

United States District Court,
D. Utah, Central Division.

ULTRADENT PRODUCTS, INC,
Plaintiff.

v.

LIFE-LIKE COSMETICS, INC. dba Life-Like Dental Products, and Rodney F. Ogrin, an Individual,
Defendants.

Civil No. 95-C-163 W

May 10, 1996.

Manufacturer of dental bleaching products brought patent infringement action against competitor and its sole owner. Competitor counterclaimed, alleging invalidity and noninfringement of patents and antitrust violation. On parties' pretrial motions, the District Court, Winder, Chief Judge, held that: (1) accused composition which met requirements of patent during manufacturing process but not at time composition was used in bleaching process would not literally infringe method patent; (2) term "carboxypolymethylene" in patent referred to slightly acidic vinyl polymer with active carboxyl groups; (3) claim's reference to dental trays with reservoirs did not contain limitation on type of reservoir used; (4) claim's requirement of sufficiently high viscosity to last for two-hour period did not require level of viscosity noted in specification; (5) dental tray did not have to be constructed in particular ways described as preferred embodiments in specification; (6) issues of fact precluded summary judgment on infringement claims; (7) patented methods were not anticipated by prior art; and (8) defendants failed to state antitrust counterclaim.

Ordered accordingly.

4,990,089, 5,098,303, 5,234,342, 5,376,006. Cited.

H. Ross Workman, Thomas R. Vuksinick, Todd E. Zenger, Workman, Nydegger & Seeley, Salt Lake City, UT, for Plaintiff.

H. Dickson Burton, Allen C. Turner, Trask, Britt & Rossa, Salt Lake City, UT, for Defendants.

**MEMORANDUM DECISION AND ORDER GRANTING IN PART AND DENYING IN PART
PLAINTIFF'S AND DEFENDANTS' MOTIONS FOR PARTIAL SUMMARY JUDGMENT,
MOTION TO STRIKE, MOTION TO DISMISS, AND MOTION FOR LEAVE TO AMEND**

WINDER, Chief Judge.

This matter is before the court on various motions filed by Plaintiff and Defendants which were argued on April 25, 1996. At the hearing, plaintiff Ultradent Products, Inc. was represented by H. Ross Workman,

Thomas R. Vuksinick, and Todd E. Zenger and defendants Life-Like Cosmetics, Inc. and Rodney F. Ogrin were represented by H. Dickson Burton and Allen C. Turner. The court has carefully considered all pleadings, memoranda, and other materials submitted by the parties. The court has further considered the law and facts relevant to the parties' motions. Now being fully advised, the court enters the following memorandum decision and order.

I. BACKGROUND

Plaintiff Ultradent Products, Inc. ("Ultradent") is a manufacturer of dental products including bleaching compositions for use in whitening teeth. Ultradent has marketed such a composition under the product name Opalescence(R)) since 1990. Defendant Life-Like Cosmetics, Inc. ("Life-Like") also manufactures and sells dental bleaching compositions. Defendant Rodney F. Ogrin ("Ogrin") is the president and sole owner of Life-Like. Because Life-Like and Ogrin are so closely associated with one another in this litigation, they will be collectively referred to in this opinion as "Life-Like" unless otherwise noted.

On February 21, 1995, Ultradent brought this action alleging Life-Like willfully infringed its rights held under United States Patents numbers 5,098,303 ("the '303 patent"), 5,234,342 ("the '342 patent"), and 5,376,006 ("the '006 patent"), and seeking remedies pursuant to 35 U.S.C. s.s. 271, 281, and 283-85. Ultradent is the assignee for each of these three related patents, initially issued to Dan E. Fischer. The '303 and '342 patents cover methods for bleaching teeth, and the '006 patent covers methods and compositions for dental bleaching. Ultradent also alleged that Life-Like infringed its registered trademark. On September 15, 1995, Ultradent amended its complaint to add Ogrin as a defendant. Ultradent later withdrew the trademark infringement claim as part of a settlement with Life-Like.

Life-Like subsequently filed a counterclaim against Ultradent seeking declaratory judgments of invalidity of Ultradent's patents and of noninfringement of Ultradent's patents by various dental bleaching formulations. Life-Like also asserted a counterclaim against Ultradent for attempted monopolization in violation of section 2 of the Sherman Act and section 4 of the Clayton Act. In addition to its counterclaims, Life-Like asserted in its answer a number of affirmative defenses against Ultradent's infringement claims, including invalidity of Ultradent's patents and inequitable conduct by Ultradent during its prosecution of the three patents in suit.

Both Ultradent and Life-Like have filed a number of pretrial motions. Those motions addressed in this memorandum decision and order are: (1) Ultradent's Motion for Claim Interpretation Under *Markman v. Westview Instruments, Inc.* in Connection with the Pending Motions for Summary Judgment; (2) Ultradent's Motion for Partial Summary Judgment of Infringement; (3) Ogrin's Motion for Partial Summary Judgment of Invalidity Under 35 U.S.C. s. 102; (4) Ultradent's Motion for Partial Summary Judgment on Defendants' Defense Under 35 U.S.C. s. 102; (5) Ultradent's Motion to Strike Life-Like's Affirmative Defense of Inequitable Conduct; (6) Ultradent's Motion to Dismiss Life-Like's Counterclaim of Attempted Monopolization; and (7) Life-Like's Motion for Leave to Amend its Answer and Counterclaims.

II. STANDARD OF REVIEW

[1] Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact, and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). In applying this standard, the court must construe all facts and reasonable inferences therefrom in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S.Ct. 1348,

1356, 89 L.Ed.2d 538 (1986); *Wright v. Southwestern Bell Tel. Co.*, 925 F.2d 1288, 1292 (10th Cir.1991).

Once the moving party has carried its burden, Rule 56(e) "requires the nonmoving party to go beyond the pleadings and by ... affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 324, 106 S.Ct. 2548, 2553, 91 L.Ed.2d 265 (1986) (quoting Fed.R.Civ.P. 56(e)); *see also Gonzales v. Millers Casualty Ins. Co.*, 923 F.2d 1417, 1419 (10th Cir.1991). FN1 The nonmoving party must "make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322, 106 S.Ct. at 2552.

FN1. The summary judgment motion may be "opposed by any of the kinds of evidentiary materials listed in Rule 56(c), except the mere pleadings themselves." *Celotex*, 477 U.S. at 324, 106 S.Ct. at 2553.

[2] In considering whether there exist genuine issues of material fact, the court does not weigh the evidence but instead inquires whether a reasonable jury, faced with the evidence presented, could return a verdict for the nonmoving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249, 106 S.Ct. 2505, 2510-11, 91 L.Ed.2d 202 (1986); *Clifton v. Craig*, 924 F.2d 182, 183 (10th Cir.), *cert. denied*, 502 U.S. 827, 112 S.Ct. 97, 116 L.Ed.2d 68 (1991). FN2 Finally, all material facts asserted by the moving party shall be deemed admitted unless specifically controverted by the opposing party. D.Utah R. 202(b)(4).

FN2. "The mere existence of a scintilla of evidence in support of the [nonmoving party's] position will be insufficient." *Liberty Lobby*, 477 U.S. at 252, 106 S.Ct. at 2512.

[3] In determining whether to grant a motion to dismiss for failure to state a claim upon which relief can be granted, the court must accept all well-pleaded facts as true. *Arnold v. McClain*, 926 F.2d 963, 965 (10th Cir.1991). In addition, all inferences that can be drawn from the allegations must be drawn in favor of the plaintiff. *Id.* at 965. "[I]f as a matter of law 'it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations,' a claim must be dismissed, without regard to whether it is based on an outlandish legal theory or on a close but ultimately unavailable one." *Neitzke v. Williams*, 490 U.S. 319, 327, 109 S.Ct. 1827, 1832, 104 L.Ed.2d 338 (1989) (citation omitted) (quoting *Hishon v. King & Spalding*, 467 U.S. 69, 73, 104 S.Ct. 2229, 2232-33, 81 L.Ed.2d 59 (1984)).

III. DISCUSSION

A. Claim Interpretation Under *Markman v. Westview Instruments*

[4] In order to resolve the issues of infringement and invalidity, both on summary judgment and at trial, this court must first interpret or construe the meaning of the claims of the patents in suit as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970 (Fed.Cir.1995) ("[T]he interpretation and construction of patent claims, which define the scope of the patentee's rights under the patent, is a matter of law exclusively for the court."), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). "[T]he question of anticipation turns on claim interpretation, a question of law." *Corning Glass Works v. Sumitomo Elec. USA, Inc.*, 868 F.2d 1251, 1256 (Fed.Cir.1989). "[C]laims must be interpreted and given the same meaning for purposes of both validity and infringement analyses." *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 882 (Fed.Cir.1988). Therefore, this court will interpret the meaning of the patent claims at issue. FN3

FN3. The court's interpretation of claims is limited to those claims Ultradent asserts Life-Like has infringed. Although Life-Like seeks a declaratory judgment of invalidity of all claims in Ultradent's three patents, the unasserted claims are not properly before the court for a determination of invalidity and therefore need not be interpreted. *See* discussion *infra* part III.C of this memorandum decision and order, addressing validity.

[5] Courts look to three sources to ascertain the meaning of patent claims: the claim language, the specification, and the prosecution history. *Markman*, 52 F.3d at 979; *SmithKline*, 859 F.2d at 882. Also relevant may be the patent's other claims as well as extrinsic evidence such as expert and inventor testimony and learned treatises, which may be helpful in explaining scientific concepts, definitions of technical terms, and terms of art. *Markman*, 52 F.3d at 979-81; *SmithKline*, 859 F.2d at 882.

I. The '303 Patent

Ultradent's '303 patent, "Method for Bleaching Teeth," issued on March 24, 1992. The background section of the patent describes the prior art in the practice of dental bleaching and typical existing methods of dentist-supervised home bleaching. The use of either hydrogen peroxide or carbamide peroxide as an active agent for dental bleaching was commonly known. The patent further describes as being within the prior art a method for bleaching teeth whereby a plastic tray is formed to fit a patient's teeth, filled with a bleaching composition, and fitted over the patient's teeth for a period of time ranging from one to two and a half hours or more, or even overnight. Methods in the prior art required the bleaching solution held in the tray to be replaced relatively frequently, sometimes hourly, depending on the composition used.

The '303 patent states that it provides an improvement over the prior art by teaching a method for bleaching teeth employing a more viscous and sticky composition than those in the prior art. Hence, the invention of the '303 patent is that it discloses a method whereby the bleaching gel will remain in a dental tray and in contact with the patient's teeth longer, require less frequent replenishment of the bleaching material, facilitate better patient compliance with the bleaching regimen, and therefore yield better results more quickly than methods in the prior art. The '303 patent also claims as an improvement over the prior art the use of an improved dental tray constructed with reservoirs to hold the bleaching composition against the patient's teeth.

Ultradent asserts as infringed by Life-Like claims 1, 2, 3, 8, 9 and 13 of the '303 patent. Those claims are as follows:

1. A method for bleaching a patient's teeth comprising:

(a) obtaining a dental tray configured to cover a patient's teeth surfaces to be bleached and configured to hold a quantity of dental bleaching composition;

(b) placing a quantity of dental bleaching composition within the dental tray, said dental bleaching composition comprising;

a quantity of dental bleaching agent capable of bleaching vital tooth surfaces in contact with said dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, said matrix material including carboxypolymethylene in the range from about 3.5% to about 12% by weight of the dental bleaching composition;

(c) positioning the dental tray over the patient's teeth surfaces such that a portion of the dental bleaching composition is in contact with the patient's teeth surfaces to be bleached;

(d) allowing the dental tray to remain positioned over the patient's teeth surfaces; and

(e) removing the dental tray from the patient's teeth.

2. A method for bleaching a patient's teeth as defined in claim 1, wherein the step of obtaining a dental tray further comprises obtaining a dental tray constructed with reservoirs for holding additional dental bleaching composition such that when the dental tray is positioned over the patient's teeth surfaces, the additional dental bleaching composition within the reservoirs is in contact with the patient's teeth surfaces to be bleached.

3. A method for bleaching a patient's teeth as defined in claim 1, further comprising the step of repeating steps (b) through (e).

8. A method for bleaching a patient's teeth as defined in claim 1, wherein the quantity of dental bleaching composition placed within the dental tray includes a carbamide peroxide as the dental bleaching agent in the range from about 3% to about 20% by weight of the dental bleaching composition.

9. A method for bleaching a patient's teeth as defined in claim 1, wherein the quantity of dental bleaching composition placed within the dental tray includes a carbamide peroxide as the dental bleaching agent in the range from about 4% to about 15% by weight of the dental bleaching composition.

13. A method for bleaching a patient's teeth as defined in claim 1, wherein the quantity of dental bleaching composition placed within the dental tray is sufficiently tacky to retain the dental tray positioned against the patient's teeth surfaces.

This court therefore must construe the meaning of these claims so that infringement and validity issues can be determined.

[6] [7] [8] The Court of Appeals for the Federal Circuit has set forth a number of guidelines for claim interpretation. Claim language should be read in accordance with the rules of the English language, using dictionary definitions to interpret the words unless it appears clear that the patentee used them in some different way. Although the patentee is permitted to be his own lexicographer, the definitions used cannot be inconsistent with the normal usage of a word. *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387-88 (Fed.Cir.1992). When terms are given uncommon meanings, the patentee must define the terms within the patent disclosure and must use words consistently in both the claims and in the specification. However, limitations from the specifications may not be read into the claims; narrow claim limitations cannot be read into broad claims either to avoid invalidity or escape infringement. *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1432-34 (Fed.Cir.), *cert. denied*, 488 U.S. 986, 109 S.Ct. 542, 102 L.Ed.2d 572 (1988); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed.Cir.), *cert. denied*, 488 U.S. 892, 109 S.Ct. 228, 102 L.Ed.2d 218 (1988).

[9] The patent specification must conclude with claims "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. s. 112. In order to be definite under 35 U.S.C. s. 112, the claims must reasonably apprise those skilled in the art both of the utilization and the scope of the invention. *Id.*

A significant interpretation issue arises from claim 1 of the '303 patent. The parties have expressed differing opinions as to the meaning of paragraph (b) of claim 1 and this court must interpret its meaning to resolve the questions of infringement and validity.

[10] Claim 1 is drawn to a method for dental bleaching that requires a quantity of dental bleaching composition be placed in a plastic tray formed to fit over a patient's teeth. Paragraph (b) of claim 1 states that the dental bleaching composition is comprised of a quantity of dental bleaching agent dispersed in a matrix material, "said matrix material including carboxypolymethylene in the range from about 3.5% to about 12% by weight of the dental bleaching composition."

Paragraph (b) describes a composition or product that is used in conjunction with a plastic tray in order to practice the claimed method for bleaching teeth. Claim 1 is not a process claim drawn to a specific method of manufacture of a bleaching composition; it is not a recipe of ingredients which when mixed together will yield a desired result. Instead, the language of paragraph (b) sets forth attributes of a chemical composition to be used in practicing the patented method of bleaching teeth. *See Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557-58 (Fed.Cir.1995) (interpreting claim as describing chemical product, not as recipe for making composition).

Therefore, literal infringement of claim 1 may be proved only by establishing that an accused infringer practiced or induced another to practice the invention using a dental bleaching composition comprising a matrix material into which active bleaching agent was dispersed, and that the matrix material included carboxypolymethylene in the range from about 3.5% to about 12% by weight. Literal infringement cannot be proved merely by a showing that about 3.5% to 12% carboxypolymethylene by weight was an initial ingredient in the formula mixed to produce the dental bleaching composition. If, during the manufacturing process, chemical reactions yield a composition including less than about 3.5% or more than about 12% carboxypolymethylene by weight, the resultant composition can not be found to literally infringe claim 1. *See Exxon*, 64 F.3d at 1558. Claim 1 requires that the end product used to bleach a patient's teeth contain the specified amount of carboxypolymethylene. FN4

FN4. 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. *Exxon*, 64 F.3d at 1558. 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 12% carboxypolymethylene by weight percent. The specified proportion of carboxypolymethylene must be found in a composition to be placed within a dental tray for bleaching a patient's teeth in order to constitute infringement of claim 1.

[11] Also at issue in claim 1 is the meaning of the term "carboxypolymethylene." Carboxypolymethylene, when combined with other chemicals to form the matrix material, provides the desired viscous and tacky

characteristics of the bleaching composition. In view of *Exxon*'s requirement that the end product contain the specified range of carboxypolymethylene, defendants assert that when an initial amount of carboxypolymethylene is combined with a neutralizing base as described in the specification, the resultant chemical reaction creates a composition that no longer includes carboxypolymethylene, but instead a neutralized salt of carboxypolymethylene. Thus, defendants maintain either that the proportion of carboxypolymethylene is reduced, or that there no longer exists any "carboxypolymethylene."

Ultradent, on the other hand, argues that the term "carboxypolymethylene" as used in claim 1 is understood by those skilled in the art to encompass both non-neutralized carboxypolymethylene as well as neutralized salts of carboxypolymethylene, and hence infringement may be shown by establishing the existence of either one in the requisite amount in an accused dental bleaching composition. Further, Ultradent claims that the mixing of chemicals to make the claimed composition only raises the pH of the carboxypolymethylene and does not change the chemical identity or the weight percentage of the carboxypolymethylene in the composition.

The language of claim 1 provides no additional clarification of the meaning of the disputed term, nor does the language of any of the other claims in the '303 patent. None of the prosecution history the court has seen has discussed the meaning of carboxypolymethylene. The specification of the '303 patent, however, is helpful in construing the term's meaning. The detailed description of the preferred embodiments states that "[o]ne currently preferred high viscosity matrix material is a concentrated carboxypolymethylene composition. Carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups." The specification further informs that "[b]ecause carboxypolymethylene is a polycarboxylic acid, it tends to lower the pH of the resulting bleaching composition." These are the only definitions found in the specification. There is additional mention elsewhere in the specification of the use of "carboxypolymethylene compositions," referring to compositions made with carboxypolymethylene as a starting ingredient, and in each of nine examples of formulas for making the claimed composition FN5 Carbopol 934P, a commercially available carboxypolymethylene resin, is listed as an ingredient to be mixed with other chemicals including the carbamide peroxide active bleaching agent and sodium hydroxide, a neutralizing base.

FN5. One of the nine examples given is a formula for a dental fluoride treatment composition, rather than a bleaching composition, also to be used with a dental tray according to the method of claim 1.

The dictionary defines carboxylic acid as "any organic acid containing one or more carboxyl groups," *The Random House Dictionary of the English Language*, 313 (2d ed. unabridged 1987), and defines a carboxyl group as "the univalent radical COOH, present in and characteristic of organic acids." *Id.* Ultradent provided the court with an excerpt from a chemical encyclopedia defining carboxypolymethylene as "[a] vinyl polymer with active carboxyl groups" and further describing it as a "white powder," "[h]ighly ionic and slightly acidic," and noted that it "[r]eacts with fatty amines to form thick and stable emulsions of oils in water." *The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals* 278 (Susan Budavari et al. eds., 1989). Similarly, one of Ultradent's experts, Dr. Garold Yost, submitted a declaration to the court stating "[c]arboxypolymethylene is a slightly acidic vinyl polymer." The defendants submitted a declaration by an expert, Dr. Harry Albers, stating that "the carboxypolymethylene ... would have reacted with (i.e., would have been neutralized by) the added [base] to form a complex or a new ingredient altogether. The resulting complex would not have the active carboxyl groups of carboxypolymethylene due to the reaction of the carboxypolymethylene with the [base]."

Ultradent nonetheless argues that claim 1 ought to be interpreted to read on all carboxypolymethylene compositions, whether they contain non-neutralized acids or neutralized salts of carboxypolymethylene. Claim 1 likely was drafted as it was because the applicant intended to define the claim by specifying an amount of carboxypolymethylene to be used as an initial ingredient used in formulating the composition. *Exxon*, however, requires that a chemical composition claim, as opposed to a process claim, must recite the components of the composition, not the ingredients to be combined to make the composition, if it wishes to claim as an invention a composition of specific proportions of particular elements. *Exxon*, 64 F.3d at 1558.

Courts "are not free to read the claims as they might have been drafted, even if as drafted they do not accomplish what the inventor may have intended." *Id.* at 1563 (Plager, J., concurring). "There is no room in patent claim interpretation for the equivalent of the *cy pres* doctrine; that would leave the claiming process too indefinite to serve the purposes which lie at the heart of the patent system." *Id.* (Plager, J., concurring).

Therefore, this court interprets "said matrix material including carboxypolymethylene in the range from about 3.5% to about 12% by weight of the dental bleaching composition" to mean that the composition used in dental bleaching in accordance with the claimed method contains from about 3.5% to about 12% by weight of carboxypolymethylene defined as a slightly acidic vinyl polymer with active carboxyl groups.

[12] Dependent claim 2 describes the step of obtaining a dental tray as further comprising obtaining a dental tray with reservoirs for holding additional bleaching composition. The reservoirs and the method for making them is described in the specification and the diagrams of the '303 patent. This claim does not further define the trays to be used, however, and although the specification describes preferred embodiments whereby dental trays are made from soft, thin plastic trimmed shy of the gumline, the specification is not part of the claim and will not be read to limit the claim. *See Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed.Cir.1988). Indeed, the specification discloses that the claimed method may even be employed with "conventional" dental trays made without reservoirs. Therefore, claim 2 reads on all dental trays made with reservoirs.

Dependent claims 8 and 9, like claim 1, specify a quantity by weight of a component element of the dental bleaching composition. Therefore, under *Exxon*, they require that the end product to be placed into dental trays contain the specified proportion of carbamide peroxide by weight.

2. The '342 Patent

Ultradent's '342 patent, "Sustained Release Method for Treating Teeth Surfaces," issued on August 10, 1993. The '342 patent is related to the '303 patent assigned to Ultradent. The specifications of the two patents are almost identical and the claims of the '342 patent are likewise very similar to those of the '303 patent.

Ultradent asserts as infringed by Life-Like claims 1, 2, and 3 of the '342 patent. Those claims are as follows:

1. A method for bleaching a patient's teeth comprising:

(a) obtaining a dental tray configured to cover a patient's teeth surfaces to be bleached and configured to hold a quantity of sustained release dental bleaching composition;

(b) placing a quantity of sustained release dental bleaching composition within the dental tray said sustained

release dental bleaching composition comprising;

a quantity of sustained release dental bleaching agent capable of bleaching vital tooth surfaces in contact with said sustained release dental bleaching agent; and

a matrix material into which the sustained release dental bleaching agent is dispersed, said matrix material including carboxypolymethylene in the range from about 3.5% to about 12% by weight of the dental bleaching composition;

(c) positioning the dental tray over the patient's teeth surfaces such that a portion of the sustained release dental bleaching agent is in contact with the patient's teeth surfaces to be bleached;

(d) allowing the dental tray to remain positioned over the patient's teeth surfaces, said sustained release dental bleaching agent remaining active during a substantial time while the dental tray is positioned over the patient's teeth surfaces; and

(e) removing the dental tray from the patient's teeth.

2. A method for bleaching a patient's teeth as defined in claim 1, wherein the step of obtaining a dental tray further comprises obtaining a dental tray constructed with reservoirs for holding dental bleaching agent such that when the dental tray is positioned over the patient's teeth surfaces, the dental bleaching agent within the reservoirs is in contact with the patient's teeth surfaces to be bleached.

3. A method for bleaching a patient's teeth as defined in claim 1, further comprising the step of repeating steps (b) through (e).

[13] The only differences between claim 1 of the '342 patent and claim 1 of the '303 patent is the inclusion of the phrase "sustained release" before each reference to "dental bleaching composition"; the substitution of the phrase "sustained release dental bleaching agent" for the phrase "dental bleaching composition" in paragraph (c); and the addition of the phrase "said sustained release dental bleaching agent remaining active during a substantial time while the dental tray is positioned over the patient's teeth surfaces" to paragraph (d).

The addition of the term "sustained release" does not alter the meaning of claim 1 such that the interpretation is any different than it is for claim 1 of the '303 patent, nor does the substitution in paragraph (c). The addition of the term "sustained release" simply emphasizes a feature inherent in the composition. Likewise, the additional language in paragraph (d) describes an inherent characteristic of a dental bleaching composition made with carboxypolymethylene. Therefore, as in the '303 patent, this court interprets "said matrix material including carboxypolymethylene in the range from about 3.5% to about 12% by weight of the sustained release dental bleaching composition" to mean that the composition used in dental bleaching in accordance with the claimed method contains from about 3.5% to about 12% by weight of carboxypolymethylene defined as a slightly acidic vinyl polymer with active carboxyl groups.

The language of claim 2 is likewise similar to that of claim 2 of the '303 patent. The only modification is the deletion of the word "additional" from the phrase "additional bleaching agent." This change has no effect on the interpretation of claim 2; it is identical to that of the '303 patent.

3. The '006 Patent

The '006 patent, Dental Bleaching Compositions and Methods for Bleaching Teeth Surfaces, is also related to the '303 and '342 patents and issued on December 27, 1994. It shares the same specification with those two earlier patents. The '006 patent, however, includes four independent method claims and four independent composition claims.

Ultradent asserts as infringed by Life-Like claims 1, 11, 18, and 19 of the '006 patent. Those claims are as follows:

1. A method for bleaching a patient's teeth comprising:

(a) 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;

(b) placing a quantity of dental bleaching composition within the dental tray, said dental bleaching composition comprising:

a quantity of dental bleaching agent that is physiologically compatible and capable of bleaching tooth surfaces in contact with said dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, said matrix material including a quantity of carboxypolymethylene or an equivalent thereto, such that said matrix material has a sufficiently high viscosity and low solubility in saliva that the matrix material provides for the dental bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 2 hours, thereby providing bleaching of the tooth surfaces, and such that said matrix material is 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;

(c) positioning the dental tray over the patient's teeth such that at least a portion of the dental bleaching composition is in contact with the patient's teeth surfaces to be bleached;

(d) allowing the dental tray to remain positioned over the patient's teeth for a period of time greater than about 2 hours;

(e) removing the dental tray from the patient's teeth.

11. 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, said dental bleaching composition comprising:

a quantity of dental bleaching agent that is physiologically compatible and capable of bleaching tooth surfaces in contact with said dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, said matrix material including a quantity of carboxypolymethylene or an equivalent thereto, such that (a) said matrix material has a sufficiently high viscosity and low solubility in saliva that the matrix material provides for the dental

bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 2 hours, thereby providing bleaching of the tooth surfaces, and such that (b) the matrix material is sufficiently sticky to retain and hold said dental tray in place over said teeth for a period of time greater than about 2 hours without any significant mechanical pressure from the dental tray;

18. A dental bleaching composition as defined in claim 11, wherein the dental bleaching agent comprises carbamide peroxide in the range from about 3% to about 20% by weight of the dental bleaching composition.

19. A dental bleaching composition as defined in claim 11, wherein the dental bleaching agent comprises carbamide peroxide in the range from about 4% to about 15% by weight of the dental bleaching composition.

The language of claim 1 is drawn to a method for dental bleaching similar to the methods set forth in the '303 and '342 patents. The parties disagree as to how paragraph (b) of claim 1 should be interpreted, particularly the two clauses that define the claimed matrix material by its function or performance characteristics.

[14] The first clause requires that "said matrix material has a sufficiently high viscosity and low solubility in saliva that the matrix material provides for the dental bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 2 hours, thereby providing bleaching of the tooth surfaces." The patent's specification provides guidance in interpreting this clause. The description of the prior art observes that a disadvantage of prior art dental bleaching products and techniques is "that the bleaching agent must be frequently replaced during the day" and that "saliva dilution and swallowing of the bleaching agent cause[s] the volume of agent on the tray to diminish rapidly over time, thereby decreasing the amount of active ingredient available for tooth bleaching." The discussion of the prior art further notes that clinical test results for at least one unidentified prior art composition "show that after one hour, less than one-half the original volume of bleaching agent was present" and therefore that prior art "bleaching agents should be replenished about every hour to be effective."

Additionally, among the stated objects of the invention are "to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced" and "to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth."

The prosecution history provides little clarification of the meaning of the clause, but it does reveal that the applicant added the two hour time specification in order to better define the claim and overcome a rejection under 35 U.S.C. s. 112 para. 2. This further indicates that the claim is drawn to a long-lasting composition that provides constant levels of bleaching.

The specification also states that compositions within the scope of the patent have such high viscosity that positive pressure is needed to dispense them from their containers, such as a syringe or a squeeze tube. In contrast, the specification observes that existing low viscosity bleaching agents can be dispensed drop-wise from a bottle.

While somewhat illustrative of the initial viscosity of formulations which may fall within the scope of the

patent, this specification cannot be read into the claims. The viscosity of the composition as it is dispensed into a dental tray is of only limited importance to the objects of the invention. The claimed inventions are improved methods and compositions that remain viscous for long periods of time and dilute more slowly in saliva. Thus, a very viscous composition that is dispensed with a syringe but which quickly loses its viscosity and dilutes rapidly in saliva might not be within the scope of the invention, while an initially less viscous material that is resistant to dilution or perhaps even reacts with saliva to become more viscous over time might be within the scope of claim 1. In fact, Proxigel(R), a commercial embodiment of U.S. Patent No. 3,657,413 to Rosenthal ("the Rosenthal patent" or "Rosenthal"), a prior art composition containing carboxypolymethylene, is dispensed from a squeeze tube, not drop-wise from a bottle. The viscosity of the claimed composition in and of itself is irrelevant; it is only important to the extent it facilitates long-lasting sustained release bleaching of a patient's teeth. This is evident from claim 1's requirement that the matrix material have a "*sufficiently* high viscosity ... that [it] provides for the dental bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 2 hours." (emphasis added). Thus, this court declines to limit claim 1 based on how a composition may be dispensed into the dental tray. Instead, the language of claim 1 must be interpreted in light of the specification language that states that "[t]he present invention ... provides sustained release dental compositions for treating tooth surfaces which permit a more constant level of the dental agent to be in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth."

In light of the claim language, the specification, and the prosecution history, this court interprets the first clause of paragraph (b) of claim 1 to mean that at the end of 2 hours there must be a significant amount of dental bleaching agent remaining in the dental tray and that as a result of the remaining bleaching agent's proximity to a patient's teeth, clinically significant bleaching is taking place. This means that a significant amount of the matrix material must remain in the tray at the end of two hours and that the bleaching agent dispersed in the matrix material must remain active so as to provide more than an insubstantial level of bleaching.

[15] The second clause of paragraph (b) requires that "said matrix material is 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." The specification indicates that a sticky composition is desirable because it keeps the active bleaching agent in close contact with the tooth surfaces, it helps to keep the tray from slipping off the teeth and diluting the composition, and it permits the use of tray designs that exert less pressure on the teeth and are therefore more comfortable to wear, specifically tray designs with reservoirs. The prosecution history sheds little light on the meaning of the language of this clause.

Ultradent urges the court to interpret this language as requiring that the dental tray be constructed of soft material, trimmed shy of the gumline, or have reservoirs. These limitations are described as preferred embodiments in the specification. However, the plain language of claim 1 simply discusses the use of a dental tray, without requiring any particular features other than it must fit the teeth and hold dental bleaching composition. By way of contrast, claim 5 specifically requires the dental tray be constructed with reservoirs. It is conceivable that dental trays may be made such that they do not exert significant mechanical pressure on the teeth, even though they are not made of soft material, trimmed shy of the gumline, or made with reservoirs. While the tray design features Ultradent urges the court to read as limitations on claim 1 may reduce mechanical pressure on a patient's teeth, those features are not the only means for doing so and are not essential to practicing claim 1, and thus will not be read into the claim.

Therefore, this court interprets the language of the second clause of paragraph (b) of claim 1 to mean that

the matrix material must be sufficiently tacky or sticky as to contribute to the retention of a dental tray over a patient's teeth at the end of two hours, and that whatever dental tray is used not exert "orthodontic" forces on a patient's teeth such that it would cause discomfort. The dental tray may exert some small amount of mechanical pressure on the teeth; in fact, Ultradent's own dental trays typically do not fall off patients' teeth even in the absence of any bleaching material. The tray may not, however, be of such a snug fit that the addition of the bleaching composition does little to improve the adhesion to the teeth.

Claim 11, an independent composition claim, is virtually identical to paragraph (b) of claim 1 and is therefore interpreted the same way as is claim 1.

Claims 18 and 19 are composition claims dependent on claim 11. They define the dental bleaching composition of claim 11 as further comprising a quantity of carbamide peroxide as the dental bleaching agent in ranges from about 3% to about 20% by weight, and from about 4% to about 15% by weight, respectively. As discussed above in the context of the '303 patent, under *Exxon* since these claims specify a proportional quantity of a component element of the dental bleaching composition, they require that the end product to be placed into dental trays contain the specified proportion of carbamide peroxide by weight, not the initial ingredients.

B. Motion for Partial Summary Judgment of Infringement

[16] Ultradent has moved for partial summary judgment finding defendants have infringed each of the asserted claims. This court denies Ultradent's motion as to all asserted claims. Because this court finds that there exist numerous disputed issues of material fact as to the asserted claims of infringement, a grant of summary judgment would be improper. Among the disputed issues are whether any of Life-Like's compositions contained about 3.5% or more carboxypolymethylene by weight; whether Life-Like actively induced infringement of the method claims of the '303, '342, and '006 patents; and whether any of Life-Like's compositions exhibit the requisite viscosity, tackiness, and bleaching characteristics claimed in the '006 patent.

C. Ogrin's Motion for Partial Summary Judgment of Invalidity Under 35 U.S.C. s. 102 and Ultradent's Motion for Partial Summary Judgment on Defendants' Defense Under 35 U.S.C. s. 102

Defendant Ogrin filed a motion for partial summary judgment finding claims 1-4 and 6-15 of the '303 patent, all claims of the '342 patent, and claims 1, 4-8, 11-13, and 17-19 of the '006 patent invalid as anticipated under 35 U.S.C. s. 102. Ultradent subsequently filed a motion for partial summary judgment finding that as a matter of law defendants have failed to establish the anticipation under 35 U.S.C. s. 102 of the three patents in suit. This court will consider the motions as to each of the three patents in suit.

[17] [18] Although defendants filed a counterclaim seeking a declaratory judgment of invalidity of all claims in Ultradent's patents, the court will consider only those claims asserted by Ultradent as infringed. In order to exercise jurisdiction in a declaratory judgment action, this court must find there is an actual controversy at all stages of review. *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058 (Fed.Cir.1995), *cert. denied*, 516 U.S. 1093, 116 S.Ct. 815, 133 L.Ed.2d 760 (1996). The Court of Appeals for the Federal Circuit has established a two-part test for determining justiciability in suits for declaratory judgments of patent rights. "There must be both (1) an explicit threat or other action by the patentee, which creates a *reasonable* apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) *present* activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed.Cir.1993); *see also*

Agridyne Technologies, Inc. v. W.R. Grace & Co.-Conn., 863 F.Supp. 1522, 1524-25 (D.Utah 1994).

[19] In this case, Ultradent has only asserted certain claims as infringed by Life-Like, and in Ultradent's Amended Notice of Asserted Claims counsel for Ultradent has promised not to assert that defendants infringe any other claims by making, using, or selling dental bleaching compositions identified in batch reports provided for this litigation. Thus, Life-Like has no reasonable apprehension it will be sued for infringing Ultradent's unasserted claims. There is no evidence that Life-Like's present activity would constitute infringement of the remaining claims. Only the asserted claims are properly before the court for a consideration of their validity.

Under 35 U.S.C. s. 102,

A person shall be entitled to a patent unless-

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this ... country, before the invention thereof by the applicant for patent, or

....

(e) the invention was described in a patent granted on application for another filed in the United States before the invention thereof by the applicant for patent....

35 U.S.C. s. 102. Life-Like asserts that the Ultradent patents are anticipated by one of two patents: U.S. Patent No. 3,657,413 to Rosenthal ("the Rosenthal patent" or "Rosenthal") or U.S. Patent No. 4,990,089 to Munro ("the Munro patent" or "Munro"), or by an article entitled "Nightguard Vital Bleaching" authored by Drs. Haywood and Heymann and published in Quintessence International, vol. 20, pp. 173-76.

[20] Patents are presumed valid under 35 U.S.C. s. 282. In order to find anticipation, a court must find that "each and every limitation of the claimed invention be disclosed in a single prior art reference." In re Paulsen, 30 F.3d 1475, 1478-79 (Fed.Cir.1994).

1. The '303 Patent

[21] As interpreted above under *Markman*, claim 1 of the '303 patent requires the dental bleaching compound employed in the claimed method to contain from about 3.5% to about 12% by weight of carboxypolymethylene, defined as a slightly acidic vinyl polymer with active carboxyl groups. Rosenthal, Munro (incorporating Rosenthal by reference), and the Haywood and Heymann article all disclose the use of Rosenthal compositions which include a gel including a pharmaceutically acceptable neutral salt of a carboxypolymethylene polymer. Therefore, because none of the prior art references disclose the use of a composition containing slightly acidic vinyl polymer with active carboxyl groups, none anticipate claim 1 of the '303 patent. *See* E.I. du Pont de Nemours & Co. v. Polaroid Graphics Imaging, Inc., 706 F.Supp. 1135, 1142 (D.Del.) ("any degree of physical difference, however slight, invalidates claims of anticipation"), *aff'd*, 887 F.2d 1095 (Fed.Cir.1989). Consequently, none of the other asserted dependent claims are anticipated. Ogrin's motion is denied as to the '303 patent and Ultradent's is granted.

2. The '342 Patent

Because the claims of the '342 patent are so similar to those of the '303 patent, the validity analysis is

identical, and the court finds that none of the prior art references anticipates the '342 patent. Therefore, Ogrin's motion is denied as to the '342 patent and Ultradent's is granted.

3. The '006 Patent

[22] This court finds that there exist numerous disputed issues of fact material to a determination of the validity of the '006 patent. For example, because claims 1 and 11 of the '006 patent are defined in terms of the performance or functional characteristics of the claimed dental bleaching composition, there are factual questions about whether any of the prior art compositions, including Proxigel(R), the Rosenthal 1.5% Standard Formulation, and perhaps other compositions, exhibit the requisite viscosity, tackiness, and bleaching characteristics claimed in the '006 patent. Therefore, a grant of summary judgment would be improper. Both Ogrin's and Ultradent's motions for summary judgment are denied as to the '006 patent.

D. Ultradent's Motion to Strike Life-Like's Affirmative Defense of Inequitable Conduct

Ultradent has moved to strike Life-Like's sixth affirmative defense, inequitable conduct. Ultradent claims Life-Like failed to allege the inequitable conduct with the particularity required under Federal Rule of Civil Procedure 9(b), and further, that there is no factual basis for Life-Like's allegations of inequitable conduct. This court finds that Life-Like has adequately alleged inequitable conduct with the required particularity, and that Life-Like has alleged a factual basis for a consideration of inequitable conduct. Ultradent's motion is therefore denied.

E. Ultradent's Motion to Dismiss Life-Like's Counterclaim of Attempted Monopolization

In its counterclaim against Ultradent, Life-Like alleged an antitrust claim for attempted monopolization in violation of section 2 of the Sherman Act and section 4 of the Clayton Act. Ultradent filed a motion to dismiss this claim for failure to state a claim upon which relief can be granted. Ultradent asserts that Life-Like has failed to allege facts that would show a dangerous probability of achieving monopoly power in the relevant market. This court agrees.

[23] Life-Like has alleged that Ultradent holds a 20%-30% share of the relevant market. Without additional factual allegations of relevant factors such as the strength of the competition, barriers to entry into the market, and elasticity of demand, a bald allegation of a 20%-30% market share is insufficient to support a claim upon which relief can be granted. *Morgenstern v. Wilson*, 29 F.3d 1291, 1296 n. 3 (8th Cir.1994); *see also Reazin v. Blue Cross & Blue Shield of Kansas*, 899 F.2d 951, 967 (10th Cir.1990) ("market share percentages may give rise to presumptions, but will rarely conclusively establish or eliminate market or monopoly power"). Life-Like has failed to allege, even in its proposed amended counterclaim, additional facts that would rebut the presumption that a 20%-30% market share is insufficient to support its claim of attempted monopolization. Therefore, Ultradent's motion is granted.

F. Life-Like's Motion for Leave to Amend its Answer and Counterclaims

Life-Like filed a motion seeking leave to amend its answer to address Ultradent's assertion that Life-Like's affirmative defense of inequitable conduct should be stricken as failing to meet the particularity of requirement of Rule 9(b), and to amend its antitrust counterclaim. This court has denied Ultradent's motion to strike Life-Like's inequitable conduct defense and granted Ultradent's motion to dismiss the attempted monopolization counterclaim, even as to the counterclaim as alleged in Life-Like's proposed amended counterclaim. Therefore, Life-Like's motion to amend its answer and counterclaim is denied.

For the foregoing reasons, and good cause appearing, IT IS HEREBY ORDERED that:

(1) Ultradent's Motion for Partial Summary Judgment of Infringement is DENIED;

(2) Rodney F. Ogrin's Motion for Partial Summary Judgment of Invalidity Under 35 U.S.C. s. 102 is DENIED;

(3) Ultradent's Motion for Partial Summary Judgment on Defendants' Defense Under 35 U.S.C. s. 102 is GRANTED IN PART AND DENIED IN PART;

(4) Ultradent's Motion to Strike Defendant Life-Like's Sixth Affirmative Defense (Inequitable Conduct) is DENIED;

(5) Ultradent's Motion to Dismiss Life-Like's Second Counterclaim (Attempted Monopolization) is GRANTED; and

(6) Life-Like's Motion for Leave to Amend Answer and Counterclaim to Address Ultradent's Rule 9(b) Objections is DENIED.

D.Utah,1996.

Ultradent Products, Inc. v. Life-Like Cosmetics, Inc.

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