of “at least” sets a lower limit on the claimed range but says nothing about the upper limit, and Lornamead has not presented intrinsic evidence that the patentee intended the claims using “at least” to have an upper bound. See *3M Innovative Prop. Co. v Tredegar Corp.*, 725 F.3d 1315, 1329-32 (Fed. Cir. 2013) (rejecting a “narrower construction” of a claim’s plain language unless “required by the specification or prosecution history.”). The Court concludes that the phrase should be given its plain and ordinary meaning, which does not have a defined upper boundary.

Dated this 25th day of March, 2014.



David G. Campbell
United States District Judge