

United States District Court,
C.D. California.

ULTRADENT PRODUCTS, INC., a Utah Corporation,
Plaintiff and Counterclaim Defendant.

v.

Robert G. HAYMAN, William M. Dorfman, and Kenneth L. Rosenblood, individuals, Discus Dental, Inc., a California Corporation, and Spectrum Dental, Inc., a California Corporation,
Defendants and Counterclaim Plaintiffs.

No. CV-00-13402 MRP (CTx)

Jan. 11, 2002.

Adina L. Witzling, Adrian L. Barton, Dean J. Zipser, Morrison and Foerster LLP, Irvine, CA, Brent P. Lorimer, David R. Todd, Sterling A. Brennan, Thomas R. Vuksinick, William R. Richter, Workman Nydegger & Seeley, APC, Salt Lake City, UT, for Plaintiff and Counterclaim Defendant.

Brian K. Brookey, Charles R. Halloran, David A. Dillard, Christie Parker and Hale LLP, Pasadena, CA, Leigh O. Curran, Bingham McCutchen LLP, Los Angeles, CA, for Defendants and Counterclaim Plaintiffs.

Larry R. Laycock, Robyn L. Phillips, Workman Nydegger & Seeley, Salt Lake City, UT, for Counter Defendant.

MEMORANDUM OF DECISION RE: CLAIM CONSTRUCTION

MARIANA R. PFAELZER, District Judge.

Plaintiff Ultradent Products Inc. (hereinafter "Ultradent") alleges that defendants Robert G. Hayman, William M. Dorfman, Kenneth L. Rosenblood, Discus Dental Inc., and Spectrum Dental, Inc. (hereinafter collectively "Discus") have infringed and/or induced infringement of United States Patents Nos. 5,376,006 ("the '006 patent"), 5,725,843 ("the '843 patent"), 5,746,598 ("the '598 patent"), 5,759,037 ("the '037 patent"), and 5,759,038 ("the '038 patent"). Defendants deny infringement and allege that the patents in suit are invalid and unenforceable.

Pursuant to a Stipulated Claim Construction Schedule, each party submitted papers in support of its proposed construction of each patent claim at issue and in opposition to the constructions proffered by the opposing party. In these papers, the parties identified a total of twenty-four allegedly disputed limitations from all but one of the patents in suit. The parties did not dispute the construction of any limitations in the claims of the '037 patent.

On August 24, 2001, after considering the papers filed in support of and in opposition to the parties' respective proposals along with the other pleadings and papers on file, this Court issued an order deciding

thirteen of the twenty-four disputed limitations and expressly limiting the *Markman* hearing to the remaining eleven terms. The order stated the Court's construction, and indicated that a memorandum of decision would be forthcoming. The Court heard argument and received evidence regarding the remaining eleven terms on August 28, 2001 pursuant to *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed.Cir.1995).

INTRODUCTION

All of the patents in this case relate to dental bleaching technology, and all of the specifications are essentially the same. They each describe dental trays and dental bleaching compositions. They also describe methods for bleaching teeth whereby the bleaching compositions are loaded into dental trays and placed in contact with the teeth.

Although the specifications are similar, the patent claims vary. The '006, '843, and '598 patents each cover dental bleaching compositions, methods of dental bleaching, or both, whereas the '037 and '038 patents cover methods of making dental trays and dental kits for the manufacture of dental trays, respectively. All of the patents descend from the same parent application (Serial No. 497,934), which was filed on March 22, 1990.

LEGAL STANDARD

Interpretation of patent claims is a matter of law reserved for the court. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). "It is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification, and, if in evidence, the prosecution history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996). "In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such situations, it is improper to rely on extrinsic evidence." *Id.* at 1583.

ANALYSIS

I. LIMITATIONS CONSTRUED PRIOR TO THE *MARKMAN* HEARING

Prior to the *Markman* hearing, this Court determined that several limitations disputed by the parties required neither oral argument nor the presentation of additional evidence. Therefore, the Court issued an order stating its construction of these limitations and limiting the *Markman* hearing to the remaining disputed terms. Specifically, the Court addressed the following disputed limitations:

-> "OR AN EQUIVALENT THERETO"

-> "TO RETAIN AND HOLD"

-> "INCLUDING ... WATER"

-> "ADAPTED TO BE LOADED INTO A DENTAL TRAY"

-> "INCLUDING ANY CARBOXYPOLYMETHYLENE THAT HAS BEEN NEUTRALIZED"

-> "A PORTION OF THE CARBOXYPOLYMETHYLENE HAS BEEN NEUTRALIZED WITH A QUANTITY OF A BASE"

-> "A DESIRED PERIOD OF TIME"

-> "REMAINING ACTIVE"

-> "ANY REACTION PRODUCTS OF CARBOXYPOLYMETHYLENE"

-> "ALLOWING THE BLEACHING AGENT TO CONTACT THE TOOTH SURFACES WHILE THE DENTAL TRAY IS HELD IN PLACE BY THE DENTAL COMPOSITION"

-> "ADAPTED TO BE DELIVERED BY A SYRINGE"

-> "THIN"

-> "FLEXIBLE"

Since the Court only briefly addressed the above limitations in the pre- *Markman* order, these terms are more fully discussed in this memorandum.

i. "OR AN EQUIVALENT THERETO"

Ultradent argues that the phrase "or an equivalent thereto," as used in the relevant claims of the patents in suit (including claims 1 and 11 of the '006 patent), should be construed, using the doctrine of equivalents standard, to mean "an ingredient or combination of ingredients that is insubstantially different from carboxypolymethylene."

Discus argues that the phrase "or an equivalent thereto" simply refers to any equivalents to which the plaintiff may be entitled under the doctrine of equivalents. Moreover, Discus concludes that Ultradent is entitled to no equivalents, with respect to this particular claim element, under the doctrine of equivalents because the patentee amended the element during prosecution in order to overcome an enablement rejection by the examiner. "When a claim amendment creates prosecution history estoppel with regard to a claim element, there is no range of equivalents available for the amended claim element. Application of the doctrine of equivalents to the claim element is completely barred." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 569 (Fed.Cir.2000) (en banc) cert. granted 533 U.S. 915, 121 S.Ct. 2519, 150 L.Ed.2d 692 (2001).

Ultradent does not dispute Discus' contention that *Festo* completely bars application of the doctrine of equivalents with respect to claim elements amended for patentability reasons. Instead, Ultradent argues that expressly reciting the phrase "or an equivalent thereto" expands the literal scope of the claim, such that the use of insubstantially different compounds constitutes literal infringement instead of infringement under the doctrine of equivalents. Ultradent maintains that *Festo* only bars equivalents under the doctrine of equivalents. Thus, it asserts, equivalents arising from the literal language of the claim are not affected by the *Festo* decision.

Whether or not the principles announced in *Festo* apply to claim elements that include express references to

"equivalents" appears to be a legal question of first impression. FN1 In support of its argument that *Festo* does not apply to such claim elements, Ultradent cites *Festo*'s treatment of three Supreme Court cases involving patents that expressly claim "equivalents." *See id.* at 570-571 (discussing *Phoenix Caster Co. v. Spiegel*, 133 U.S. 360, 10 S.Ct. 409, 33 L.Ed. 663 (1890); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 26 L.Ed. 149 (1880); and *Hurlbut v. Schillinger*, 130 U.S. 456, 9 S.Ct. 584, 32 L.Ed. 1011 (1889)). The *Festo* court distinguished these cases, concluding that none of them address whether an amended claim element subject to prosecution history estoppel is entitled to a range of equivalents under the doctrine of equivalents. *See Festo*, 234 f.3d at 571.

FN1. This is not surprising. Little over a year has passed since the decision was issued on November 9, 2000.

Ultradent argues that the Federal Circuit distinguished these cases because equivalents fall within the literal scope of the claims when express references to "equivalents" appear therein. However, *Festo* itself clearly states that a claim element reciting structure, as opposed to one drafted in means-plus-function language, does **not** literally encompass equivalents of that structure. *See id.* at 589. "A claim recited in means-plus-function language literally encompasses the corresponding structure and its equivalents. *Laitram Corp. v. Rexnord Inc.*, 939 F.2d 1533, 1536, 19 U.S.P.Q.2d 1367, 1370 (Fed.Cir.1991). In contrast, a claim element that recites the corresponding structure does not literally encompass equivalents of that structure." *Id.*

None of the patents in the three Supreme Court cases cited by Ultradent and distinguished by *Festo* contain claims drafted in means-plus-function form. Instead, each of the relevant claim elements recites a specific structure. *See Phoenix Caster Co.*, 133 U.S. at 362 (claiming "a rocker-formed collar-bearing or its mechanical equivalent"); *Goodyear Dental Vulcanite Co.*, 102 U.S. at 223 (claiming "hard rubber or vulcanite, or its equivalent"); and *Hurlbut*, 130 U.S. at 463 (claiming "tar-paper or its equivalent"). Therefore, according to *Festo*, none of these claim elements literally encompass their equivalents. If the *Festo* decision is internally consistent, then Ultradent's argument that *Festo* distinguished the cited Supreme Court cases because the equivalents in those cases fell within the literal scope of the claims is without merit.

Like its general statement regarding the literal scope of patent claims, the court's reasoning in *Festo* necessarily leads to the conclusion that Ultradent's argument should be rejected. In justifying its decision to afford no range of equivalents to claim elements amended for patentability reasons, the *Festo* court relied heavily on the principle of certainty in patent law.

[T]he notice function of patent claims has become paramount, and the need for certainty as to the scope of patent protection has been emphasized. A problem with the flexible bar approach is that it is virtually impossible to predict before the decision on appeal where the line of surrender is drawn.... These considerations, we think, contribute to the difficulty under the flexible bar approach to predicting with any degree of certainty the scope of surrender that will be found when prosecution history estoppel applies.

....

A complete bar, unlike a flexible bar, thus lends certainty to the process of determining the scope of protection afforded by a patent. With a complete bar, both the public and the patentee know that once an element of a claim is narrowed by amendment for a reason related to patentability, that element's scope of coverage will not extend beyond its literal terms. There is no speculation or uncertainty as to the exact range

of equivalents that might be available.

Festo, 234 F.3d at 575, 577. In *Festo*, the Federal Circuit was concerned with public uncertainty regarding the scope of equivalents available to patentees under the so-called "flexible bar" approach to prosecution history estoppel. The Federal Circuit was not troubled by the possibility that the public might not know that equivalents are potentially protected by the patent claims. FN2

FN2. Indeed, any such concern would have been fully addressed by the inclusion of "or equivalents" in the literal language of the claims.

While the express inclusion of the phrase "or equivalents" in patent claim language may ensure that the public is apprised of the potential importance of equivalent claim elements, it does nothing to clarify the scope of equivalents available to the patentee after a claim has been amended for patentability reasons. To the extent it exists, public uncertainty regarding the scope of equivalents will continue regardless of whether or not a patent claim expressly recites the word "equivalents." Thus, there is no principled reason to distinguish *Festo* as applying only to claims that have no express references to equivalents. *See, generally, id.* at 605 (Michel, J., dissenting) ("The tension at the heart of these disputes-between meaningful patent protection and adequate public notice-persists regardless of whether 'equivalents' are recited in the claims or are claimed implicitly through the doctrine of equivalents.")

ii. "TO RETAIN AND HOLD"

Ultradent essentially argues that the phrase "to retain and hold," as it is used in the relevant claims of the patents in suit (including claims 1, 3 and 11 of the '006 patent), means "to contribute support." FN3 Discus asserts that the phrase "to retain and hold" means "to keep or support in place."

FN3. Ultradent never actually proposed a precise construction for this phrase. Instead, it simply argued its construction conceptually.

Ultradent claims that if Discus' interpretation is adopted, the patent claims will not read on any embodiment of the invention disclosed in the specification because the tray of the invention is at least initially retained, in part, by mechanical force. Such an interpretation, Ultradent argues, is therefore presumptively incorrect. Though Ultradent also cites to Judge Winder's similar construction in *Ultradent Products, Inc. v. Life-Like Cosmetics, Inc.*, 924 F.Supp. 1101 (D.Utah 1996), Ultradent does not argue that the decision in that case is binding on this Court-and it is not.

Discus primarily relies on dictionary definitions of "retain" and "hold" for its construction. Discus also references an excerpt from the prosecution history of the '006 patent, wherein the patentee references "hold[ing] a dental tray against the patient's tooth surfaces, especially in the absence of any mechanical assistance from the tray." File History of Patent 5,376,006, Amendment B and Response, p. 18. Finally, Discus argues that under Ultradent's construction, Ultradent's own tests show that prior art invalidates the claims because Ultradent's tests show that prior art compositions "contribute" to the retention of a dental tray.

The parties do not dispute that the phrase "to retain and hold" refers to some degree of "support" for the

dental tray, and that this support is provided by the matrix. The dispute concerns the amount of support required. Ultradent argues that the matrix need only contribute to support, while Discus argues that the matrix must constitute the sole support for the dental tray.

The phrase "to retain and hold," alone, neither mandates nor precludes exclusivity. If a chandelier hangs from a single bolt in the ceiling, the bolt can be said to "retain and hold" the chandelier. Likewise, if the chandelier is attached to the ceiling via four bolts, it is not improper to assert that each of the four bolts individually functions to "retain and hold" the chandelier. In the first example, the single bolt constitutes the sole support for the chandelier and in the second example, each of four bolts contributes support. Thus, the common, ordinary and plain meaning of "to retain and hold" is simply "to support." No additional limitations are inherent in the word itself.

Although the word "support," like the phrase "retain and hold," can be used both in exclusive and non-exclusive contexts,^{FN4} the meaning of the word itself never changes. It is the presence of modifying phrases or words such as "sole" or "joint" that specifically narrow its contextual application. In the case at bar, the phrase "without any significant mechanical pressure from the dental tray" in the claims modifies "to retain and hold." Since "to retain and hold" simply means "to support," the meaning of which does not change, the dispute over the extent to which the matrix must support the dental tray will be resolved upon construction of "without any significant mechanical pressure," not upon construction of "to retain and hold." *See infra* Section II, Part 4.

FN4. If a table is balanced atop a single post, the post is said to "support" the table. Likewise, one can individually refer to each leg of a second table with four legs as providing "support" for the table.

The other intrinsic evidence does not address the meaning of "to retain and hold" in the context of the '006 patent. The claims do not define the phrase, except inasmuch as they modify it as discussed above, and neither party argues that the patentee disclosed any special definition in the specification. Ultradent's argument that the definition of "to retain and hold" should be informed by the characteristics of the dental tray described in the specification is without merit since the dental tray is not retaining and holding anything. It is the matrix material that retains and holds. The dental tray is what is being retained and held by the matrix material.

Finally, Discus' prosecution history argument is based on another modifying phrase, namely "especially in the absence of any mechanical assistance from the tray," instead of on an alternative definition of "to retain and hold." Like the modifying phrase "without any significant mechanical pressure," it provides little assistance with this stage of claim construction. There is no need to resort to extrinsic evidence since the common, ordinary and plain meaning of "to retain and hold" is "to support."

iii. "INCLUDING ... WATER"

Ultradent asserts that the phrase "including ... water," as it is used in the relevant claims of the patents in suit (including claim 3 of the '006 patent), means " 'water is present.' " Discus argues that the phrase means " 'water is intentionally added.' "

In support of its more limited construction, Discus asserts that whenever the specification refers to water, the water is always "intentionally added" as an ingredient instead of as an impurity in another ingredient or

through absorption from the atmosphere during processing. Discus stresses that each of the exemplary bleaching compositions includes water as a separately-added element. However, the specification of the '006 patent explicitly notes that "[i]t will be appreciated that the quantity of water in the total dental composition may come from different sources. For instance, the dental bleaching agent and base ... may come as aqueous solutions." U.S. Patent No. 5,376,006, col. 6, lns. 34-37 (issued Dec. 27, 1994).

Discus also alleges that the disputed term should be construed as "intentionally-added water" because it is described in the specification as a critical component of the claimed compositions. In fact, this description only appears in a discussion of preferred embodiments. However, even assuming that this characterization of water as "critical" is accurate and generally applicable, there is no logical reason why critical components should necessarily be construed to be "intentionally-added." Moreover, there is no reason why allowing for the addition of water as an "impurity" in another ingredient or providing for its absorption from the atmosphere during processing could not constitute the intentional addition of water.

Finally, Discus' argument that the doctrine of claim differentiation requires a construction encompassing intention is also without merit. Discus argues that Claim 1 and Claim 3 of the '006 patent would be identical in scope if Ultradent's construction of "including ... water" were adopted by the Court. Although it is true that the primary difference between Claim 1 and Claim 3 is the presence of the "including ... water" limitation in Claim 3, the two claims would not be identical in scope if the Court adopted Ultradent's construction. Under Ultradent's construction, Claim 1 dental compositions may or may not contain water, but Claim 3 compositions must contain water. Thus, the doctrine of claim differentiation does not apply here.

The intrinsic evidence in this case makes clear that "including ... water" simply means "water is present." The claims do not place limitations on the source of the water, or the circumstances under which it is added. Moreover, the specification explicitly suggests that the water may come from various sources. The parties have not highlighted any prosecution history to the contrary. Therefore, the phrase "including ... water" simply means "water is present." Resorting to extrinsic evidence is unnecessary.

iv. "ADAPTED TO BE LOADED INTO A DENTAL TRAY"

The phrase "adapted to be loaded into a dental tray" is found in the preamble of Claim 11 of the '006 patent. Ultradent argues that this phrase does not constitute a claim limitation because the body of Claim 11 intrinsically sets forth the complete invention. Discus chooses to completely ignore this argument, never addressing the fact that the limitation is found in the preamble. Instead, Discus simply asserts that "to adapt" means "to make suitable to requirements" according to the *American College Dictionary*. Ultradent concurs with this definition, but maintains that it is of no consequence since the preamble does not constitute a limitation.

"Whether a preamble stating the purpose and context of the invention constitutes a limitation of the claimed [invention] is determined on the facts of each case in light of the overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history." *Applied Materials Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1573 (Fed.Cir.1996). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed.Cir.1999) (quoting *Kropa v. Robie*, 38 C.C.P.A. 858, 187 F.2d 150, 152 (C.C.P.A.1951)).

If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation.

Id.; see also *Rowe v. Dror*, 112 F.3d 473, 478 (Fed.Cir.1997) ("[W]here a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation.").

Claim 11 of the '006 patent describes a dental bleaching composition. The preamble recites: "A dental bleaching composition *adapted to be loaded into a dental tray* designed for placement over teeth such that the dental bleaching composition will contact tooth surfaces when the dental tray is placed over the teeth." U.S. Patent No. 5,276,006, col. 16, lns. 6-10 (issued Dec. 27, 1994) (emphasis added). This is clearly a statement of purpose or intended use. The bleaching composition is designed to be loaded into a dental tray. As noted by Ultradent, the body of the claim fully describes the composition of the matrix, albeit in terms of its functional properties. Thus, there is no need to refer to the preamble to complete the invention or define any claim terms. Moreover, neither the specification nor the file history address adaptation. The phrase "adapted to be loaded into a dental tray" in the preamble is not necessary to give life, meaning, and vitality to the claim. Therefore, the preamble does not constitute a limitation on the claims.

v. "INCLUDING ANY CARBOXPOLYMETHYLENE THAT HAS BEEN NEUTRALIZED"

Ultradent asserts that the phrase "INCLUDING ANY CARBOXPOLYMETHYLENE THAT HAS BEEN NEUTRALIZED," as used in the relevant claims of the patents in suit (including claims 1 and 14 of the '843 patent), means " 'including any carboxypolymethylene that is less acidic by reason of the addition of a base.' " Discus argues that the phrase means "including 'carboxypolymethylene that has reacted with a quantity of base to become less acidic.' "

In support of its construction, Ultradent argues that the specification discloses the addition of a base to neutralize the carboxypolymethylene and make the mixture less acidic. Ultradent also alleges that, in *Ultradent Products, Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065 (Fed.Cir.1997), the Federal Circuit held that acidic carboxypolymethylene in a composition can be neutralized by adding a base, and that after the addition of a base the composition contains carboxypolymethylene in a less acidic form. Ultradent does not contend that the Federal Circuit's "holding" is binding on this Court. Discus offers its construction without supporting argument.

The parties agree that neutralizing an acidic material renders it less acidic. Both parties also agree that the claim should be construed to require the addition of a quantity of a base in order to effect the neutralization. The primary difference between the Ultradent and Discus constructions is that the Discus construction also includes a "reaction" limitation.

Although one skilled in the art might conclude that "neutralized" means "rendered chemically neutral so as to have a pH of 7," the intrinsic evidence clearly indicates that the patentee simply used the word to mean "rendered less acidic." "It is a well-established axiom in patent law that a patentee is free to be his or her own lexicographer, ... and thus may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings." *Hormone Research Found., Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1563

(Fed.Cir.1990) (citations omitted). "For this reason, an analysis of the specification and prosecution history is important to proper claim construction." *Id.*

Claim 12 of the '843 patent recites a method for bleaching teeth wherein the carboxypolymethylene is neutralized to within a pH from about 5 to about 7. *See* U.S. Patent No. 5,725,843, col. 13, lns. 50-53 (issued March 10, 1998). Though the claim refers to neutralization, it does not specify that the mixture must have an exact pH of 7. Additionally, the patentee notes in the specification that dental compositions with a pH below 5 are able to etch enamel, and that it is therefore preferable to ensure that the pH of the dental composition is between 5 and 7. The implication is that the pH of the composition should be raised. The parties do not dispute that raising the pH of a composition renders it less acidic. Thus, both the claims alone, and the specification in conjunction with the claims, indicate that the patentee used the word "neutralized" to mean "rendered less acidic." As a result, the phrase "including any carboxypolymethylene that has been neutralized" means "including any carboxypolymethylene that has been rendered less acidic."

Both parties suggest that the neutralization must result from the addition of a base. However, because claim construction is exclusively a question of law, *see* *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), this court is not required to accept such shared aspects of the parties' interpretations. *See* *Exxon Chem. Patents v. Lubrizol Corp.*, 64 F.3d 1553, 1555 (Fed.Cir.1995) ("[T]he trial judge has an independent obligation to determine the meaning of [patent] claims, notwithstanding the views asserted by the adversary parties."). In this case, importing such a limitation into the claims at issue would be improper. The relevant claims of the '843 patent encompass "carboxypolymethylene that has been neutralized." They do not specify *how* the carboxypolymethylene is neutralized.

The specification discloses the addition of a base to reduce acidity. However, it also makes clear that the addition of a base is simply the easiest way to reduce acidity. *See* U.S. Patent No. 5,725,843, col. 6, lns. 37-41 (issued March 10, 1998) ("To avoid etching enamel, it is currently preferred to have the pH of the sustained release bleaching composition in the range from about 5 to about 7. This is most *easily* accomplished by adding a base to the composition to adjust the pH.") (emphasis added). The specification does not state that the addition of a base is the only way to render the composition less acidic.FN5 Neither did the Federal Circuit hold in *Life-Like* that the neutralization must be accomplished via the addition of a base. The Federal Circuit merely held that neutralization *can* be accomplished via the addition of a base. Ultradent concedes this.

FN5. The fact that the Court is unaware of any other way to render a composition less acidic is irrelevant. Indeed, if the addition of a base is the only way to render a composition less acidic then there is no need for an explicit limitation requiring neutralization via the addition of a base.

Even if the claims and specification of the patent were not determinative, the principle of claim differentiation would support the omission of any reference to the addition of a base. "Under the doctrine of claim differentiation, it is presumed that different words used in different claims result in a difference in meaning and scope for each of the claims." *Clearstream Wastewater Sys., Inc. v. Hydro-Action, Inc.*, 206 F.3d 1440, 1446 (Fed.Cir.2000). "This doctrine cannot be used to make a claim broader than what is contained in the written description, but it prevents the narrowing of broad claims by reading into them the limitations of narrower claims." *Id.* (citation omitted); *see also* *Envntl. Designs Ltd. v. Union Oil Co. Of California*, 713 F.2d 693, 699 (Fed.Cir.1985) (holding that it is improper for courts to read into an

independent claim a limitation explicitly set forth in another claim). While Claim 1 does not describe how the carboxypolymethylene is to be neutralized, Claim 11, which depends on Claim 1, specifies that the carboxypolymethylene is "neutralized with a quantity of base." U.S. Patent No. 5,725,843, col. 13, ln. 49. Under the doctrine of claim differentiation, the "quantity of base" limitation of Claim 11 should not be read into Claim 1.

Finally, Discus provides no argument to support the inclusion of a "reaction" element in the construction of this limitation, and none of its arguments for the inclusion of a "reaction" element in a similar limitation have merit. *See infra* Section I, Part vi.

vi. "A PORTION OF THE CARBOXPOLYMETHYLENE HAS BEEN NEUTRALIZED WITH A QUANTITY OF A BASE"

Ultradent argues that the phrase "a portion of the carboxypolymethylene has been neutralized with a quantity of a base," as used in the relevant claims of the patents in suit (including claim 11 of the '843 patent), means " 'the carboxypolymethylene has been rendered less acidic by reason of the addition of a base.' " Discus argues that it means " 'the carboxypolymethylene has reacted with a base to neutralize a portion of the active carboxyl groups and hence becomes less acidic.' " Once again, the parties agree that neutralizing an acidic material renders it less acidic, and that the claim should be construed to require the addition of a quantity of a base in order to effect the neutralization. The primary difference between the Ultradent and Discus constructions is that the Discus construction also includes a "reaction" limitation.

As discussed above, the intrinsic evidence clearly indicates that the patentee simply used the word "neutralized" to mean "rendered less acidic." *See supra* Section I, Part v. Moreover, in this context, the "addition of a base" element in each of the proposed constructions is proper since the claims explicitly require such a limitation. Therefore, the phrase "a portion of the carboxypolymethylene has been neutralized with a quantity of base" means "a portion of the carboxypolymethylene has been rendered less acidic by the addition of a base."

Discus argues that there should also be a "reaction" limitation because "neutralization **requires** reaction of the base and the carboxyl groups of the carboxypolymethylene" in this context. *See* Defendant's Memorandum of Points and Authorities RE Claim Construction Issues, p. 37, lns. 7-8 (emphasis in original). However, if a reaction necessarily occurs between the base and the carboxyl groups, as Discus argues, then there is no need for the Court to include a "reaction" limitation in its construction because such an addition will not further limit the claims.

Vii. "A DESIRED PERIOD OF TIME"

Ultradent asserts that the phrase "A DESIRED PERIOD OF TIME," as used in the relevant claims of the patents in suit (including claims 1 and 14 of the '843 patent), means " 'a period of time selected for the bleaching treatment.' " Discus argues that it means " 'any period of time.' "

There appears to be no actual dispute over this phrase. Neither party attempts to place restrictions on the period of time that is to be desired. Discus is concerned that Ultradent's "period of time selected" refers to a period selected by the manufacturer. However, no such specific limitation was proposed by Ultradent.

The specification of the '843 patent suggests several possible treatment periods ranging from the length of one's nighttime slumber to 18-20 hours a day. *See* U.S. Patent No. 5,725,843, col. 8, lns. 26-54. The

specification does not limit the "desired period[s] of time" to these ranges. Thus, the phrase "a desired period of time" simply means "any period of time." Resorting to extrinsic evidence is unnecessary.

viii. "REMAINING ACTIVE"

Ultradent argues that the phrase "remaining active," as used in the relevant claims of the patents in suit (including claims 1 and 14 of the '843 patent), means " 'remain[ing] active during at least a portion of the time the dental tray is positioned over the teeth.' " Discus asserts that the phrase means " 'remain[ing] capable of bleaching teeth." The phrase describes dental bleaching compositions.

Ultradent incorporates into its proposed construction the very phrase it purports to construe: "remain[s] active." As a result, Ultradent ultimately construes nothing at all with respect to this limitation. Moreover, Ultradent effectively reads the word "active" out of the claim by alleging that "[t]here is nothing in the claim language requiring any particular level of activity, that the activity lasts for any particular length of time or that the activity bleach teeth." *See* Memorandum in Support of Ultradent's Claim Construction, p. 33, Ins. 17-19. If this is true, then the word "active" does not constitute a limitation. Discus argues that it is a limitation, and maintains that the bleaching composition cannot logically be considered "active" if it is no longer capable of bleaching teeth.

The specification of the '843 patent is rife with references to the "activity" of dental bleaching compositions in terms of tooth bleaching capability. *See, e.g.*, U.S. Patent 5,725,843, col. 2, ln. 17; col. 8, Ins. 62-64; col. 9, ln. 63; col. 10, Ins. 17, 38 & 60; col. 11, Ins. 14 & 35. Thus, the word "active" clearly means "capable of bleaching teeth." It follows, then, that the phrase "remaining active" means "remaining capable of bleaching teeth." Resorting to extrinsic evidence is unnecessary.

ix. "ANY REACTION PRODUCTS OF CARBOXYPOLYMETHYLENE"

Ultradent asserts that the phrase "any reaction products of carboxypolymethylene," as used in the relevant claims of the patents in suit (including claims 1 and 21 of the '598 patent), means "any 'carboxypolymethylene that is less acidic by reason of the addition of a base.' " Discus argues that it means " 'any product that is the result of the reaction of carboxypolymethylene and another compound.' "

The parties do not dispute the meaning of the individual words "reaction" and "products." Instead, they disagree about the scope of their application. Ultradent argues that during prosecution of the '598 patent, the applicant explained to the examiner that "reaction products" refers only to carboxypolymethylene to which a base has been added. In fact, however, the applicant only stated that "[p]artially neutralized carboxypolymethylene as a 'reaction product' should ... be understood to be 'carboxypolymethylene' for purposes of interpreting the scope of the claims." *See* Preliminary Amendment for U.S. Patent No. 5,746,598, p. 8 (filed September 27, 1996). Thus, though the applicant implicitly identified partially-neutralized carboxypolymethylene as a "reaction product" of carboxypolymethylene, he did not assert that partially-neutralized carboxypolymethylene was the *only* such "reaction product." Therefore, it would be improper to confine "reaction products" to carboxypolymethylene that is less acidic by reason of the addition of a base, as Ultradent urges.

The phrase "any reaction products of carboxypolymethylene" does not appear in the specification of the '598 patent, and the parties do not point out any prosecution history that is relevant to its interpretation. However, the ordinary and plain scope of this phrase is clear. It means "any products of reactions between carboxypolymethylene and other compounds." There is no basis for confining "reaction products" to any

particular reactions other than to those involving carboxypolymethylene, as the explicit language of the claim requires. Nor is there any basis to confine the term to any particular products. The use of the word "any" and the plural form of "products" suggests that the phrase encompasses more than a single particular substance. Resorting to extrinsic evidence is unnecessary.

X. "ALLOWING THE BLEACHING AGENT TO CONTACT THE TOOTH SURFACES WHILE THE DENTAL TRAY IS HELD IN PLACE BY THE DENTAL COMPOSITION"

Ultradent argues that the phrase "allowing the bleaching agent to contact the tooth surfaces while the dental tray is held in place by the dental composition," as used in the relevant claims of the patents in suit (including claims 1, 13 and 21 of the '598 patent), " 'should be interpreted to require only that there is at least some active bleaching agent in contact with the teeth after at least about two hours during the bleaching process.' " Discus does not address this limitation in its briefs. However, in the Joint Claim Construction Chart filed by the parties, Discus proposes that the phrase should be construed to mean that "[t]here is sufficient bleaching composition having sufficient stickiness remaining in the tray after about two hours to retain and hold a bleaching tray over a person's teeth without any assistance from the bleaching tray."

Ultradent does not offer any argument in support of its construction, and the Court finds absolutely no basis for reading limitations regarding the activity of the bleaching agent or the duration of the contact with the teeth into this claim limitation. Likewise, the Court finds no basis for reading in any "stickiness" limitation, as proposed by Discus.

The construction offered by Discus calls into question the meaning of the phrase "held in place." Discus attempts to construe "hold in place," the present tense of the phrase, to mean "retain and hold ... without any assistance from the bleaching tray." However, in this case, "hold in place" simply means "support." Thus, for the sake of clarity and consistency, the Court construes the phrase "held in place" to mean "supported." This construction is the same as the construction of the phrase "retain and hold," and is based on the same reasoning. *See supra* Section I, Part ii. Since "held in place" means "supported," the phrase "allowing the bleaching agent to contact the tooth surfaces while the dental tray is held in place by the dental composition," simply means "allowing the bleaching agent to contact the tooth surfaces while the dental tray is supported by the dental composition."

xi. "ADAPTED TO BE DELIVERED BY A SYRINGE"

Ultradent asserts that the phrase "adapted to be delivered by a syringe," as used in the relevant claims of the patents in suit (including claim 10 of the '598 patent), means " 'suitable for delivery by a syringe.' " Discus argues that it means " 'something is done to the matrix to make it suitable for delivery by syringe.' "

The parties agree that "adapt" means "to make suitable to requirements." *See* Memorandum in Support of Ultradent's Claim Construction, p. 37, lns. 4-56; Defendants' Memorandum of Points and Authorities in Response to Ultradent's Memorandum RE Claim Construction Issues, p. 22, lns. 18-22. However, Ultradent's construction of the phrase "adapted to be delivered by a syringe" inexplicably omits the verb "to make." Alternatively, Discus' construction overemphasizes the act of adapting by requiring that "something is done to the matrix," instead of allowing for adaptation prior to matrix formation; for example, through variations in the starting ingredients.

The word "adapt" does not appear in the specification of the '598 patent, and the parties have not highlighted

any prosecution history that is relevant to its interpretation. Although the Court rejects the parties' constructions, the Court agrees with their definition of adapt. Therefore, "adapted to be delivered by a syringe" simply means "made suitable for delivery by a syringe." Resorting to extrinsic evidence is unnecessary.

xii. "THIN"

Ultradent argues that the word "thin," as used in the relevant claims of the patents in suit to describe a preformed polymeric sheet for forming a dental tray from a stone cast (including claims 1 and 13 of the '038 patent), means " 'less than or equal to about 0.060 inch thick.' " Discus maintains that it means " 'any thickness less than 0.15 inch thick.' "

The construction offered by Ultradent is based on the thickness of a preferred embodiment disclosed in the specification of the '038 patent. The specification states that the dental tray "is preferably constructed of soft transparent vinyl material having a preformed thickness of about 0.04 inch to about 0.06 inch." U.S. Patent No. 5,759,038, col. 7, ln. 38-41 (issued on June 2, 1998). From this alone, Ultradent concludes that "thin" means "less than or equal to about 0.060 inch thick." The construction urged by Discus is based on the maximum thickness of polymer sheets from which bleaching trays were made at the time the patentee first filed his application: about 0.15 inch. Discus also relies on the doctrine of claim differentiation.

Ordinarily, an element that is claimed using general, descriptive words is not limited to numerical ranges recited in the specification or other claims. *See Modine Mfg. Co. v. United States Int'l Trade Comm'n*, 75 F.3d 1545, 1551 (Fed.Cir.1996). Moreover, "[i]t is usually incorrect to read numerical precision into a claim from which it is absent." *Id.*

The claim elements that describe the preformed polymeric sheet as "thin" do not contain any numerical limitations. Although the specification discloses the use of a polymeric sheet with a thickness between 0.04 and 0.06 inch thick, this numerical range appears only in the context of a preferred embodiment. Even if it were disclosed as a description of the invention itself, this particular numerical range would not provide a reasonable basis for concluding that "thin" means "less than or equal to about 0.060 inch thick" because the recited range does not include the span from 0.00 to 0.04 inches. Further while it may be true that prior art trays were formed from polymeric sheets up to 0.15 inch thick, there is no compelling reason to use this particular thickness as the standard and characterize as "thin" all polymeric sheets with a smaller corresponding dimension.

The word "thin" is a relative term. However, the '038 patent does not specify to what, if anything, "thinness" is to be compared. The numerical ranges cited by the parties are based on benchmarks that are wholly arbitrary. In any case, it would be improper for this Court to read quantitative limits into such qualitative claim language. The ordinary and plain meaning of "thin" is manifest. Therefore, the word "thin" requires no construction.

xiii. "FLEXIBLE"

Ultradent asserts that the word "flexible," as used in the relevant claims of the patents in suit (including claims 1 and 13 of the '038 patent), means " 'similar in flexibility to the 0.060 vinyl tray materials described in the specification.' " Discus argues that the word means " 'more flexible than hard transparent tray materials used for making bleaching trays.' "

Ultradent offers no argument in support of its proposed construction. Discus supports its claim construction by stressing the fact that the specification refers to "hard transparent material" in connection with prior art dental tray formation. U.S. Patent No. 5,759,038, col. 1, ln. 51. Discus argues that "[t]o the extent 'flexible' can be equated with 'not hard,' ... 'flexible' should be construed to mean more flexible than hard transparent materials."

It is not proper to equate the word "flexible" with the word "not hard." "Not hard" means the opposite of "hard." However, the opposite of "hard" is "soft," not "flexible." "Flexible" is the opposite of "rigid." Although materials that are soft may also be flexible, there is no necessary correlation between the two properties. In fact, the flexibility of an object is more often a function of its geometry than it is a function of its tendency to yield to physical pressure. Steel is hard. However, a thin strip of steel can also be quite flexible.

The word "flexible," like the word "thin," is a relative term for which the '038 patent does not provide any numerical limitation or other specific basis for comparison. The benchmarks cited by the parties are wholly arbitrary. There is no reason to choose the vinyl tray materials described in the specification over the hard transparent materials referenced in the specification, or *vice versa*. Like the ordinary and plain meaning of "thin," the ordinary and plain meaning of "flexible" is manifest. Therefore, the word "flexible" requires no construction.

xiv. SUMMARY

For the above reasons, on August 24, 2001, this court held that:

- a. The phrase "OR AN EQUIVALENT THERETO," as used in the relevant claims of the patents in suit (including claims 1 and 11 of the '006 patent), simply refers to any equivalents to which the plaintiff may be entitled under the doctrine of equivalents; the phrase does *not* affect the literal scope of the claims.
- b. The phrase "TO RETAIN AND HOLD," as used in the relevant claims of the patents in suit (including claims 1, 3 and 11 of the '006 patent), means "**to support.**"
- c. The phrase "INCLUDING ... WATER," as used in the relevant claims of the patents in suit (including claim 3 of the '006 patent), means "**water is present.**"
- d. The phrase "ADAPTED TO BE LOADED INTO A DENTAL TRAY," as used in the preambles of the relevant claims of the patents in suit (including claim 11 of the '006 patent), does *not* constitute a limitation on those claims.
- e. The phrase "INCLUDING ANY CARBOXPOLYMETHYLENE THAT HAS BEEN NEUTRALIZED," as used in the relevant claims of the patents in suit (including claims 1 and 14 of the '843 patent), means "**including any carboxypolyethylene that has been rendered less acidic.**"
- f. The phrase "A PORTION OF THE CARBOXPOLYMETHYLENE HAS BEEN NEUTRALIZED WITH A QUANTITY OF A BASE," as used in the relevant claims of the patents in suit (including claim 11 of the '843 patent), means "**a portion of the carboxypolyethylene has been rendered less acidic by the addition of a base.**"

g. The phrase "A DESIRED PERIOD OF TIME," as used in the relevant claims of the patents in suit (including claims 1 and 14 of the '843 patent), means "**any period of time.**"

h. The phrase "REMAINING ACTIVE," as used in the relevant claims of the patents in suit (including claims 1 and 14 of the '843 patent), means "**remaining capable of bleaching teeth.**"

i. The phrase "ANY REACTION PRODUCTS OF CARBOXYPOLYMETHYLENE," as used in the relevant claims of the patents in suit (including claims 1 and 21 of the '598 patent), means "**any products of reactions between carboxypolymethylene and other compounds.**"

j. The phrase "ALLOWING THE BLEACHING AGENT TO CONTACT THE TOOTH SURFACES WHILE THE DENTAL TRAY IS HELD IN PLACE BY THE DENTAL COMPOSITION," as used in the relevant claims of the patents in suit (including claims 1, 13 and 21 of the '598 patent), means "**allowing the bleaching agent to contact the tooth surfaces while the dental tray is supported by the dental composition.**"

k. The phrase "ADAPTED TO BE DELIVERED BY A SYRINGE," as used in the relevant claims of the patents in suit (including claim 10 of the '598 patent), means "**made suitable for delivery by a syringe.**"

l. The word "THIN," as used in the relevant claims of the patents in suit (including claims 1 and 13 of the '038 patent), requires no construction.

m. The word "FLEXIBLE," as used in the relevant claims of the patents in suit (including claims 1 and 13 of the '038 patent), requires no construction.

II. LIMITATIONS CONSTRUED AFTER THE *MARKMAN* HEARING

At the *Markman* hearing, the Court heard oral argument and received evidence concerning the following eleven remaining limitations:

-> DENTAL TRAY ('006)

-> CARBOXYPOLYMETHYLENE

-> A QUANTITY OF ... SUCH THAT ('006)

-> WITHOUT ANY SIGNIFICANT MECHANICAL PRESSURE ('006)

-> DENTAL TRAY ('843)

-> COMPRISES A MIXTURE WHICH/THAT INCLUDES ... AND HAS/HAVING ('843)

-> WITHOUT SIGNIFICANT ORTHODONTIC PRESSURE ('843)

-> WITHOUT SIGNIFICANT PRESSURE ('598)

-> MATRIX MATERIAL COMPRISES ... WHEREIN ('598)

-> POLYETHYLENE GLYCOL ('598)

-> KIT ('038)

The parties argue that several of these limitations should be construed in the same way as one or more other terms in the list even though the limitations are found in different patents and amidst different claim language. The Court will address each limitation in turn.

1. DENTAL TRAY ('006)

Ultradent argues that the phrase "dental tray," as used in the relevant claims of the '006 patent (including claims 1, 3 and 11), means "dental tray ... that does not exert significant mechanical pressure." Discus asserts that it means "any [dental] tray, whether rigid or flexible, loose or tight fitting," regardless of how much mechanical pressure it exerts.

The term "dental tray" appears several times in Claim 1 of the '006 patent. Ultradent stresses that all such references to "dental tray" are to the same tray, and that one cannot determine the meaning of "dental tray" without considering all of the limitations that the claim imposes on the tray. Discus apparently agrees with these general principles, and the Court finds them unobjectionable. *See* *Phonometrics, Inc. v. Northern Telecom, Inc.*, 133 F.3d 1459, 1465 (Fed.Cir.1998) ("A word or phrase used consistently throughout a claim should be interpreted consistently."); *Pitney Bowes, Inc. v. Hewlett Packard, Co.*, 182 F.3d 1298, 1310 (Fed.Cir.1999) ("Certainly, 'the same word appearing in the same claim should be interpreted consistently.'") (quoting *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1345 (Fed.Cir.1998)). The dispute between the parties concerns whether the phrase "without any significant mechanical pressure from the dental tray" constitutes a limitation on the dental tray.

Claim 1 of the '006 patent covers a five-step method for bleaching teeth. FN6 Step (a) calls for "obtaining a dental tray configured to cover a patient's tooth surfaces to be bleached and configured to hold a quantity of dental bleaching composition." U.S. Patent No. 5,376,006, col. 12, lns. 61-63. Step (b) teaches "placing a quantity of dental bleaching composition within the dental tray; said bleaching composition comprising: a quantity of dental bleaching agent [having certain functional characteristics] ... and a matrix material into which the dental bleaching agent is dispersed, said matrix material [having certain functional characteristics of its own]." *Id.* at col. 12, ln. 64-col. 13, ln. 17.

FN6. Claim 3 of the '006 patent essentially contains the same five steps. Claim 11 recasts the second step as a composition claim.

According to the description of the matrix material in Step (b), the matrix material must be "sufficiently tacky to retain and hold the dental tray positioned over the patient's teeth for a period greater than about 2 hours without any significant mechanical pressure from the dental tray." *Id.* at col. 13, lns. 13-17. Ultradent argues that this limitation applies to the dental tray despite the fact that it appears in the functional description of the matrix material. Discus maintains that the limitation applies exclusively to the matrix material.

The description of the dental tray appears in Step (a) of Claim 1. It contains no mechanical pressure

limitation. According to Step (a), the dental tray need only cover tooth surfaces and have the ability to hold a quantity of dental bleaching composition. The "mechanical pressure" limitation that Ultradent focuses on appears in the functional description of the matrix material in Step (b), not in the description of the dental tray in Step (a).FN7 Step (b) does not specify that the dental tray cannot exert significant mechanical pressure, it simply states that the matrix material must be sufficiently tacky to retain and hold the dental tray for about 2 hours in the absence of such pressure from the dental tray. Thus satisfaction of this claim element is measured according to the tackiness of the matrix, not the amount of mechanical pressure exerted by the dental tray that contains it.

FN7. Since Claim 11 does not contain a description of a dental tray, there is no "mechanical pressure" limitation in it either.

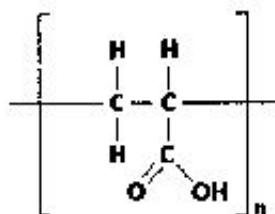
The specification of the '006 patent does not place restrictions on the type of dental tray that can be used with the patented dental bleaching methods. Moreover, although the specification discloses a dental tray with reservoirs that allegedly reduce orthodontic pressures on teeth, *see* Patent No. 5,376,006, col. 8, lns. 3-12, the specification also explicitly suggests that conventional trays can be used with the claimed bleaching compositions. *See* Patent No. 5,376,006, col. 8, lns. 18-25.

For these reasons, the Court construes "dental tray" to mean "any dental tray, whether rigid or flexible, loose or tight-fitting." Therefore, the dental tray described in Step (a) of Claim 1 can be any dental tray, whether rigid or flexible, loose or tight-fitting, so long as it is configured to cover a patient's tooth surfaces to be bleached and configured to hold a quantity of dental bleaching composition. Resorting to extrinsic evidence is unnecessary.

2. CARBOXYPOLYMETHYLENE

Ultradent's construction of the term "carboxypolymethylene," as used in all of the claims of the patents in suit, has evolved over time. In its opening *Markman* brief, Ultradent argued that "carboxypolymethylene" means "a slightly acidic vinyl polymer with active carboxyl groups." In its brief in reply to Discus' opening *Markman* memorandum, Ultradent modified its construction, arguing that "carboxypolymethylene" includes those "slightly acidic vinyl polymers with active carboxyl groups that are also carboxypolymethylenes." During the *Markman* hearing, Ultradent offered yet a third construction that eliminates the circular carboxypolymethylene limitation and instead requires the formation of carboxypolymethylene via the polymerization of acrylic acid. This third incarnation also includes a reference to cross-linking.

Discus consistently maintains that "carboxypolymethylene" means a chemical with the general structure:



where the bracketed formula represents a molecular repeat unit and the "n" notation represents the number of times the unit repeats.

Ultradent offers several arguments in support of its interpretation. First, Ultradent asserts that the Court of Appeals for the Federal Circuit construed the term "carboxypolymethylene," as it appears in the '006 patent, in *Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065 (Fed.Cir.1997), and that the Federal Circuit's interpretation is binding on this Court under the doctrine of *stare decisis*.FN8 Since the construction of patent claims is a question of law, *see Markman*, 517 U.S. at 372, and district courts are indisputably bound by Federal Circuit decisions, there is no question that district courts must defer to the Federal Circuit's construction of patent claims. *See Key Pharm. v. Hercon Lab. Corp.*, 161 F.3d 709, 716 (Fed.Cir.1998) ("We do not take our task lightly in this regard, as we recognize the national *stare decisis* effect that this court's decisions on claim construction have."). However the Court of Appeals for the Federal Circuit did not construe "carboxypolymethylene" in the *Life-Like* case.

FN8. Ultradent did not explicitly argue in its *Markman* briefs that the Federal Circuit decision in *Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.* 127 F.3d 1065 (Fed.Cir.1997), is binding on this Court. It is noteworthy that Ultradent presented this argument for the first time during oral argument at the *Markman* hearing itself.

In *Life-Like*, Ultradent alleged infringement of United States Patents Nos. 5,098,303 (hereafter "the '303 patent"), 5,234,342 (hereafter "the '342 patent"), and the '006 patent at issue in the present case. The defendant appealed a summary judgment ruling that certain claims of the '303 and '342 patents are invalid for anticipation, the jury's finding that Life-Like infringed the '303 and '342 patents, the jury's conclusion that certain claims of the '006 patent are not invalid as being anticipated by the prior art, and the district court's rejection of Life-Like's inequitable conduct claim.

According to Ultradent, the following excerpt demonstrates that the Federal Circuit construed the term "carboxypolymethylene":

In addressing the summary judgment motion, the district court defined the term "carboxypolymethylene" to mean "a slightly acidic vinyl polymer with active carboxyl groups." That definition was taken directly from the specification of both patents. The court then held that the carboxypolymethylene recited in the claims must exist in the specified amounts (i.e., "about 3.5% to about 12%") at the time the composition is applied to a patient's teeth in accordance with the claimed method for bleaching. Ultradent does not argue for a different interpretation on appeal, and we adopt the district court's interpretation.

Life-Like, 127 F.3d at 1067-68. There are several reasons why this does not constitute a construction of the term "carboxypolymethylene" as it appears in the '006 patent. First, the Federal Circuit expressly stated that the parties did not dispute the district court's interpretation of the '006 patent claims. *See id.* at 1071. Indeed, neither party challenged the district court's construction on appeal. Life-Like's summary judgment challenge was based on its contention "that the district court erroneously interpreted the disclosures of the prior art, and thereby erred in concluding, as a matter of law, that the claims of the '303 and '342 patents were not anticipated." *Id.* at 1067. Life-Like's challenges to the jury's finding of infringement of the '303 and '342 patents,FN9 and Life-Like's challenge to the jury's conclusion regarding whether the '006 patent was anticipated by the prior art, were both based on the argument that the respective verdicts were against the

weight of the evidence. *See id.* at 1069-1070. Finally, Life-Like's inequitable conduct claim was based on Ultradent's alleged failure to disclose certain dental bleaching formulations. The parties did not raise the issue of claim construction on appeal.

FN9. Life-like did not challenge the jury's finding that Life-Like infringed the '006 patent claims. *See id.* at 1069.

At the *Markman* hearing, Ultradent argued that the Court of Appeals for the Federal Circuit has a duty to construe patent claims, even if both parties fail to raise the issue on appeal, because claim construction affects entities beyond the parties to the case. As a result, Ultradent argued, the Federal Circuit had a duty to construe the patent claims in *Life-Like* even if the parties neglected to challenge the district court's claim construction. Ultradent urged the Court to infer, from the legal proposition that such a duty exists, that the Federal Circuit actually construed the term "carboxypolymethylene" in the *Life-Like* case.

Whether or not the Court of Appeals for the Federal Circuit has a duty to construe patent claims when neither party challenges the district court's claim construction on appeal is an open question. *Compare* *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1302 (Fed.Cir.1999) (holding that a party's concession with respect to claim construction "does not relieve ... [the Federal Circuit] of its responsibility to interpret the claims as a matter of law.") *with* *Seal-Flex, Inc. v. Athletic Track and Court Constr.*, 172 F.3d 836, 842 (Fed.Cir.1999) ("[W]here, as here, the parties agree to a particular construction of the claims which is adopted by the district court, and neither party disputes that construction on appeal, this court declines to raise an issue sua sponte which the parties have not presented on appeal.") (citations omitted). However, even if the Federal Circuit does have a duty to interpret patent claims when neither party challenges the district court's claim construction on appeal, it does not necessarily follow, from the fact that such a duty exists, that the duty is always discharged. Here, the written opinion indicates that the Federal Circuit did not actually construe the term "carboxypolymethylene."

Second, the above excerpt does not constitute a construction of the term "carboxypolymethylene" because the Federal Circuit was apparently referring to the district court's interpretation of *Exxon Chemical Patents, Inc. v. Lubrizol Corporation*, 64 F.3d 1553 (Fed.Cir.1995), not the district court's uncontested interpretation of the term "carboxypolymethylene," when it wrote that it chose to "adopt the district court's interpretation." *Life-Like*, 127 F.3d at 1068. The trial court held:

In *Exxon*, the Court of Appeals for the Federal Circuit interpreted a chemical composition claim directed to lubricating oil additives as reading on any product that at any time contains the specified ingredients in the claimed proportions. In the instant case, however, claim 1 of the '303 patent is a method claim employing a specific dental bleaching composition, rather than a composition claim. Therefore, an intermediate formulation occurring only during the manufacturing process and not used as a consumer product cannot infringe even if it contains from about 3.5% to about 12% carboxypolymethylene by weight percent. The specified proportion of carboxypolymethylene must be found in a composition and placed within a dental tray for bleaching a patient's teeth in order to constitute infringement of claim 1.

Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc., 924 F.Supp. 1101, 1108 n. 4 (D.Utah 1996) (citation omitted); *see also supra* at 1109. This holding was unfavorable to Ultradent because it narrowed the scope of the claims to cover only those bleaching compositions containing the specified proportions of carboxypolymethylene at the point of application.

On appeal, after describing the district court's construction of "carboxypolymethylene," the Federal Circuit noted: "The [district] court then held that the carboxypolymethylene recited in the claims must exist in the specified amounts (i.e., 'about 3.5% to about 12%') at the time the composition is applied to a patient's teeth in accordance with the claimed method of bleaching." *Life-Like*, 127 F.3d at 1067-68. The Federal Circuit continued: "Ultradent does not argue for a different interpretation on appeal, and we adopt the district court's interpretation." *Id.* at 1068. Thus, the Federal Circuit adopted the district court's interpretation of *Exxon*, not its construction of "carboxypolymethylene."

This conclusion is supported by the statement of adoption itself. There would have been no reason to note that Ultradent failed to argue for a different interpretation on appeal if the Court was referring to claim construction because the district court construed "carboxypolymethylene" in a way that was favorable to Ultradent—as evidenced by Ultradent's argument for the same construction in this case. It was the district court's interpretation of *Exxon* that might have prompted an objection by Ultradent.

Finally, the above excerpt does not constitute a construction of the term "carboxypolymethylene" in the '006 patent because the text is found in the Court's discussion of the summary judgment motion involving the '303 and the '342 patents. *See id.* at 1067. The '006 patent was not implicated. If it construed "carboxypolymethylene" at all, the Federal Circuit construed the term as it appears in the '303 and '342 patents, not as it appears in the '006 patent. Although the Federal Circuit's construction of a patent term is binding on lower courts, it is only binding in connection with the patent for which it was construed. The Federal Circuit's construction of a term is not final with respect to the same term as it may appear in all past, present, and future patents.

The fact that the specifications of all three patents in this case are similar, or even the same, FN10 is not determinative. The specification is only one of three sources of intrinsic evidence used for claim interpretation. *See Vitronics Corp.*, 90 F.3d at 1582 (holding that, in interpreting claims, courts should look to "the claims, the specification, and, if in evidence, the prosecution history"). Moreover, it cannot be argued that the Federal Circuit was construing "carboxypolymethylene" for all three patents. Construction of the term was not necessary for the disposition of any part of the case involving the '006 patent.

FN10. *See Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.*, 924 F.Supp. 1101, 1111 (D.Utah 1996).

Ultradent's second argument in support of its interpretation relies on the specifications of the patents in suit. Although they are not identical, each specification contains the statement: "Carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups." U.S. Patent No. 5,376,006, col. 5, lns. 1-2; U.S. Patent No. 5,725,843, col. 5, lns. 3-5; U.S. Patent No. 5,746,598, col. 5, lns. 5-7; U.S. Patent No. 5,759,037, col. 5, lns. 4-6; U.S. Patent No. 5,759,038, col. 5, lns. 4-6. Ultradent argues that this statement constitutes a definition. Discus maintains that it only amounts to a description.

It is clear that carboxypolymethylene is only one of many slightly acidic vinyl polymers with active carboxyl groups. Discus' expert demonstrated this explicitly (McCormick Decl. para. 13), and Ultradent admitted as much by offering, in its reply brief, a twice-revised interpretation of carboxypolymethylene covering only "slightly acidic vinyl polymers with active carboxyl groups *that are also carboxypolymethylenes*" (emphasis added). Thus, not all slightly acidic vinyl polymers with active carboxyl groups are also carboxypolymethylenes—one is not the definition of the other. FN11 Nevertheless, "a patentee

is free to be his or her own lexicographer, and thus may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings." *Hormone Research Found. v. Genentech, Inc.*, 904 F.2d 1558, (Fed.Cir.1990) (citation omitted). Thus, the patentee in this case could have defined carboxypolymethylene to encompass all slightly acidic vinyl polymers with active carboxyl groups.

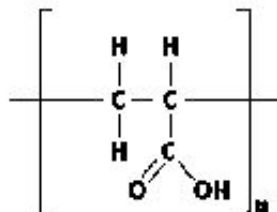
FN11. For this reason, the passage from the *Merck Index*, also stating that "carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups," must be understood to be a description and not a definition.

"The patentee's lexicography must, of course, appear 'with reasonable clarity, deliberateness, and precision' before it can affect the claim." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed.Cir.1998) (quoting *In re Paulsen*, 30 F.3d 1475, 1480 s. Fed. Cir.1994)). Ultradent's proposed lexicography does not display such virtues. One skilled in the art would undoubtedly find the statement "carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups" to be accurate, as a description, because carboxypolymethylene is one such polymer, as discussed above. However, there is nothing in the specification to indicate that the patentee is redefining the species "carboxypolymethylene" to include the entire recited genus of "slightly acidic vinyl polymers with active carboxyl groups." FN12

FN12. The words "genus" and "species" are used generically here. They are not intended to reference the body of patent law regarding genus or species claims.

Moreover, in addition to describing carboxypolymethylene as a slightly acidic vinyl polymer with active carboxyl groups, the specification of each patent also asserts that "carboxypolymethylene is a polycarboxylic acid." See U.S. Patent No. 5,376,006, col. 6, lns. 38-39; U.S. Patent No. 5,725,843, col. 6, lns. 32; U.S. Patent No. 5,746,598, col. 6, lns. 33; U.S. Patent No. 5,759,037, col. 6, lns. 33; U.S. Patent No. 5,759,038 col 6., ln. 33. Ultradent offers no explanation as to why the former statement should prevail over the latter as a definition. Each identifies "carboxypolymethylene" in qualitative terms. If the former constitutes a definition, as Ultradent suggests, then so too must the latter. However, the presence of two definitions in the specification would indicate that the patentee did not act as his own lexicographer by assigning a special meaning to the term "carboxypolymethylene" with reasonable clarity, deliberateness, and precision. Therefore, both passages must be understood to be descriptions, not definitions.

For these reasons, the Court finds that "carboxypolymethylene" means a chemical with the general structure:



where the bracketed formula represents a molecular repeat unit and the "n" notation represents the number of times the unit repeats.

A significant portion of the parties' briefing and oral argument focused on whether or not carboxypolymethylene that has been neutralized in whole or in part by the addition of a base, is still carboxypolymethylene. The parties, however, do not dispute the chemical composition or structure of carboxypolymethylene before any base has been added. The parties agree that the construction offered by Discus accurately describes "carboxypolymethylene" as a starting ingredient. The dispute is over the breadth of the term.

Ultradent argues that if the definition of "carboxypolymethylene" excludes neutralized mixtures of carboxypolymethylene, then none of the relevant claims of the patents in suit read on any of the embodiments disclosed in the specifications. However, the Court's construction of "carboxypolymethylene" does not necessarily exclude neutralized mixtures of the same. Defining "carboxypolymethylene" without reference to neutralization does not preclude a finding that neutralized carboxypolymethylene is also "carboxypolymethylene" under such a definition. In any case, the court must explicitly define "carboxypolymethylene" before any such comparisons can be made.

3. A QUANTITY OF ... SUCH THAT ('006)

Ultradent argues that the phrase "including a quantity of carboxypolymethylene ... such that said matrix material has [certain physical properties]," as it appears in the relevant claims of the '006 patent, "requires that the matrix include carboxypolymethylene, and that the matrix formed from the carboxypolymethylene and other ingredients in the matrix exhibit [the recited physical properties]." Discus argues that the phrase means that there must be "a sufficient quantity of carboxypolymethylene to impart the required [physical properties] ... to the matrix."

Ultradent asserts that the physical properties of the matrix material need not arise exclusively from the addition of carboxypolymethylene because the invention resides in the novel physical properties of the material, not in the particular quantity of carboxypolymethylene used to create it. Ultradent also stresses that there is no fixed relationship between the amount of carboxypolymethylene and the recited physical properties. Discus focuses on the ordinary meaning of "such that," and highlights the fact that both the specification and file history provide little, if any, guidance for its interpretation.

The fact that the heart of the invention may reside in the novel physical properties of the matrix material, as Ultradent suggests, does not foreclose the possibility that the patentee claimed a single source for such properties. Moreover, the absence of a fixed relationship between the amount of carboxypolymethylene and the recited physical properties does not mean that no relationship exists. Finally, even if the addition of another chemical alters the physical effect of the carboxypolymethylene, it may still be the carboxypolymethylene that imparts the recited physical properties to the matrix.

The ordinary and plain meaning of the phrase "such that," in the present context, is "sufficient to." As counsel for Discus argued at the *Markman* hearing, "If I needed a quantity of cherries such that I could make five cherry pies, I would need enough cherries to make five pies." Transcript of Proceedings, at 230-31 (August 29, 2001). The patentee elected to claim the physical properties of the matrix material in functional terms,^{FN13} and chose to specify the compound which would impart to the matrix the recited properties. Therefore, "a quantity of carboxypolymethylene ... such that said matrix material has [certain

physical properties]," means "a quantity of carboxypolymethylene ... sufficient to impart to the matrix [the recited physical properties]."

FN13. The Court will not adopt any particular numerical range.

According to Ultradent's proposed construction, even the presence of trace amounts of carboxypolymethylene in a dental composition would satisfy the claim as long as the composition happened to exhibit the recited physical properties and regardless of whether it was the carboxypolymethylene that imparted those properties. Thus, other matrix materials would effectively fall within the scope of the claims. Such a result is prohibited by the prosecution history.

During prosecution of the '006 patent, the examiner rejected claims covering a multitude of matrix materials "because the specification only enables those claims to where the matrix material is selected to be a carboxypolymethylene." Office Action dated September 13, 1993, p. 2. In the words of the examiner, "[a]pplicant has not disclosed any other matrix material to be used in their dental bleaching composition." *Id.* In response to the office action, Ultradent introduced the term "carboxypolymethylene" into the patent claims. In doing so, Ultradent surrendered the "other matrix materials" that previously fell within the scope of its claims. *See Southwall Techs. Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed.Cir.1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.").

4. WITHOUT ANY SIGNIFICANT MECHANICAL PRESSURE ('006)

Ultradent asserts that "without any significant mechanical pressure from the dental tray" effectively means "without any mechanical pressure from the dental tray that would cause discomfort to the patient due to the exertion of pressure on the teeth and gums." Discus maintains that the phrase essentially means "without any mechanical pressure from the dental tray that would be sufficient to retain and hold the dental tray in the absence of aid from the bleaching composition."

In support of its claim construction, Ultradent argues that the purpose of the claimed invention is to facilitate patient compliance with home teeth-bleaching techniques. According to Ultradent, the invention accomplishes this by employing a more comfortable dental tray and a unique sustained-release dental bleaching composition. The improved dental tray is allegedly more comfortable because orthodontic pressures on the patient's teeth are minimized by the presence of reservoirs that are built into the tray, and by the use of tray materials that are thinner and softer than those previously used in the art. Ultradent argues that the claimed dental bleaching composition is novel because it can retain and hold a comfortable dental tray such as the one described in the '006 specification, unlike the prior art compositions which were designed to be used with dental trays held in place by mechanical pressure exerted on the teeth and gums. Thus, Ultradent maintains, the matrix material only needs to be tacky enough to retain and hold a dental tray that does not exert mechanical pressure significant enough to cause patient discomfort; the matrix does not need to be tacky enough to retain and hold a dental tray in the absence of any aid from the bleaching composition.

Although the inventive aspect of the dental tray disclosed in the '006 patent specification may be its comfortable fit, the novelty of the claimed bleaching composition does not reside primarily in its ability to retain and hold such a tray. In fact, the specification of the '006 patent does not even mention this property

of the composition when it lists the "objects" of the disclosed invention. *See* U.S. Patent No. 5,376,006, col. 4, lns. 3-23. Instead, the patentee stresses the goals of providing "sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced," *id.* at lns. 8-10, and which provide "a more constant level of dental [bleaching] agent in contact with the teeth surfaces." *Id.* at lns. 13-15. In the Detailed Description of the Preferred Embodiment, reference to the retentive character of the bleaching composition is made, in passing, only after the sustained-release property of the composition has been discussed, and only in the broader context of preventing migration of bleaching composition from the dental tray. *See id.* at col.6, lns 1-4 ("The concentrated carboxypolymethylene composition also has a unique tackiness or stickiness which retains and seals the thin soft tray material against the teeth thereby preventing migration of the composition out of the tray. The tackiness of the composition also keeps the composition within the reservoirs.").

Even if the novelty of the claimed dental bleaching composition did reside in its ability to retain and hold a comfortable dental tray, the Court would still construe "without any significant mechanical pressure" in terms of mechanical assistance, instead of in terms of patient discomfort, because of certain representations made by the patent applicant to the examiner during prosecution. During prosecution of the '006 patent, the patent examiner cited United States Patents Nos. 3,499,890 and 3,657,413 to Kibbel, Jr. et al. and Rosenthal, respectively, as rendering the applicant's invention unpatentable. *See* Amendment B and Response, September 24, 1992, p. 17 (noting the examiner's argument). In response, the applicant argued that these references do not contain any teaching relating to stickiness or tackiness, and do not teach that such properties are functionally important. The applicant continued:

As noted by the Examiner, while these references do contain a simple statement that increasing the amount of carboxypolymethylene will increase the *viscosity* of the composition, increasing the viscosity alone is insufficient and will not impart the necessary stickiness or tackiness required to hold a dental tray against the patient's tooth surfaces, especially in the absence of any mechanical assistance from the tray.

Amendment B and Response, September 24, 1992, p. 18.

"[S]tatements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of a claim." *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1378 (Fed.Cir.1998); *see also* *Southwall Techs. Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed.Cir.1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution."). This principle is similar to the doctrine of prosecution history estoppel, which limits patent protection under the doctrine of equivalents when a claim has been distinguished over relevant prior art. *See* *Spectrum Int'l Inc.*, 164 F.3d at 1378 n.2.

In this case, the patent applicant distinguished his invention over the Kibbel and Rosenthal patents based, at least in part, on the fact that these references do not enable one skilled in the art to obtain a composition with the stickiness or tackiness required to hold a dental tray against a patient's tooth surfaces in the absence of any mechanical assistance from the tray. By so distinguishing his invention, the patentee disclaimed bleaching compositions that are not sticky or tacky enough to hold a dental tray against a patient's tooth surfaces without any mechanical assistance from the tray.

Ultradent claims that the absence of the word "significant" from the language preceding the phrase "mechanical assistance" reflects a simple error of omission. Ultradent cites authority for the proposition that a Court may properly ignore an error if it would have been sufficiently apparent to an interested reader that

the error was made. *See* Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp Inc., 249 F.3d 1341, 1348 (Fed.Cir.2001). The Court is not convinced that an error was made in this case. The phrase "in the absence of any mechanical assistance from the tray" is substantially different from the phrase "without significant mechanical pressure from the dental tray." In addition to omitting the word "significant," the former phrase uses the word "assistance" instead of "pressure" and "in the absence of" instead of "without." Thus, it is far from clear that it would be apparent to an interested reader that the patentee intended to insert the word "significant" before "mechanical assistance." This is not a case where there is only a one-word difference between the two phrases.

Ultradent also claims that Discus' proposed construction impermissibly reads "significant" out of the phrase "significant mechanical pressure from the dental tray." According to Discus' construction, a dental tray that does not exert significant mechanical pressure will fall off the teeth in the absence of bleaching composition. Ultradent apparently assumes that such a tray exerts absolutely no mechanical pressure on the teeth or gums. However, the exertion of mechanical pressure always accompanies physical contact between bodies. Thus, a dental tray that contacts the teeth or gums but falls off in the absence of bleaching composition still exerts some amount of mechanical pressure on the teeth or gums. The exertion of mechanical pressure need not result in retention of the dental tray. As a result, Discus' construction does not read "significant" out of the claim. The claimed compositions need only be sufficiently tacky to retain and hold a dental tray that exerts insignificant mechanical pressure. They need not be sufficiently tacky to retain and hold a dental tray that exerts no mechanical pressure at all.

As additional support for its claim construction, Ultradent argues that the patent examiner's acceptance of certain study results comparing Ultradent's Opalescence product to the compositions of the Kibbel and Rosenthal patents demonstrates that the patented compositions need not be capable of retaining and holding a dental tray on their own. The study, which was commissioned by Ultradent during prosecution, was conducted using dental trays that did not immediately fall off the teeth in the absence of the bleaching composition. According to Ultradent, the examiner's acceptance of the study indicates his understanding that a tray without significant mechanical pressure can remain in contact with teeth even in the absence of bleaching composition, and that a composition that retains and holds such a tray therefore falls within the scope of the claimed invention.

Ultradent confuses evidence offered to distinguish a composition over prior art with proof that a composition falls within the scope of a claim. If anything, the study constitutes the former, not the latter. According to the clinical report, the purpose of the study was "to measure the adhesiveness and bleaching effect of Opalescence gel as compared to two standard formulations s. [Kibbel] and Rosenthal." *Clinical Evaluation of the Adhesive Property and Bleaching Effectiveness of Opalescence Bleaching Gel*, October 1992. The study never validated Opalescence as a claimed composition. Moreover, Ultradent offers no evidence that the patent examiner demanded, or that the applicant provided, proof that Opalescence is covered by the claims.

The study was not used to demonstrate that the claimed compositions could retain and hold a dental tray without significant mechanical pressure; it was used to show that Opalescence exhibits improved stickiness and, as a result, superior bleaching results as compared to the compositions disclosed in Kibbel and Rosenthal. *See* Amendment and Response A, June 1, 1993, at p. 10 ('006 patent prosecution history). If the patent examiner accepted the study under the assumption that Opalescence satisfies the relevant claim language, then he did so somewhat arbitrarily. In order to demonstrate that Opalescence satisfies the claim language, as construed by Ultradent, the study would have had to address the issue of patient discomfort.

However, the study is silent on this subject.

Finally, Ultradent argues that the "significant mechanical pressure" limitation was inserted into the claims to distinguish over prior art dental trays, and that Discus' construction of the phrase is impermissibly at odds with all the embodiments of dental trays disclosed in the patent. These arguments are inapposite because the mechanical pressure limitation appears in the description of the dental composition, not the description of the dental tray. *See supra* Section II, Part 1 (construing "dental tray"). Moreover, the '006 patent does not claim a new and improved dental tray. Thus, fidelity to any disclosed dental tray embodiments is unnecessary. It is clear, from the documentary evidence and the evidence presented at the *Markman* hearing, that one of ordinary skill in the art is capable of fabricating a common dental tray. Even if this were not true, the generic description provided in the patent itself is more than sufficient to guide one of ordinary skill in the art in this regard. *See* U.S. Patent No. 5,376,006, col. 1, ln. 36.

Apart from the claims, the specification contains no mention of "mechanical pressure" or how its significance should be interpreted. Although the specification states that "patients may experience less tooth discomfort from tray pressures when using a tray with built in reservoirs," it does not equate the absence of significant mechanical pressure to the elimination of patient discomfort. U.S. Patent No. 5,376,006, col. 3, ln. 50 and col. 8, ln. 4; *see also supra* col. 4, ln. 23 and col. 12, ln. 46 (explaining that reservoirs in the dental tray appear to "enhance" patient comfort); col. 7, ln. 49. (asserting that "[s]oft [tray] material is more comfortable for the patient to wear"). Nor does the specification associate the absence of such pressure with mechanical assistance. However, as described above, the patent applicant distinguished his invention over the prior art during prosecution by essentially arguing that his bleaching composition could hold a dental tray against a patient's tooth surfaces in the absence of any mechanical assistance from the tray. *See* Amendment B and Response, September 24, 1992, p. 18. In so doing, the applicant indicated how "significant mechanical pressure" was used in the claims. If a composition that is tacky enough to retain and hold a dental tray without any significant mechanical pressure from the dental tray must retain and hold the dental tray in the absence of any mechanical assistance from the tray, then "significant mechanical pressure" must mean "mechanical assistance."

Even if the claims did not contain a "significant mechanical pressure" limitation, the applicant would be deemed to have disclaimed all compositions incapable of retaining a dental tray on their own by virtue of the arguments he made during prosecution. *See* *Spectrum Int'l. Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1378 (Fed.Cir.1998) (holding that statements made during prosecution may narrow the scope of the claims).

Therefore, the Court construes "significant mechanical pressure" in terms of "mechanical assistance." A composition that is tacky enough to retain and hold a dental tray "without any significant mechanical pressure" from the tray must be tacky enough to retain and hold the tray in the absence of any mechanical assistance from the tray. Although a dental tray that does not mechanically assist with its own retention may exert some mechanical pressure on the teeth or gums, it must immediately fall from the teeth in the absence of bleaching composition.

The foregoing construction does not conflict with this Court's construction of "dental tray." The dental tray described in Step (a) of Claim 1 can be any dental tray that is configured to cover a patient's tooth surfaces to be bleached and configured to hold a quantity of dental bleaching composition. *See supra* Section II, Part 1 (construing "dental tray"). This definition includes self-retaining dental trays. However, the description of the dental tray is completely separate from the description of the bleaching composition. The bleaching composition must be tacky enough to retain and hold a dental tray that immediately falls from the teeth in

the absence of bleaching composition regardless of which dental tray is used to practice the patented invention. Whether this composition is actually used in conjunction with a self-retaining dental tray is irrelevant.

5. DENTAL TRAY ('843)

The dental trays described in claims 1 and 14 of the '843 patent must be "configured to exert no significant pressure on the person's teeth and gums." Instead of separately arguing over the construction of this limitation, Ultradent simply states that the limitation should be interpreted in the same way as corresponding language in the '006 patent. Likewise, Discus is content asserting that the Court's interpretation should parallel its construction of similar language in the '006 and '598 patents. Neither party offers any new argument or introduces any new evidence in connection with this limitation.

The specifications of the '006, '598, and '843 patents are identical except with respect to the claims and only a handful of insubstantial differences. Thus, like '006 patent specification, the specification of the '843 patent contains no mention of "significant pressure." *See supra* Part II, Section 4. Moreover, the claims themselves offer no guidance with respect to interpretation of the "significant pressure" limitation on the dental tray. Since the specification and claims do not resolve the claim construction issues and neither party has entered the prosecution history of the '843 patent into evidence, the Court is free to rely on extrinsic evidence to construe the claims in this case. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996) (holding that reliance on extrinsic evidence for claim construction is permissible only if "the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification, and, **if in evidence**, the prosecution history" fail to resolve ambiguity in the claim term) (emphasis added).

Although neither party introduced or referenced any extrinsic evidence in connection with the claim term at issue, as noted above, the record does contain extrinsic evidence that is relevant to interpretation of the '843 patent claims. The prosecution history of the '006 patent, which was offered as intrinsic evidence for the purpose of interpreting terms in the '006 patent, constitutes extrinsic evidence in connection with the construction of limitations found in the '843 patent. The patents share the same applicant. FN14

FN14. Dan E. Fischer is the applicant for both the '006 and the '843 patents.

The prosecution history of the '006 patent reveals when dental tray pressures are "significant" according to the claims. During prosecution of the '006 patent, the applicant argued that his invention is tacky enough to hold a dental tray against a patient's teeth in the absence of any mechanical assistance from the tray. *See* Part II, Section 4 (construing the '006 patent term "without any significant mechanical pressure"). In the claims of the same patent, the composition of the invention is described as tacky enough to retain and hold a dental tray "without any significant mechanical pressure" from the tray. Thus, the patent applicant considered dental tray pressures significant if they mechanically assist with retention of the dental tray.

As a result, the Court construes "configured to exert no significant pressure on the person's teeth and gums," in the description of the dental tray described in claims 1 and 14 of the '843 patent, in terms of "mechanical assistance." A dental tray "configured to exert no significant pressure on the teeth or gums" does not mechanically assist with its own retention and therefore immediately falls from the teeth in the absence of bleaching composition.

Although now arguably relevant, since the dental tray described in the claims of the '843 patent must be configured to exert no significant mechanical pressure, Ultradent's previous arguments regarding the potential for inconsistency between the Court's construction of "significant mechanical pressure" and the dental tray embodiments disclosed in the patent are unpersuasive. Ultradent argues that a dental tray configured to exert no significant mechanical pressure need not immediately fall from the teeth in the absence of bleaching composition because the dental trays described in the specification stay in contact with the teeth even when they are empty. "A patent claim should be construed to encompass at least one disclosed embodiment in the written description portion of the patent specification." *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1355 (Fed.Cir.1998). "A claim construction that does not encompass a disclosed embodiment is thus 'rarely, if ever, correct and would require highly persuasive evidentiary support.'" *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed.Cir.1996)).

There is no inconsistency between the Court's construction of "significant mechanical pressure" and the dental tray embodiments disclosed in the patent. The '843 patent discloses a dental tray having reservoirs for holding the dental composition adjacent to the teeth. *See* U.S. Patent 5,725,843, col. 7. These reservoirs are created by applying a coating of rigid material to a stone cast of the teeth surfaces before vacuum forming the dental tray to the cast. *See id.* This process could easily be used to make reservoirs so large that the dental tray immediately falls from a patient's teeth in the absence of bleaching composition. Thus, the Court's construction encompasses at least one dental tray embodiment disclosed in the specification.

6. COMPRISES A MIXTURE WHICH/THAT INCLUDES ... AND HAS/HAVING ('843)

Ultradent asserts that the phrase "comprising a mixture which includes carboxypolymethylene ... and has [certain physical properties]" in claim 1 of the '843 patent, and the phrase "comprises a mixture that includes carboxypolymethylene ... and having [specific physical properties]" in claim 14 of the '843 patent, each "requires that the matrix include carboxypolymethylene, and that the matrix formed from the carboxypolymethylene and other ingredients in the matrix exhibit [the recited physical properties]." Discus argues that the limitations each call for a quantity of carboxypolymethylene sufficient to impart the required physical properties to the matrix.

Each party simply offers the same construction it asserted in connection with construction of the phrase "a quantity of ... such that" in the '006 patent. *See supra* Section II, Part 3. The parties also rely exclusively on the corresponding arguments they previously offered in support of these proposed constructions. *See id.*

The Court declines to construe the claim language at issue here. No construction is required. Unlike the phrase "such that" in the limitation "including a quantity of carboxypolymethylene ... such that said matrix material has [certain physical properties]," the phrase "and has" in the limitation "includes carboxypolymethylene ... and has [certain physical properties]" does not necessarily create a causal link between the carboxypolymethylene and the recited physical properties. Moreover, neither party has cited any prosecution history that would mandate an alternative construction. *Cf. supra* Section II, Part 3 (citing relevant prosecution history in connection with construction of the '006 patent).

7. WITHOUT SIGNIFICANT ORTHODONTIC PRESSURE ('843)

Claim 14 of the '843 patent describes a dental bleaching composition that retains a "dental tray in place without significant orthodontic pressure from the dental tray." *See* U.S. Patent 5,725,843, col. 14, lns. 44-45. Ultradent argues that the phrase "without significant orthodontic pressure from the dental tray" effectively means "without any mechanical pressure from the dental tray that would cause discomfort to the patient due

to the exertion of pressure on the teeth and gums." Discus maintains that the phrase essentially means "without any mechanical pressure from the dental tray that would be sufficient to retain and hold the dental tray in the absence of aid from the bleaching composition."

Just as it did in connection with construction of "significant pressure," each party simply offers the same interpretation it asserted in connection with construction of the corresponding phrase in the '006 patent, *see supra* Section II, Part 4 (construing "without any significant mechanical pressure from the dental tray"), and relies exclusively on the corresponding arguments it offered in support of those proposed constructions. *See id.*

Neither party ascribes any significance to the presence of the word "orthodontic" in the claim language. At the *Markman* hearing, Ultradent explained that the word "orthodontic" was used simply because the dental tray described in Claim 14 is trimmed shy of the gums and therefore can only exert mechanical pressure on the teeth. *See* Transcript of Proceedings, at 214 (August 29, 2001). At least one witness at the *Markman* hearing testified that "orthodontic pressure" is "pressure on a tooth that, over time, would eventually move that tooth." *See* Transcript of Proceedings, at 41 (August 28, 2001). However, neither party incorporated this extrinsic evidence into its proposed claim construction, and it is not necessary for the Court to resort to extrinsic evidence either.

The Court construes the phrase "significant orthodontic pressure" in the same way it construed the "significant pressure" limitation on the dental trays of the '843 patent, and for the same reasons. *See supra* Section II, Part 5. The term "significant orthodontic pressure," in the description of the bleaching composition in claim 14 of the '843 patent, refers to "mechanical assistance." A composition that retains a "dental tray in place without significant orthodontic pressure from the dental tray," retains the tray in the absence of any mechanical assistance from the tray. A dental tray that does not mechanically assist with its own retention immediately falls from the teeth in the absence of bleaching composition.

8. WITHOUT SIGNIFICANT PRESSURE ('598)

Claim 1 of the '598 patent describes a dental bleaching composition comprising a matrix material that has a stickiness and resistance to dilution by saliva such that "the dental composition will retain the dental tray in position over the teeth for at least about 2 hours without significant pressure exerted by the dental tray." *See* U.S. Patent 5,746,598, col 12, lns. 55-58. Once again, the parties offer the same constructions and make the same arguments they made in connection with the construction of similar limitations in the '006 and '843 patents.FN15 *See supra* Section II, Parts 4 & 5.

FN15. The only difference between Ultradent's construction of the ' 598 patent term and its constructions of the corresponding '006 and '843 terms relates to the anatomical scope of the pressure. For the '006 and ' 843 patent terms, Ultradent argues that the dental tray must not cause discomfort to the patient due to the exertion of pressure on the teeth only. For the '598 patent, Ultradent argues that there must not be discomfort due to pressure on the teeth and gums.

The Court construes the phrase "significant pressure" limitation in the ' 598 patent in the same way it construed the "significant pressure" limitation on the dental trays of the '843 patent, and for the same reasons. *See supra* Section II, Part 5. The term "significant pressure," in the description of the bleaching composition of the '598 patent, refers to "mechanical assistance." A composition that retains a "dental tray

in place without significant pressure from the dental tray," retains the tray in the absence of any mechanical assistance from the tray. A dental tray that does not mechanically assist with its own retention immediately falls from the teeth in the absence of bleaching composition.

9. MATRIX MATERIAL COMPRISES ... WHEREIN ('598)

The '598 patent claims describe a dental bleaching composition comprising "a matrix material into which the dental bleaching agent is dispersed, wherein the matrix material comprises carboxypolymethylene, which includes any reaction products of carboxypolymethylene, wherein the matrix material has [certain physical properties]." *See* U.S. Patent 5,746,598, col. 12, lns. 48-52.

Each party simply offers the same construction it asserted in connection with the interpretation of the phrase "a quantity of ... such that" in the '006 patent, *see supra* Section II, Part 3, and relies exclusively on the corresponding arguments it previously offered in support of those proposed constructions. *See id.*

The Court declines to construe the claim language at issue here for the same reasons it declined to construe the language "comprises a mixture which/that includes ... and has/having." *See supra* Section II, Part 6. No construction is required. *See id.*

10. POLYETHYLENE GLYCOL ('598)

The parties have resolved their differences regarding the construction of "polyethylene glycol" in the '598 patent. *See* Transcript of Proceedings, at 215 (August 29, 2001) ("[T]here was a dispute about polyethylene glycol but that has been resolved by the parties. We're going to adopt Discus' interp [r]etation of that term.") (quoting Mr. Lorimer).

11. KIT ('038)

The word "kit" appears in the preambles of certain '038 patent claims. Ultradent argues that the word means "a collection of supplies." Discus asserts that the word means "a packaged set of related articles."

Discus argues that its construction corresponds to the ordinary and customary meaning of "kit," as defined in the *American Heritage Dictionary*. Discus also alleges that its construction reflects the parties' commercial use of the term "kit." Ultradent responds that the claims, which distinctly point out what comprises a "kit," do not refer to any packaging or containers. Ultradent also points out that the patent specification never describes the recited components as a packaged set.

If a "claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then ... [it] should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed.Cir.1999) (quoting *Kropa v. Robie*, 38 C.C.P.A. 858, 187 F.2d 150, 152 (C.C.P.A.1951)). Conversely, if "the body of the claim fully and intrinsically sets forth the complete invention ... and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention," then the preamble does not constitute a claim limitation. *Id.*

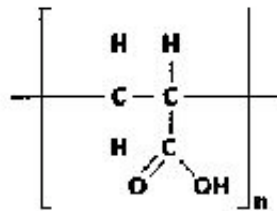
The preamble common to the independent claims of the '038 patent recites: "A dental kit for manufacturing a dental tray incorporating one or more reservoirs therein and for applying a dental composition to a person's teeth, the kit comprising" U.S. Patent 5,759,038, col. 12, lns. 46-48. This is clearly a statement

of purpose or intended use. The dental kit is designed to provide materials for the manufacture of a dental tray incorporating reservoirs and the application of a dental composition to the teeth. Moreover, the body of the claim fully describes the contents of the kit. Thus, there is no need to refer to the preamble to complete the invention or define any claim terms. Moreover, the word "kit" is absent from the specification, and neither party points to any evidence in the prosecution history regarding "kit." The preamble is simply not necessary to give life, meaning, and vitality to the claim. Therefore, the preamble does not constitute a limitation on the claims.

CONCLUSION

Having considered the papers filed in support of each party's claim construction, the evidence presented by the parties, the other pleadings and papers on file, and the oral argument at the *Markman* hearing, the Court holds:

1. The phrase "DENTAL TRAY," as used in the relevant claims of the '006 patent, *means "any dental tray, whether rigid or flexible loose or tight-fitting."*
2. The word "CARBOXPOLYMETHYLENE," as used in the relevant claims of the patents in suit, means a chemical with the general structure:



where the bracketed formula represents a molecular repeat unit and the "n" notation represents the number of times the unit repeats.

3. The phrase "A QUANTITY OF ... SUCH THAT," as used in the relevant claims of the '006 patent, means **"a quantity of carboxypolymethylene ... sufficient to impart to the matrix [the recited physical properties]."**
4. The phrase "WITHOUT ANY SIGNIFICANT MECHANICAL PRESSURE," as used in the relevant claims of the '006 patent, means **"without any mechanical assistance."**
5. The phrase "SIGNIFICANT PRESSURE" in the description of the "DENTAL TRAY" described by the relevant claims of the '843 patent, means **"mechanical assistance."**
6. The phrase "COMPRISES A MIXTURE WHICH/THAT INCLUDES ... AND HAS/HAVING," as used in the relevant claims of the '843 patent, requires no construction.

7. The phrase "WITHOUT SIGNIFICANT ORTHODONTIC PRESSURE," as used in the relevant claims of the '843 patent, means "**without mechanical assistance.**"

8. The phrase "WITHOUT SIGNIFICANT PRESSURE," as used in the relevant claims of the '598 patent, means "**without mechanical assistance.**"

9. The phrase "MATRIX MATERIAL COMPRISES ... WHEREIN," as used in the relevant claims of the '598 patent, requires no construction.

10. The phrase "POLYETHYLENE GLYCOL," as used in the relevant claims of the ' 598 patent, no longer requires construction.

11. The word "KIT," as used in the '038 patent claim preambles, does *not* constitute a limitation on those claims.

IT IS SO ORDERED.

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